

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).

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

Overview for Request to09y05_mpr_wp26_v01, Report 1 of 2

Request ID: to09y05_mpr_wp26_v01, Report 1 of 2

Request Description: This report investigated diagnosis of agranulocytosis following new use of several anti-epileptic drugs, as well as clozapine and olanzapine.

Sentinel Modular Program Tool Used: Modular Program #3 (MP3)

Data Source: Data from January 1, 2000 to May 31, 2013 from 18 Data Partners contributing to the Mini-Sentinel Distributed Database (MSDD) were included in this request. The request was distributed to Data Partners on April 11, 2014. Please see Appendix A for dates of available data.

Study Design: The purpose of this request was to examine users, episodes, dispensings, and events of several anti-epileptic drugs, as well as clozapine and olanzapine, with varying incident definitions, agranulocytosis event washout periods (7 and 183 days), and agranulocytosis event primary diagnosis indicators (primary and nonsecondary). Please see Appendices B and C for generic names used to define exposures in this request. Please see Appendix D for International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes used to define outcomes. In total, 40 scenarios with differing exposures of interest, incidence criteria, event washout periods, and event care settings were examined. This report gives results for scenarios 1-24, which required the exposures to be incident to the exposure of interest only. Please see Appendix E more details on each scenario.

Cohort Eligibility Criteria: Patients were required to be continuously enrolled in plans with both medical and drug coverage for at least six months (183 days) before their first valid dispensing of the exposure medication, during which gaps in coverage of up to 45 days were allowed. The following age groups were included in the cohort: <18, 18-<45, 45-<60, 65 + years.

Limitations: Algorithms used to define exposures and outcomes are imperfect; thus, it is possible that there may be misclassification.

Notes: 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.

Table of Contents for Request to09y05_mpr_wp26_v01, Report 1 of 2

<u>Glossary</u>	Glossary of Terms in Modular Program 3
<u>Table 1</u>	Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, and Primary Diagnosis Indicator
<u>Table 2</u>	Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Age Group
<u>Table 3</u>	Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Sex
<u>Table 4</u>	Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Year
<u>Appendix A</u>	Available Data in the Mini-Sentinel Distributed Database (MSDD) for Each Data Partner (DP) as of Request Send Date (April 11, 2014)
<u>Appendix B</u>	Group and Generic Names Used to Define Exposures in this Report
<u>Appendix C</u>	Generic Names Used to Assess Incidence of Exposures in this Report
<u>Appendix D</u>	International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Agranulocytosis Events in this Report
<u>Appendix E</u>	Specifications for Request to09y05_mpr_wp26_v01

Glossary of Terms in Modular Program 3*

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing. This is equivalent to

Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs

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

Cohort Definition (drug/exposure)- Indicates how the cohort will be defined: (1) 01: Cohort includes only the first valid incident treatment episode during the query period; (2) 02: Cohort includes all valid incident treatment episodes during the

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

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

Eligible Members - Number of members eligible for an incident treatment episode (defined by the drug/exposure and event

Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a "continuously

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be

Event Deduplication - specifies how events are counted by the MP algorithm: A value of 0 counts all occurrences of an event group code of interest; a value of 1 de-duplicates occurrences of the same event code on the same day (i.e., de-duplicates at

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

Lookback Period (pre-existing condition) - number of days wherein a member is required to have evidence of pre-existing

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

Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be

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

New Episodes with Events - number of unique episodes during which at least one incident event occurs. Each episode may

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

Number of Events - total number of incident events. An individual or a treatment episode can have more than one incident

Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the

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

Treatment Episode Truncation Indicator - indicates whether observation of the incident query code during follow-up requires truncation of valid treatment episodes. A value of Y indicates that the treatment episodes should be truncated at

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: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, and Primary Diagnosis Indicator

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ 10K Years at Risk	Total Number of Events / 10K Years at Risk
Carbamazepine																
<i>7-day event washout</i>																
Nonsecondary diagnosis	151,565	151,565	491,847	18,569,462	61,016,759	55,255.8	69	75	94,006,099	#####	1.61	122.52	3.25	37.75	12.49	13.57
Primary diagnosis	151,567	151,567	491,849	18,569,522	61,016,879	55,260.1	50	56	94,006,104	#####	1.61	122.52	3.25	37.75	9.05	10.13
<i>183-day event washout</i>																
Nonsecondary diagnosis	151,482	151,482	491,607	18,561,738	60,982,704	55,233.8	62	65	94,004,042	#####	1.61	122.53	3.25	37.76	11.23	11.77
Primary diagnosis	151,506	151,506	491,651	18,562,962	60,986,269	55,241.8	44	47	94,004,958	#####	1.61	122.52	3.25	37.76	7.96	8.51
Lamotrigine																
<i>7-day event washout</i>																
Nonsecondary diagnosis	381,771	381,771	1,839,719	64,835,756	130,576,486	188,919.7	113	116	93,894,007	#####	4.07	169.83	4.82	35.24	5.98	6.14
Primary diagnosis	381,780	381,780	1,839,754	64,837,173	130,580,386	188,936.8	70	72	93,894,012	#####	4.07	169.83	4.82	35.24	3.70	3.81
<i>183-day event washout</i>																
Nonsecondary diagnosis	381,663	381,663	1,839,070	64,815,570	130,529,983	188,862.3	105	107	93,891,955	#####	4.06	169.82	4.82	35.24	5.56	5.67
Primary diagnosis	381,722	381,722	1,839,363	64,824,525	130,548,543	188,900.9	66	67	93,892,875	#####	4.07	169.82	4.82	35.24	3.49	3.55
Levetiracetam																
<i>7-day event washout</i>																
Nonsecondary diagnosis	195,215	195,215	999,039	34,803,470	121,077,303	100,707.9	639	742	94,021,443	#####	2.08	178.28	5.12	34.84	63.45	73.68
Primary diagnosis	195,278	195,278	999,385	34,813,585	121,121,806	100,789.4	402	450	94,021,448	#####	2.08	178.28	5.12	34.84	39.89	44.65
<i>183-day event washout</i>																
Nonsecondary diagnosis	194,418	194,418	996,151	34,715,218	120,790,606	100,470.0	536	608	94,019,403	#####	2.07	178.56	5.12	34.85	53.35	60.52
Primary diagnosis	194,785	194,785	997,496	34,755,997	120,937,312	100,638.9	339	371	94,020,310	#####	2.07	178.43	5.12	34.84	33.68	36.86
Topiramate																
<i>7-day event washout</i>																
Nonsecondary diagnosis	591,194	591,194	1,811,493	62,737,585	149,581,742	189,248.2	110	119	93,923,630	#####	6.29	106.12	3.06	34.63	5.81	6.29
Primary diagnosis	591,206	591,206	1,811,508	62,737,980	149,582,654	189,264.0	75	83	93,923,635	#####	6.29	106.12	3.06	34.63	3.96	4.39
<i>183-day event washout</i>																
Nonsecondary diagnosis	591,008	591,008	1,810,798	62,715,428	149,530,966	189,186.5	102	107	93,921,563	#####	6.29	106.12	3.06	34.63	5.39	5.66
Primary diagnosis	591,097	591,097	1,811,046	62,722,777	149,551,777	189,220.3	71	77	93,922,485	#####	6.29	106.11	3.06	34.63	3.75	4.07
Clozapine																
<i>7-day event washout</i>																
Nonsecondary diagnosis	5,246	5,246	107,826	1,707,019	6,132,675	4,864.1	8	9	94,079,803	#####	0.06	325.39	20.55	15.83	16.45	18.50
Primary diagnosis	5,246	5,246	107,826	1,707,019	6,132,675	4,864.5	6	6	94,079,808	#####	0.06	325.39	20.55	15.83	12.33	12.33
<i>183-day event washout</i>																
Nonsecondary diagnosis	5,240	5,240	107,709	1,705,350	6,129,472	4,859.4	7	8	94,077,750	#####	0.06	325.45	20.56	15.83	14.41	16.46
Primary diagnosis	5,245	5,245	107,812	1,706,921	6,132,502	4,864.2	6	6	94,078,664	#####	0.06	325.44	20.56	15.83	12.34	12.34
Olanzapine																
<i>7-day event washout</i>																
Nonsecondary diagnosis	248,261	248,261	873,095	28,035,353	39,996,795	83,800.1	217	244	94,040,710	#####	2.64	112.93	3.52	32.11	25.89	29.12
Primary diagnosis	248,279	248,279	873,134	28,036,545	39,998,165	83,808.3	161	179	94,040,715	#####	2.64	112.92	3.52	32.11	19.21	21.36
<i>183-day event washout</i>																
Nonsecondary diagnosis	247,823	247,823	872,150	28,008,586	39,961,283	83,719.1	170	185	94,038,654	#####	2.64	113.02	3.52	32.11	20.31	22.10
Primary diagnosis	247,984	247,984	872,491	28,018,411	39,972,819	83,753.1	136	148	94,039,572	#####	2.64	112.98	3.52	32.11	16.24	17.67

Table 2: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Age Group

	New Users	New Episodes	Days Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk
Carbamazepine																
7-day event washout																
Nonsecondary diagnosis																
00 to 17 Years	13,979	13,979	74,148	2,801,856	13,565,587	8,106.7	10	13	23,142,788	57,654,407.2	0.60	200.43	5.30	37.79	12.34	16.04
18 to 44 Years	55,340	55,340	175,007	6,122,657	19,900,159	18,384.0	24	24	43,370,696	90,438,281.0	1.28	110.64	3.16	34.99	13.05	13.05
45 to 64 Years	54,085	54,085	167,147	6,456,803	19,056,351	19,242.5	21	22	27,284,765	72,410,403.7	1.98	119.38	3.09	38.63	10.91	11.43
65+ Years	28,161	28,161	75,545	3,188,146	8,494,662	9,522.6	14	16	8,693,914	27,338,709.9	3.24	113.21	2.68	42.20	14.70	16.80
Primary diagnosis																
00 to 17 Years	13,979	13,979	74,148	2,801,856	13,565,587	8,106.9	8	11	23,142,788	57,654,454.3	0.60	200.43	5.30	37.79	9.87	13.57
18 to 44 Years	55,340	55,340	175,007	6,122,657	19,900,159	18,386.3	16	16	43,370,697	90,438,383.6	1.28	110.64	3.16	34.99	8.70	8.70
45 to 64 Years	54,087	54,087	167,149	6,456,863	19,056,471	19,244.3	14	15	27,284,767	72,410,631.0	1.98	119.38	3.09	38.63	7.27	7.79
65+ Years	28,161	28,161	75,545	3,188,146	8,494,662	9,522.7	12	14	8,693,916	27,338,855.7	3.24	113.21	2.68	42.20	12.60	14.70
183-day event washout																
Nonsecondary diagnosis																
00 to 17 Years	13,972	13,972	74,065	2,798,923	13,548,241	8,099.1	9	9	23,142,496	57,649,846.7	0.60	200.32	5.30	37.79	11.11	11.11
18 to 44 Years	55,306	55,306	174,939	6,120,808	19,894,497	18,378.5	19	19	43,370,232	90,431,953.5	1.28	110.67	3.16	34.99	10.34	10.34
45 to 64 Years	54,058	54,058	167,088	6,454,786	19,047,041	19,236.4	20	21	27,283,713	72,396,582.7	1.98	119.40	3.09	38.63	10.40	10.92
65+ Years	28,146	28,146	75,515	3,187,221	8,492,924	9,519.8	14	16	8,693,271	27,329,801.7	3.24	113.24	2.68	42.21	14.71	16.81
Primary diagnosis																
00 to 17 Years	13,972	13,972	74,065	2,798,923	13,548,241	8,099.2	7	7	23,142,599	57,650,786.7	0.60	200.32	5.30	37.79	8.64	8.64
18 to 44 Years	55,319	55,319	174,969	6,121,641	19,897,207	18,383.4	12	12	43,370,461	90,434,297.8	1.28	110.66	3.16	34.99	6.53	6.53
45 to 64 Years	54,068	54,068	167,101	6,455,147	19,047,836	19,239.2	13	14	27,284,199	72,401,428.4	1.98	119.39	3.09	38.63	6.76	7.28
65+ Years	28,147	28,147	75,516	3,187,251	8,492,984	9,520.0	12	14	8,693,527	27,332,590.5	3.24	113.24	2.68	42.21	12.61	14.71
Lamotrigine																
7-day event washout																
Nonsecondary diagnosis																
00 to 17 Years	49,016	49,016	267,839	9,054,028	22,045,590	26,272.9	11	12	23,132,352	57,603,316.9	2.12	184.72	5.46	33.80	4.19	4.57
18 to 44 Years	#####	209,115	930,100	#####	61,787,412	92,567.1	57	58	43,282,888	90,057,765.9	4.83	150.69	4.45	33.88	6.16	6.27
45 to 64 Years	#####	107,240	564,560	#####	40,485,604	61,005.4	37	38	27,237,784	72,258,020.4	3.94	196.98	5.26	37.42	6.07	6.23
65+ Years	16,400	16,400	77,220	3,146,677	6,257,880	9,074.2	8	8	8,698,392	27,420,259.4	1.89	191.87	4.71	40.75	8.82	8.82
Primary diagnosis																
00 to 17 Years	49,018	49,018	267,842	9,054,118	22,045,695	26,274.8	7	8	23,132,352	57,603,362.0	2.12	184.71	5.46	33.80	2.66	3.04
18 to 44 Years	#####	209,121	930,112	#####	61,788,087	92,574.6	36	36	43,282,889	90,057,864.2	4.83	150.68	4.45	33.88	3.89	3.89
45 to 64 Years	#####	107,241	564,580	#####	40,488,724	61,012.8	21	22	27,237,785	72,258,246.7	3.94	196.99	5.26	37.42	3.44	3.61
65+ Years	16,400	16,400	77,220	3,146,677	6,257,880	9,074.5	6	6	8,698,394	27,420,405.5	1.89	191.87	4.71	40.75	6.61	6.61
183-day event washout																
Nonsecondary diagnosis																
00 to 17 Years	49,008	49,008	267,801	9,052,781	22,042,715	26,269.7	8	8	23,132,059	57,598,753.4	2.12	184.72	5.46	33.80	3.05	3.05
18 to 44 Years	#####	209,077	929,880	#####	61,773,448	92,547.0	54	55	43,282,424	90,051,499.9	4.83	150.68	4.45	33.88	5.83	5.94
45 to 64 Years	#####	107,189	564,225	#####	40,459,645	60,976.2	35	36	27,236,733	72,244,262.7	3.94	196.98	5.26	37.42	5.74	5.90
65+ Years	16,389	16,389	77,164	3,145,030	6,254,176	9,069.4	8	8	8,697,756	27,411,321.7	1.88	191.90	4.71	40.76	8.82	8.82
Primary diagnosis																
00 to 17 Years	49,013	49,013	267,818	9,053,337	22,043,564	26,272.7	5	5	23,132,163	57,599,684.1	2.12	184.71	5.46	33.80	1.90	1.90
18 to 44 Years	#####	209,105	929,986	#####	61,779,475	92,563.0	34	34	43,282,656	90,053,813.5	4.83	150.68	4.45	33.88	3.67	3.67
45 to 64 Years	#####	107,211	564,378	#####	40,469,918	60,994.3	21	22	27,237,218	72,249,084.7	3.94	196.98	5.26	37.42	3.44	3.61
65+ Years	16,393	16,393	77,181	3,145,448	6,255,586	9,071.0	6	6	8,698,010	27,414,115.5	1.88	191.88	4.71	40.75	6.61	6.61

Table 2: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Age Group

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk
Levetiracetam																
<i>7-day event washout</i>																
Nonsecondary diagnosis																
00 to 17 Years	28,976	28,976	206,860	6,935,366	39,395,404	19,797.0	107	148	23,138,212	57,636,024.3	1.25	239.35	7.14	33.53	54.05	74.76
18 to 44 Years	58,395	58,395	278,947	9,380,828	31,166,691	27,364.5	114	130	43,378,868	90,518,401.6	1.35	160.64	4.78	33.63	41.66	47.51
45 to 64 Years	63,640	63,640	306,047	#####	30,767,225	31,173.0	291	324	27,301,182	72,529,654.8	2.33	168.91	4.81	35.12	93.35	103.94
65+ Years	44,204	44,204	207,185	7,737,626	19,747,984	22,373.4	127	140	8,699,433	27,388,631.6	5.08	175.04	4.69	37.35	56.76	62.57
Primary diagnosis																
00 to 17 Years	28,982	28,982	206,951	6,938,019	39,417,467	19,810.1	87	115	23,138,212	57,636,067.1	1.25	239.39	7.14	33.52	43.92	58.05
18 to 44 Years	58,405	58,405	278,989	9,382,022	31,169,541	27,380.7	74	82	43,378,868	90,518,499.7	1.35	160.64	4.78	33.63	27.03	29.95
45 to 64 Years	63,674	63,674	306,178	#####	30,781,741	31,208.0	169	177	27,301,184	72,529,869.0	2.33	168.88	4.81	35.12	54.15	56.72
65+ Years	44,217	44,217	207,267	7,740,087	19,753,057	22,390.6	72	76	8,699,435	27,388,770.9	5.08	175.05	4.69	37.34	32.16	33.94
183-day event washout																
Nonsecondary diagnosis																
00 to 17 Years	28,842	28,842	206,222	6,915,027	39,318,421	19,752.8	74	99	23,137,924	57,631,695.7	1.25	239.76	7.15	33.53	37.46	50.12
18 to 44 Years	58,209	58,209	278,192	9,358,629	31,081,974	27,302.0	89	96	43,378,420	90,512,283.0	1.34	160.78	4.78	33.64	32.60	35.16
45 to 64 Years	63,299	63,299	304,975	#####	30,676,054	31,079.9	261	289	27,300,141	72,516,177.9	2.32	169.31	4.82	35.14	83.98	92.99
65+ Years	44,068	44,068	206,762	7,724,346	19,714,157	22,335.4	112	124	8,698,805	27,379,844.9	5.07	175.28	4.69	37.36	50.14	55.52
Primary diagnosis																
00 to 17 Years	28,879	28,879	206,466	6,922,409	39,355,893	19,777.9	61	77	23,138,027	57,632,585.3	1.25	239.70	7.15	33.53	30.84	38.93
18 to 44 Years	58,282	58,282	278,421	9,365,045	31,109,604	27,332.6	60	66	43,378,642	90,514,543.1	1.34	160.69	4.78	33.64	21.95	24.15
45 to 64 Years	63,482	63,482	305,561	#####	30,734,654	31,157.3	153	160	27,300,622	72,520,863.4	2.33	169.11	4.81	35.13	49.11	51.35
65+ Years	44,142	44,142	207,048	7,733,039	19,737,160	22,371.1	65	68	8,699,056	27,382,563.2	5.07	175.19	4.69	37.35	29.06	30.40
Topiramate																
<i>7-day event washout</i>																
Nonsecondary diagnosis																
00 to 17 Years	52,350	52,350	167,652	5,567,502	16,138,458	16,823.9	18	20	23,139,235	57,609,522.3	2.26	106.35	3.20	33.21	10.70	11.89
18 to 44 Years	#####	315,254	919,347	#####	72,661,651	93,651.5	43	46	43,303,212	89,892,649.2	7.28	97.66	2.92	33.49	4.59	4.91
45 to 64 Years	#####	198,126	649,086	#####	54,344,178	70,001.7	42	45	27,222,860	72,021,493.5	7.28	118.32	3.28	36.12	6.00	6.43
65+ Years	25,464	25,464	75,408	2,941,191	6,437,455	8,771.0	7	8	8,696,669	27,399,277.3	2.93	115.50	2.96	39.00	7.98	9.12
Primary diagnosis																
00 to 17 Years	52,352	52,352	167,656	5,567,634	16,138,882	16,827.9	13	15	23,139,235	57,609,569.1	2.26	106.35	3.20	33.21	7.73	8.91
18 to 44 Years	#####	315,259	919,353	#####	72,661,868	93,655.9	30	33	43,303,212	89,892,744.2	7.28	97.66	2.92	33.49	3.20	3.52
45 to 64 Years	#####	198,130	649,090	#####	54,344,388	70,008.6	27	29	27,222,862	72,021,713.7	7.28	118.32	3.28	36.12	3.86	4.14
65+ Years	25,465	25,465	75,409	2,941,222	6,437,516	8,771.7	5	6	8,696,671	27,399,423.1	2.93	115.50	2.96	39.00	5.70	6.84
183-day event washout																
Nonsecondary diagnosis																
00 to 17 Years	52,327	52,327	167,544	5,564,254	16,129,408	16,818.2	12	12	23,138,943	57,604,991.2	2.26	106.34	3.20	33.21	7.14	7.14
18 to 44 Years	#####	315,187	919,165	#####	72,648,859	93,634.2	42	43	43,302,741	89,886,475.5	7.28	97.66	2.92	33.49	4.49	4.59
45 to 64 Years	#####	198,050	648,774	#####	54,321,184	69,971.3	41	44	27,221,803	72,007,845.4	7.28	118.31	3.28	36.12	5.86	6.29
65+ Years	25,444	25,444	75,315	2,938,386	6,431,514	8,762.8	7	8	8,696,027	27,390,349.4	2.93	115.48	2.96	39.01	7.99	9.13
Primary diagnosis																
00 to 17 Years	52,334	52,334	167,569	5,565,016	16,132,532	16,821.0	10	10	23,139,045	57,605,918.3	2.26	106.34	3.20	33.21	5.94	5.94
18 to 44 Years	#####	315,221	919,257	#####	72,655,299	93,646.3	30	33	43,302,972	89,888,748.8	7.28	97.66	2.92	33.49	3.20	3.52
45 to 64 Years	#####	198,089	648,880	#####	54,330,083	69,987.3	26	28	27,222,291	72,012,620.0	7.28	118.31	3.28	36.12	3.71	4.00
65+ Years	25,453	25,453	75,340	2,939,200	6,433,862	8,765.8	5	6	8,696,283	27,393,135.3	2.93	115.48	2.96	39.01	5.70	6.84

Table 2: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Age Group

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk
Clozapine																
<i>7-day event washout</i>																
Nonsecondary diagnosis																
00 to 17 Years	397	397	10,397	154,895	513,821	437.3	2	2	23,148,126	57,718,361.8	0.02	390.16	26.19	14.90	45.74	45.74
18 to 44 Years	2,740	2,740	59,682	974,348	3,864,050	2,767.3	2	3	43,406,939	90,671,927.0	0.06	355.60	21.78	16.33	7.23	10.84
45 to 64 Years	1,554	1,554	28,992	465,264	1,458,592	1,332.2	3	3	27,327,272	72,689,048.8	0.06	299.40	18.66	16.05	22.52	22.52
65+ Years	555	555	8,755	112,512	296,212	327.3	1	1	8,713,068	27,488,708.3	0.06	202.72	15.77	12.85	30.55	30.55
Primary diagnosis																
00 to 17 Years	397	397	10,397	154,895	513,821	437.4	1	1	23,148,126	57,718,409.1	0.02	390.16	26.19	14.90	22.86	22.86
18 to 44 Years	2,740	2,740	59,682	974,348	3,864,050	2,767.6	1	1	43,406,940	90,672,030.2	0.06	355.60	21.78	16.33	3.61	3.61
45 to 64 Years	1,554	1,554	28,992	465,264	1,458,592	1,332.2	3	3	27,327,274	72,689,278.6	0.06	299.40	18.66	16.05	22.52	22.52
65+ Years	555	555	8,755	112,512	296,212	327.3	1	1	8,713,070	27,488,854.9	0.06	202.72	15.77	12.85	30.55	30.55
<i>183-day event washout</i>																
Nonsecondary diagnosis																
00 to 17 Years	396	396	10,391	154,845	513,750	437.2	1	1	23,147,834	57,713,777.8	0.02	391.02	26.24	14.90	22.87	22.87
18 to 44 Years	2,737	2,737	59,604	973,064	3,861,675	2,763.7	2	3	43,406,478	90,665,516.0	0.06	355.52	21.78	16.33	7.24	10.86
45 to 64 Years	1,553	1,553	28,986	465,130	1,458,175	1,331.8	3	3	27,326,212	72,675,119.9	0.06	299.50	18.66	16.05	22.53	22.53
65+ Years	554	554	8,728	112,311	295,872	326.7	1	1	8,712,425	27,479,726.9	0.06	202.73	15.75	12.87	30.61	30.61
Primary diagnosis																
00 to 17 Years	397	397	10,397	154,895	513,821	437.4	1	1	23,147,937	57,714,719.1	0.02	390.16	26.19	14.90	22.86	22.86
18 to 44 Years	2,739	2,739	59,668	974,250	3,863,877	2,767.3	1	1	43,406,705	90,667,886.7	0.06	355.70	21.78	16.33	3.61	3.61
45 to 64 Years	1,554	1,554	28,992	465,264	1,458,592	1,332.2	3	3	27,326,701	72,680,004.3	0.06	299.40	18.66	16.05	22.52	22.52
65+ Years	555	555	8,755	112,512	296,212	327.3	1	1	8,712,680	27,482,535.3	0.06	202.72	15.77	12.85	30.55	30.55
Olanzapine																
<i>7-day event washout</i>																
Nonsecondary diagnosis																
00 to 17 Years	20,875	20,875	77,848	2,491,347	4,021,394	7,435.5	22	24	23,146,014	57,655,738.1	0.90	119.35	3.73	32.00	29.59	32.28
18 to 44 Years	#####	102,921	313,599	9,743,110	15,176,653	29,614.9	64	79	43,381,497	90,306,310.4	2.37	94.67	3.05	31.07	21.61	26.68
45 to 64 Years	70,062	70,062	263,588	8,630,524	11,985,080	25,639.0	97	106	27,293,497	72,365,059.4	2.57	123.18	3.76	32.74	37.83	41.34
65+ Years	54,403	54,403	218,060	7,170,372	8,813,667	21,110.7	34	35	8,696,203	27,333,910.7	6.26	131.80	4.01	32.88	16.11	16.58
Primary diagnosis																
00 to 17 Years	20,876	20,876	77,849	2,491,377	4,021,424	7,436.1	18	19	23,146,014	57,655,784.7	0.90	119.34	3.73	32.00	24.21	25.55
18 to 44 Years	#####	102,926	313,607	9,743,334	15,176,882	29,616.4	53	64	43,381,498	90,306,409.5	2.37	94.66	3.05	31.07	17.90	21.61
45 to 64 Years	70,069	70,069	263,603	8,631,034	11,985,740	25,642.4	71	77	27,293,499	72,365,284.2	2.57	123.18	3.76	32.74	27.69	30.03
65+ Years	54,408	54,408	218,075	7,170,800	8,814,118	21,113.4	19	19	8,696,205	27,334,056.2	6.26	131.80	4.01	32.88	9.00	9.00
<i>183-day event washout</i>																
Nonsecondary diagnosis																
00 to 17 Years	20,838	20,838	77,764	2,488,780	4,017,704	7,428.3	13	13	23,145,723	57,651,213.6	0.90	119.43	3.73	32.00	17.50	17.50
18 to 44 Years	#####	102,792	313,365	9,736,537	15,168,165	29,594.6	51	62	43,381,039	90,300,145.8	2.37	94.72	3.05	31.07	17.23	20.95
45 to 64 Years	69,853	69,853	263,118	8,617,731	11,967,319	25,600.0	76	80	27,292,449	72,351,427.3	2.56	123.37	3.77	32.75	29.69	31.25
65+ Years	54,340	54,340	217,903	7,165,538	8,808,094	21,096.2	30	30	8,695,563	27,325,028.4	6.25	131.86	4.01	32.88	14.22	14.22
Primary diagnosis																
00 to 17 Years	20,851	20,851	77,796	2,489,749	4,018,865	7,431.1	13	13	23,145,827	57,652,145.9	0.90	119.41	3.73	32.00	17.49	17.49
18 to 44 Years	#####	102,842	313,478	9,739,845	15,172,160	29,605.6	44	53	43,381,263	90,302,451.4	2.37	94.71	3.05	31.07	14.86	17.90
45 to 64 Years	69,929	69,929	263,264	8,621,777	11,972,048	25,614.3	60	63	27,292,935	72,356,230.3	2.56	123.29	3.76	32.75	23.42	24.60
65+ Years	54,362	54,362	217,953	7,167,040	8,809,745	21,102.0	19	19	8,695,817	27,327,810.0	6.25	131.84	4.01	32.88	9.00	9.00

Table 3: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Sex

	New Users	New Episodes	Dispensing s	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Days Dispensing/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk
Carbamazepine																
<i>7-day event washout</i>																
Nonsecondary diagnosis																
Female	92,155	92,155	279,039	10,487,347	32,631,144	31,380.6	40	43	47,832,453	128,080,811.1	1.93	113.80	3.03	37.58	12.75	13.70
Male	59,370	59,370	212,696	8,078,658	28,376,612	23,864.8	29	32	46,152,694	119,717,357.8	1.29	136.07	3.58	37.98	12.15	13.41
Unknown	40	40	112	3,457	9,003	10.4	0	0	20,952	43,633.0	1.91	86.43	2.80	30.87	0.00	0.00
Primary diagnosis																
Female	92,157	92,157	279,041	10,487,407	32,631,264	31,384.0	26	29	47,832,456	128,081,071.5	1.93	113.80	3.03	37.58	8.28	9.24
Male	59,370	59,370	212,696	8,078,658	28,376,612	23,865.7	24	27	46,152,696	119,717,620.3	1.29	136.07	3.58	37.98	10.06	11.31
Unknown	40	40	112	3,457	9,003	10.4	0	0	20,952	43,633.0	1.91	86.43	2.80	30.87	0.00	0.00
<i>183-day event washout</i>																
Nonsecondary diagnosis																
Female	92,107	92,107	278,870	10,481,672	32,602,198	31,364.5	38	38	47,831,439	128,063,112.1	1.93	113.80	3.03	37.59	12.12	12.12
Male	59,335	59,335	212,625	8,076,609	28,371,503	23,858.9	24	27	46,151,651	119,701,442.3	1.29	136.12	3.58	37.99	10.06	11.32
Unknown	40	40	112	3,457	9,003	10.4	0	0	20,952	43,630.3	1.91	86.43	2.80	30.87	0.00	0.00
Primary diagnosis																
Female	92,122	92,122	278,899	10,482,489	32,604,486	31,370.4	24	24	47,831,903	128,068,778.5	1.93	113.79	3.03	37.59	7.65	7.65
Male	59,344	59,344	212,640	8,077,016	28,372,780	23,861.0	20	23	46,152,103	119,706,694.6	1.29	136.11	3.58	37.98	8.38	9.64
Unknown	40	40	112	3,457	9,003	10.4	0	0	20,952	43,630.3	1.91	86.43	2.80	30.87	0.00	0.00
Lamotrigine																
<i>7-day event washout</i>																
Nonsecondary diagnosis																
Female	254,357	254,357	1,190,337	41,896,034	83,105,193	122,306.9	79	82	47,751,636	127,689,639.0	5.33	164.71	4.68	35.20	6.46	6.70
Male	127,288	127,288	648,876	22,924,260	47,447,606	66,568.1	34	34	46,121,424	119,606,106.5	2.76	180.10	5.10	35.33	5.11	5.11
Unknown	126	126	506	15,462	23,687	44.6	0	0	20,947	43,617.2	6.02	122.71	4.02	30.56	0.00	0.00
Primary diagnosis																
Female	254,363	254,363	1,190,368	41,897,337	83,108,943	122,320.2	48	50	47,751,639	127,689,898.4	5.33	164.71	4.68	35.20	3.92	4.09
Male	127,291	127,291	648,880	22,924,374	47,447,756	66,571.9	22	22	46,121,426	119,606,362.7	2.76	180.09	5.10	35.33	3.30	3.30
Unknown	126	126	506	15,462	23,687	44.6	0	0	20,947	43,617.2	6.02	122.71	4.02	30.56	0.00	0.00
<i>183-day event washout</i>																
Nonsecondary diagnosis																
Female	254,291	254,291	1,189,929	41,883,024	83,079,697	122,270.0	73	75	47,750,631	127,672,019.1	5.33	164.71	4.68	35.20	5.97	6.13
Male	127,246	127,246	648,635	22,917,084	47,426,599	66,547.7	32	32	46,120,377	119,590,204.1	2.76	180.10	5.10	35.33	4.81	4.81
Unknown	126	126	506	15,462	23,687	44.6	0	0	20,947	43,614.5	6.02	122.71	4.02	30.56	0.00	0.00
Primary diagnosis																
Female	254,331	254,331	1,190,138	41,889,671	83,093,624	122,298.6	45	46	47,751,096	127,677,638.9	5.33	164.71	4.68	35.20	3.68	3.76
Male	127,265	127,265	648,719	22,919,392	47,431,232	66,557.6	21	21	46,120,832	119,595,444.3	2.76	180.09	5.10	35.33	3.16	3.16
Unknown	126	126	506	15,462	23,687	44.6	0	0	20,947	43,614.5	6.02	122.71	4.02	30.56	0.00	0.00

Table 3: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Sex

	New Users	New Episodes	Dispensing s	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensing/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk
Levetiracetam																
<i>7-day event washout</i>																
Nonsecondary diagnosis																
Female	106,382	106,382	526,915	18,338,365	61,887,690	53,167.9	331	380	47,841,499	128,236,085.4	2.22	172.38	4.95	34.80	62.26	71.47
Male	88,779	88,779	471,882	16,457,733	59,168,369	47,518.6	308	362	46,158,991	119,792,937.5	1.92	185.38	5.32	34.88	64.82	76.18
Unknown	54	54	242	7,372	21,244	21.4	0	0	20,953	43,689.2	2.58	136.52	4.48	30.46	0.00	0.00
Primary diagnosis																
Female	106,419	106,419	527,082	18,343,344	61,913,468	53,206.5	215	241	47,841,502	128,236,327.9	2.22	172.37	4.95	34.80	40.41	45.30
Male	88,805	88,805	472,061	16,462,869	59,187,094	47,561.5	187	209	46,158,993	119,793,189.6	1.92	185.38	5.32	34.87	39.32	43.94
Unknown	54	54	242	7,372	21,244	21.4	0	0	20,953	43,689.2	2.58	136.52	4.48	30.46	0.00	0.00
<i>183-day event washout</i>																
Nonsecondary diagnosis																
Female	105,986	105,986	525,359	18,291,375	61,734,913	53,041.0	279	308	47,840,494	128,218,820.6	2.22	172.58	4.96	34.82	52.60	58.07
Male	88,379	88,379	470,551	16,416,500	59,034,507	47,407.7	257	300	46,157,956	119,777,494.4	1.91	185.75	5.32	34.89	54.21	63.28
Unknown	53	53	241	7,343	21,186	21.3	0	0	20,953	43,686.6	2.53	138.55	4.55	30.47	0.00	0.00
Primary diagnosis																
Female	106,175	106,175	526,033	18,311,694	61,811,898	53,123.7	181	199	47,840,952	128,224,302.9	2.22	172.47	4.95	34.81	34.07	37.46
Male	88,557	88,557	471,222	16,436,960	59,104,228	47,493.9	158	172	46,158,405	119,782,565.6	1.92	185.61	5.32	34.88	33.27	36.22
Unknown	53	53	241	7,343	21,186	21.3	0	0	20,953	43,686.6	2.53	138.55	4.55	30.47	0.00	0.00
Topiramate																
<i>7-day event washout</i>																
Nonsecondary diagnosis																
Female	472,517	472,517	1,464,409	50,798,822	119,254,351	153,112.1	85	88	47,738,223	127,170,544.1	9.90	107.51	3.10	34.69	5.55	5.75
Male	118,520	118,520	346,673	11,925,696	30,295,125	36,096.7	25	31	46,164,460	119,708,921.6	2.57	100.62	2.93	34.40	6.93	8.59
Unknown	157	157	411	13,067	32,266	39.3	0	0	20,947	43,476.6	7.50	83.23	2.62	31.79	0.00	0.00
Primary diagnosis																
Female	472,529	472,529	1,464,424	50,799,217	119,255,263	153,124.0	56	58	47,738,226	127,170,789.6	9.90	107.50	3.10	34.69	3.66	3.79
Male	118,520	118,520	346,673	11,925,696	30,295,125	36,100.7	19	25	46,164,462	119,709,183.9	2.57	100.62	2.93	34.40	5.26	6.93
Unknown	157	157	411	13,067	32,266	39.3	0	0	20,947	43,476.6	7.50	83.23	2.62	31.79	0.00	0.00
<i>183-day event washout</i>																
Nonsecondary diagnosis																
Female	472,385	472,385	1,463,990	50,785,001	119,223,663	153,071.4	82	83	47,737,202	127,153,144.2	9.90	107.51	3.10	34.69	5.36	5.42
Male	118,466	118,466	346,397	11,917,360	30,275,037	36,075.8	20	24	46,163,414	119,693,043.5	2.57	100.60	2.92	34.40	5.54	6.65
Unknown	157	157	411	13,067	32,266	39.3	0	0	20,947	43,473.9	7.50	83.23	2.62	31.79	0.00	0.00
Primary diagnosis																
Female	472,449	472,449	1,464,134	50,789,183	119,235,412	153,094.6	55	57	47,737,670	127,158,663.3	9.90	107.50	3.10	34.69	3.59	3.72
Male	118,491	118,491	346,501	11,920,527	30,284,099	36,086.4	16	20	46,163,868	119,698,285.3	2.57	100.60	2.92	34.40	4.43	5.54
Unknown	157	157	411	13,067	32,266	39.3	0	0	20,947	43,473.9	7.50	83.23	2.62	31.79	0.00	0.00

Table 3: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Sex

	New Users	New Episodes	Dispensing s	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensing/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk
Clozapine																
<i>7-day event washout</i>																
Nonsecondary diagnosis																
Female	2,466	2,466	47,054	742,772	2,473,636	2,126.1	2	2	47,872,880	128,514,326.9	0.05	301.21	19.08	15.79	9.41	9.41
Male	2,780	2,780	60,772	964,247	3,659,039	2,738.0	6	7	46,185,961	120,009,941.0	0.06	346.85	21.86	15.87	21.91	25.57
Unknown	0	0	0	0	0	0.0	0	0	20,962	43,778.1	0.00	---	---	---	---	---
Primary diagnosis																
Female	2,466	2,466	47,054	742,772	2,473,636	2,126.2	1	1	47,872,883	128,514,590.0	0.05	301.21	19.08	15.79	4.70	4.70
Male	2,780	2,780	60,772	964,247	3,659,039	2,738.3	5	5	46,185,963	120,010,204.7	0.06	346.85	21.86	15.87	18.26	18.26
Unknown	0	0	0	0	0	0.0	0	0	20,962	43,778.1	0.00	---	---	---	---	---
<i>183-day event washout</i>																
Nonsecondary diagnosis																
Female	2,461	2,461	46,943	741,237	2,470,850	2,121.8	1	1	47,871,870	128,496,454.9	0.05	301.19	19.07	15.79	4.71	4.71
Male	2,779	2,779	60,766	964,113	3,658,622	2,737.6	6	7	46,184,918	119,993,910.3	0.06	346.93	21.87	15.87	21.92	25.57
Unknown	0	0	0	0	0	0.0	0	0	20,962	43,775.4	0.00	---	---	---	---	---
Primary diagnosis																
Female	2,465	2,465	47,040	742,674	2,473,463	2,125.9	1	1	47,872,332	128,502,170.4	0.05	301.29	19.08	15.79	4.70	4.70
Male	2,780	2,780	60,772	964,247	3,659,039	2,738.3	5	5	46,185,370	119,999,199.6	0.06	346.85	21.86	15.87	18.26	18.26
Unknown	0	0	0	0	0	0.0	0	0	20,962	43,775.4	0.00	---	---	---	---	---
Olanzapine																
<i>7-day event washout</i>																
Nonsecondary diagnosis																
Female	140,642	140,642	488,295	15,678,189	21,853,565	46,923.3	116	132	47,851,818	127,989,112.0	2.94	111.48	3.47	32.11	24.72	28.13
Male	107,573	107,573	384,662	12,352,562	18,137,960	36,863.1	101	112	46,167,935	119,628,249.2	2.33	114.83	3.58	32.11	27.40	30.38
Unknown	46	46	138	4,602	5,270	13.7	0	0	20,957	43,657.4	2.19	100.04	3.00	33.35	0.00	0.00
Primary diagnosis																
Female	140,650	140,650	488,315	15,678,859	21,854,205	46,927.6	86	97	47,851,821	127,989,369.4	2.94	111.47	3.47	32.11	18.33	20.67
Male	107,583	107,583	384,681	12,353,084	18,138,690	36,867.0	75	82	46,167,937	119,628,507.8	2.33	114.82	3.58	32.11	20.34	22.24
Unknown	46	46	138	4,602	5,270	13.7	0	0	20,957	43,657.4	2.19	100.04	3.00	33.35	0.00	0.00
<i>183-day event washout</i>																
Nonsecondary diagnosis																
Female	140,424	140,424	487,745	15,662,635	21,832,877	46,876.5	90	98	47,850,809	127,971,612.3	2.93	111.54	3.47	32.11	19.20	20.91
Male	107,353	107,353	384,267	12,341,349	18,123,136	36,828.9	80	87	46,166,888	119,612,548.0	2.33	114.96	3.58	32.12	21.72	23.62
Unknown	46	46	138	4,602	5,270	13.7	0	0	20,957	43,654.7	2.19	100.04	3.00	33.35	0.00	0.00
Primary diagnosis																
Female	140,512	140,512	487,939	15,668,444	21,839,771	46,895.9	76	84	47,851,272	127,977,222.5	2.94	111.51	3.47	32.11	16.21	17.91
Male	107,426	107,426	384,414	12,345,365	18,127,778	36,843.5	60	64	46,167,343	119,617,760.5	2.33	114.92	3.58	32.11	16.29	17.37
Unknown	46	46	138	4,602	5,270	13.7	0	0	20,957	43,654.7	2.19	100.04	3.00	33.35	0.00	0.00

Table 4: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Year

	New Users	New Episodes	Days Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Days Dispensings/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk
Carbamazepine																
<i>7-day event washout</i>																
Nonsecondary diagnosis																
2000	5,296	5,296	20,563	846,366	3,058,362	2,480.5	2	2	7,255,102	3,360,885.2	0.73	159.81	3.88	41.16	8.06	8.06
2001	9,677	9,677	39,330	1,538,318	5,575,441	4,508.6	4	4	7,827,672	6,650,222.0	1.24	158.97	4.06	39.11	8.87	8.87
2002	8,273	8,273	32,391	1,393,098	4,769,035	4,064.5	5	5	7,967,894	6,741,535.3	1.04	168.39	3.92	43.01	12.30	12.30
2003	7,619	7,619	36,625	1,550,422	5,849,853	4,478.7	3	3	7,908,274	6,687,855.4	0.96	203.49	4.81	42.33	6.70	6.70
2004	6,930	6,930	26,652	1,141,641	5,372,323	3,332.2	1	1	8,463,808	6,894,686.8	0.82	164.74	3.85	42.84	3.00	3.00
2005	7,028	7,028	23,446	1,028,483	3,428,346	3,018.7	1	1	8,723,660	7,272,476.7	0.81	146.34	3.34	43.87	3.31	3.31
2006	8,203	8,203	31,399	1,258,199	4,221,841	3,692.9	4	4	19,648,778	12,066,106.7	0.42	153.38	3.83	40.07	10.83	10.83
2007	9,885	9,885	33,637	1,293,252	3,989,688	3,837.4	6	6	23,475,449	17,199,731.7	0.42	130.83	3.40	38.45	15.64	15.64
2008	15,523	15,523	48,361	1,744,370	5,285,303	5,234.9	8	11	44,735,189	28,411,239.4	0.35	112.37	3.12	36.07	15.28	21.01
2009	18,429	18,429	55,780	1,930,436	5,689,219	5,833.3	15	16	46,610,012	36,498,851.0	0.40	104.75	3.03	34.61	25.71	27.43
2010	17,299	17,299	50,445	1,751,733	5,191,610	5,298.6	6	6	44,838,628	35,272,957.6	0.39	101.26	2.92	34.73	11.32	11.32
2011	16,100	16,100	44,851	1,529,803	4,382,662	4,651.6	8	10	43,681,836	34,718,878.3	0.37	95.02	2.79	34.11	17.20	21.50
2012	15,709	15,709	38,161	1,256,815	3,389,100	3,865.9	5	5	42,591,280	33,544,711.0	0.37	80.01	2.43	32.93	12.93	12.93
2013	5,594	5,594	10,206	306,526	813,976	958.0	1	1	33,131,016	12,521,664.7	0.17	54.80	1.82	30.03	10.44	10.44
Primary diagnosis																
2000	5,296	5,296	20,563	846,366	3,058,362	2,480.5	2	2	7,255,102	3,360,885.2	0.73	159.81	3.88	41.16	8.06	8.06
2001	9,677	9,677	39,330	1,538,318	5,575,441	4,508.6	4	4	7,827,672	6,650,222.0	1.24	158.97	4.06	39.11	8.87	8.87
2002	8,273	8,273	32,391	1,393,098	4,769,035	4,064.5	5	5	7,967,894	6,741,535.3	1.04	168.39	3.92	43.01	12.30	12.30
2003	7,619	7,619	36,625	1,550,422	5,849,853	4,478.7	3	3	7,908,274	6,687,855.4	0.96	203.49	4.81	42.33	6.70	6.70
2004	6,930	6,930	26,652	1,141,641	5,372,323	3,332.2	1	1	8,463,808	6,894,686.8	0.82	164.74	3.85	42.84	3.00	3.00
2005	7,028	7,028	23,446	1,028,483	3,428,346	3,018.7	1	1	8,723,660	7,272,477.7	0.81	146.34	3.34	43.87	3.31	3.31
2006	8,203	8,203	31,399	1,258,199	4,221,841	3,692.9	4	4	19,648,779	12,066,113.5	0.42	153.38	3.83	40.07	10.83	10.83
2007	9,885	9,885	33,637	1,293,252	3,989,688	3,837.4	5	5	23,475,449	17,199,745.7	0.42	130.83	3.40	38.45	13.03	13.03
2008	15,523	15,523	48,361	1,744,370	5,285,303	5,236.3	5	8	44,735,193	28,411,302.4	0.35	112.37	3.12	36.07	9.55	15.28
2009	18,430	18,430	55,781	1,930,466	5,689,279	5,834.6	6	7	46,610,019	36,498,959.7	0.40	104.75	3.03	34.61	10.28	12.00
2010	17,300	17,300	50,446	1,751,763	5,191,670	5,299.0	4	4	44,838,631	35,273,053.3	0.39	101.26	2.92	34.73	7.55	7.55
2011	16,100	16,100	44,851	1,529,803	4,382,662	4,651.7	7	9	43,681,838	34,718,971.5	0.37	95.02	2.79	34.11	15.05	19.35
2012	15,709	15,709	38,161	1,256,815	3,389,100	3,866.8	3	3	42,591,281	33,544,809.1	0.37	80.01	2.43	32.93	7.76	7.76
2013	5,594	5,594	10,206	306,526	813,976	958.1	0	0	33,131,017	12,521,707.2	0.17	54.80	1.82	30.03	0.00	0.00

Table 4: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Year

	New Users	New Episodes	Days Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Days Dispensings/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk
183-day event washout																
Nonsecondary diagnosis																
2000	5,292	5,292	20,557	846,115	3,057,811	2,479.8	1	1	7,255,014	3,360,695.7	0.73	159.89	3.88	41.16	4.03	4.03
2001	9,674	9,674	39,323	1,538,118	5,574,259	4,508.0	4	4	7,827,597	6,649,850.0	1.24	159.00	4.06	39.11	8.87	8.87
2002	8,267	8,267	32,371	1,392,289	4,762,580	4,062.1	5	5	7,967,821	6,741,135.5	1.04	168.42	3.92	43.01	12.31	12.31
2003	7,616	7,616	36,622	1,550,361	5,849,697	4,478.5	2	2	7,908,213	6,687,495.9	0.96	203.57	4.81	42.33	4.47	4.47
2004	6,924	6,924	26,640	1,141,275	5,371,271	3,331.1	1	1	8,463,733	6,894,276.7	0.82	164.83	3.85	42.84	3.00	3.00
2005	7,026	7,026	23,436	1,027,817	3,426,886	3,016.9	1	1	8,723,596	7,272,055.3	0.81	146.29	3.34	43.86	3.31	3.31
2006	8,198	8,198	31,389	1,257,889	4,221,291	3,692.2	3	3	19,648,193	12,064,805.9	0.42	153.44	3.83	40.07	8.13	8.13
2007	9,879	9,879	33,623	1,292,859	3,988,701	3,836.1	6	6	23,474,703	17,197,496.8	0.42	130.87	3.40	38.45	15.64	15.64
2008	15,518	15,518	48,330	1,743,409	5,274,968	5,232.6	7	7	44,733,671	28,406,972.9	0.35	112.35	3.11	36.07	13.38	13.38
2009	18,418	18,418	55,722	1,928,666	5,683,004	5,828.4	13	14	46,608,588	36,493,183.5	0.40	104.72	3.03	34.61	22.30	24.02
2010	17,290	17,290	50,432	1,751,347	5,190,280	5,297.3	5	5	44,837,404	35,267,622.8	0.39	101.29	2.92	34.73	9.44	9.44
2011	16,091	16,091	44,832	1,529,259	4,381,315	4,649.9	8	10	43,680,574	34,713,559.5	0.37	95.04	2.79	34.11	17.20	21.51
2012	15,701	15,701	38,138	1,256,199	3,387,508	3,864.0	5	5	42,590,067	33,539,392.4	0.37	80.01	2.43	32.94	12.94	12.94
2013	5,588	5,588	10,192	306,135	813,133	956.8	1	1	33,129,067	12,519,641.7	0.17	54.78	1.82	30.04	10.45	10.45
Primary diagnosis																
2000	5,292	5,292	20,557	846,115	3,057,811	2,479.8	1	1	7,255,014	3,360,695.7	0.73	159.89	3.88	41.16	4.03	4.03
2001	9,674	9,674	39,323	1,538,118	5,574,259	4,508.0	4	4	7,827,597	6,649,850.4	1.24	159.00	4.06	39.11	8.87	8.87
2002	8,267	8,267	32,371	1,392,289	4,762,580	4,062.1	5	5	7,967,821	6,741,135.6	1.04	168.42	3.92	43.01	12.31	12.31
2003	7,616	7,616	36,622	1,550,361	5,849,697	4,478.5	2	2	7,908,213	6,687,495.9	0.96	203.57	4.81	42.33	4.47	4.47
2004	6,924	6,924	26,640	1,141,275	5,371,271	3,331.1	1	1	8,463,733	6,894,276.8	0.82	164.83	3.85	42.84	3.00	3.00
2005	7,026	7,026	23,436	1,027,817	3,426,886	3,016.9	1	1	8,723,599	7,272,075.5	0.81	146.29	3.34	43.86	3.31	3.31
2006	8,199	8,199	31,391	1,257,979	4,221,471	3,692.4	3	3	19,648,287	12,064,956.4	0.42	153.43	3.83	40.07	8.12	8.12
2007	9,880	9,880	33,627	1,292,964	3,989,001	3,836.5	5	5	23,474,752	17,197,765.7	0.42	130.87	3.40	38.45	13.03	13.03
2008	15,521	15,521	48,335	1,743,560	5,275,433	5,234.6	4	4	44,734,396	28,408,328.3	0.35	112.34	3.11	36.07	7.64	7.64
2009	18,423	18,423	55,727	1,928,816	5,683,364	5,830.0	5	6	46,609,232	36,495,456.7	0.40	104.70	3.02	34.61	8.58	10.29
2010	17,295	17,295	50,441	1,751,575	5,191,120	5,298.4	3	3	44,837,914	35,269,686.9	0.39	101.28	2.92	34.73	5.66	5.66
2011	16,093	16,093	44,836	1,529,360	4,381,517	4,650.3	7	9	43,681,048	34,715,453.2	0.37	95.03	2.79	34.11	15.05	19.35
2012	15,706	15,706	38,151	1,256,538	3,388,516	3,866.0	3	3	42,590,565	33,541,426.8	0.37	80.00	2.43	32.94	7.76	7.76
2013	5,590	5,590	10,194	306,195	813,343	957.2	0	0	33,129,849	12,520,499.5	0.17	54.78	1.82	30.04	0.00	0.00

Table 4: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Year

	New Users	New Episodes	Days Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Days Dispensings/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk
Lamotrigine																
<i>7-day event washout</i>																
Nonsecondary diagnosis																
2000	910	910	5,494	259,863	721,637	738.6	0	0	7,274,679	3,372,479.6	0.13	285.56	6.04	47.30	0.00	0.00
2001	2,471	2,471	14,855	679,178	1,914,362	1,931.8	1	1	7,847,087	6,673,186.6	0.31	274.86	6.01	45.72	5.18	5.18
2002	3,355	3,355	22,418	1,049,258	2,920,334	2,976.2	0	0	7,991,267	6,766,559.4	0.42	312.74	6.68	46.80	0.00	0.00
2003	6,734	6,734	47,611	1,883,463	6,247,685	5,370.2	1	1	7,933,042	6,712,533.2	0.85	279.69	7.07	39.56	1.86	1.86
2004	10,227	10,227	64,521	2,492,642	7,608,942	7,146.8	1	1	8,486,366	6,914,861.6	1.21	243.73	6.31	38.63	1.40	1.40
2005	11,245	11,245	59,574	2,410,612	5,297,002	6,948.9	2	2	8,739,992	7,286,348.6	1.29	214.37	5.30	40.46	2.88	2.88
2006	19,748	19,748	118,403	4,617,410	9,381,122	13,276.7	5	6	19,646,589	12,066,634.4	1.01	233.82	6.00	39.00	3.77	4.52
2007	29,579	29,579	176,237	6,456,256	13,172,788	18,643.0	7	7	23,459,210	17,180,500.5	1.26	218.27	5.96	36.63	3.75	3.75
2008	51,013	51,013	271,353	9,473,021	17,823,094	27,574.5	17	17	44,656,406	28,351,258.4	1.14	185.70	5.32	34.91	6.17	6.17
2009	60,774	60,774	300,091	10,327,621	19,253,623	30,185.6	20	21	46,506,547	36,397,881.2	1.31	169.93	4.94	34.41	6.63	6.96
2010	56,806	56,806	271,801	9,294,420	17,201,984	27,194.4	24	24	44,715,599	35,156,792.2	1.27	163.62	4.78	34.20	8.83	8.83
2011	55,374	55,374	244,861	8,211,889	14,987,359	24,112.8	16	17	43,541,690	34,587,970.8	1.27	148.30	4.42	33.54	6.64	7.05
2012	53,766	53,766	195,080	6,288,964	11,441,471	18,631.4	14	14	42,437,464	33,403,054.8	1.27	116.97	3.63	32.24	7.51	7.51
2013	19,769	19,769	47,420	1,391,159	2,605,083	4,188.8	5	5	33,001,887	12,469,301.3	0.60	70.37	2.40	29.34	11.94	11.94
Primary diagnosis																
2000	910	910	5,494	259,863	721,637	738.6	0	0	7,274,679	3,372,479.6	0.13	285.56	6.04	47.30	0.00	0.00
2001	2,471	2,471	14,855	679,178	1,914,362	1,931.8	1	1	7,847,087	6,673,186.7	0.31	274.86	6.01	45.72	5.18	5.18
2002	3,355	3,355	22,418	1,049,258	2,920,334	2,976.2	0	0	7,991,267	6,766,559.4	0.42	312.74	6.68	46.80	0.00	0.00
2003	6,734	6,734	47,611	1,883,463	6,247,685	5,370.2	1	1	7,933,042	6,712,533.2	0.85	279.69	7.07	39.56	1.86	1.86
2004	10,227	10,227	64,521	2,492,642	7,608,942	7,146.8	1	1	8,486,366	6,914,861.6	1.21	243.73	6.31	38.63	1.40	1.40
2005	11,245	11,245	59,574	2,410,612	5,297,002	6,948.9	2	2	8,739,992	7,286,349.6	1.29	214.37	5.30	40.46	2.88	2.88
2006	19,748	19,748	118,403	4,617,410	9,381,122	13,276.7	5	6	19,646,590	12,066,641.2	1.01	233.82	6.00	39.00	3.77	4.52
2007	29,579	29,579	176,237	6,456,256	13,172,788	18,643.0	7	7	23,459,210	17,180,514.5	1.26	218.27	5.96	36.63	3.75	3.75
2008	51,013	51,013	271,353	9,473,021	17,823,094	27,575.7	11	11	44,656,410	28,351,321.1	1.14	185.70	5.32	34.91	3.99	3.99
2009	60,775	60,775	300,092	10,327,651	19,253,683	30,189.0	14	15	46,506,554	36,397,989.7	1.31	169.93	4.94	34.41	4.64	4.97
2010	56,807	56,807	271,802	9,294,444	17,202,029	27,197.4	11	11	44,715,601	35,156,886.9	1.27	163.61	4.78	34.20	4.04	4.04
2011	55,377	55,377	244,884	8,212,952	14,990,584	24,119.4	6	6	43,541,691	34,588,061.8	1.27	148.31	4.42	33.54	2.49	2.49
2012	53,770	53,770	195,090	6,289,264	11,442,041	18,634.3	8	8	42,437,463	33,403,150.7	1.27	116.97	3.63	32.24	4.29	4.29
2013	19,769	19,769	47,420	1,391,159	2,605,083	4,188.9	3	3	33,001,884	12,469,342.3	0.60	70.37	2.40	29.34	7.16	7.16

Table 4: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Year

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk
183-day event washout																
Nonsecondary diagnosis																
2000	910	910	5,494	259,863	721,637	738.6	0	0	7,274,592	3,372,289.6	0.13	285.56	6.04	47.30	0.00	0.00
2001	2,470	2,470	14,854	679,163	1,914,332	1,931.7	1	1	7,847,009	6,672,809.7	0.31	274.96	6.01	45.72	5.18	5.18
2002	3,355	3,355	22,418	1,049,258	2,920,334	2,976.2	0	0	7,991,192	6,766,153.6	0.42	312.74	6.68	46.80	0.00	0.00
2003	6,733	6,733	47,610	1,883,403	6,247,565	5,370.0	1	1	7,932,976	6,712,168.7	0.85	279.73	7.07	39.56	1.86	1.86
2004	10,224	10,224	64,517	2,492,532	7,608,656	7,146.4	1	1	8,486,284	6,914,443.1	1.20	243.79	6.31	38.63	1.40	1.40
2005	11,245	11,245	59,574	2,410,612	5,297,002	6,948.9	2	2	8,739,926	7,285,920.9	1.29	214.37	5.30	40.46	2.88	2.88
2006	19,740	19,740	118,384	4,616,744	9,379,974	13,274.5	5	6	19,646,001	12,065,326.5	1.00	233.88	6.00	39.00	3.77	4.52
2007	29,574	29,574	176,209	6,455,454	13,170,582	18,640.7	7	7	23,458,458	17,178,268.5	1.26	218.28	5.96	36.64	3.76	3.76
2008	50,993	50,993	271,153	9,466,706	17,803,734	27,556.5	16	16	44,654,879	28,347,008.5	1.14	185.65	5.32	34.91	5.81	5.81
2009	60,751	60,751	299,943	10,322,406	19,242,941	30,170.9	19	19	46,505,122	36,392,233.5	1.31	169.91	4.94	34.41	6.30	6.30
2010	56,792	56,792	271,745	9,293,061	17,199,319	27,190.3	23	23	44,714,370	35,151,485.3	1.27	163.63	4.78	34.20	8.46	8.46
2011	55,358	55,358	244,766	8,209,138	14,982,950	24,105.5	12	13	43,540,427	34,582,664.3	1.27	148.29	4.42	33.54	4.98	5.39
2012	53,753	53,753	195,000	6,286,552	11,436,527	18,624.7	13	13	42,436,251	33,397,773.8	1.27	116.95	3.63	32.24	6.98	6.98
2013	19,765	19,765	47,403	1,390,678	2,604,431	4,187.4	5	5	32,999,955	12,467,291.7	0.60	70.36	2.40	29.34	11.94	11.94
Primary diagnosis																
2000	910	910	5,494	259,863	721,637	738.6	0	0	7,274,592	3,372,289.6	0.13	285.56	6.04	47.30	0.00	0.00
2001	2,470	2,470	14,854	679,163	1,914,332	1,931.7	1	1	7,847,009	6,672,810.1	0.31	274.96	6.01	45.72	5.18	5.18
2002	3,355	3,355	22,418	1,049,258	2,920,334	2,976.2	0	0	7,991,192	6,766,153.7	0.42	312.74	6.68	46.80	0.00	0.00
2003	6,733	6,733	47,610	1,883,403	6,247,565	5,370.0	1	1	7,932,976	6,712,168.7	0.85	279.73	7.07	39.56	1.86	1.86
2004	10,224	10,224	64,517	2,492,532	7,608,656	7,146.4	1	1	8,486,284	6,914,443.2	1.20	243.79	6.31	38.63	1.40	1.40
2005	11,245	11,245	59,574	2,410,612	5,297,002	6,948.9	2	2	8,739,929	7,285,941.5	1.29	214.37	5.30	40.46	2.88	2.88
2006	19,742	19,742	118,388	4,616,922	9,380,267	13,275.1	5	6	19,646,095	12,065,477.4	1.00	233.86	6.00	39.00	3.77	4.52
2007	29,575	29,575	176,215	6,455,634	13,170,882	18,641.2	7	7	23,458,507	17,178,536.5	1.26	218.28	5.96	36.63	3.76	3.76
2008	51,004	51,004	271,233	9,469,003	17,807,873	27,564.4	10	10	44,655,614	28,348,357.9	1.14	185.65	5.32	34.91	3.63	3.63
2009	60,759	60,759	299,985	10,323,746	19,246,109	30,178.1	13	13	46,505,767	36,394,500.4	1.31	169.91	4.94	34.41	4.31	4.31
2010	56,801	56,801	271,777	9,293,859	17,201,028	27,195.7	11	11	44,714,881	35,153,539.1	1.27	163.62	4.78	34.20	4.04	4.04
2011	55,370	55,370	244,811	8,210,830	14,987,186	24,113.5	5	5	43,540,901	34,584,552.7	1.27	148.29	4.42	33.54	2.07	2.07
2012	53,766	53,766	195,073	6,288,733	11,440,803	18,632.8	7	7	42,436,748	33,399,787.8	1.27	116.96	3.63	32.24	3.76	3.76
2013	19,768	19,768	47,414	1,390,967	2,604,869	4,188.3	3	3	33,000,724	12,468,139.3	0.60	70.36	2.40	29.34	7.16	7.16

Table 4: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Year

	New Users	New Episodes	Days Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Days Dispensings/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk
Levetiracetam																
<i>7-day event washout</i>																
Nonsecondary diagnosis																
2000	459	459	3,323	113,348	442,776	325.1	1	1	7,277,388	3,374,016.7	0.06	246.95	7.24	34.11	30.76	30.76
2001	1,408	1,408	10,736	399,892	1,547,088	1,143.6	2	2	7,849,493	6,675,949.8	0.18	284.01	7.63	37.25	17.49	17.49
2002	1,847	1,847	12,418	514,020	1,744,383	1,466.0	1	1	7,994,395	6,770,040.2	0.23	278.30	6.72	41.39	6.82	6.82
2003	4,078	4,078	28,544	1,035,464	4,808,057	2,970.8	1	1	7,937,517	6,717,435.8	0.51	253.91	7.00	36.28	3.37	3.37
2004	4,864	4,864	30,345	1,103,952	5,577,118	3,172.5	5	5	8,494,638	6,923,928.2	0.57	226.96	6.24	36.38	15.76	15.76
2005	4,570	4,570	26,777	1,000,724	4,308,338	2,877.0	3	3	8,753,674	7,301,308.9	0.52	218.98	5.86	37.37	10.43	10.43
2006	6,904	6,904	50,631	1,896,852	7,511,037	5,408.9	17	17	19,680,948	12,094,169.0	0.35	274.75	7.33	37.46	31.43	31.43
2007	11,215	11,215	77,118	2,793,668	10,363,429	7,997.2	39	40	23,508,607	17,227,581.2	0.48	249.10	6.88	36.23	48.77	50.02
2008	21,395	21,395	128,877	4,547,732	15,658,435	13,095.6	83	92	44,766,378	28,437,774.4	0.48	212.56	6.02	35.29	63.38	70.25
2009	30,652	30,652	175,365	6,071,568	20,547,558	17,512.1	127	148	46,631,950	36,515,571.9	0.66	198.08	5.72	34.62	72.52	84.51
2010	30,391	30,391	159,824	5,507,788	18,093,997	15,950.5	101	127	44,847,820	35,278,726.8	0.68	181.23	5.26	34.46	63.32	79.62
2011	32,047	32,047	147,849	5,093,018	16,098,536	14,826.7	101	115	43,679,795	34,713,768.7	0.73	158.92	4.61	34.45	68.12	77.56
2012	33,055	33,055	118,968	3,899,517	12,068,215	11,486.7	117	142	42,577,543	33,528,788.7	0.78	117.97	3.60	32.78	101.86	123.62
2013	12,330	12,330	28,264	825,927	2,308,335	2,475.4	41	48	33,112,182	12,513,652.0	0.37	66.99	2.29	29.22	165.63	193.91
Primary diagnosis																
2000	459	459	3,323	113,348	442,776	325.1	1	1	7,277,388	3,374,016.7	0.06	246.95	7.24	34.11	30.76	30.76
2001	1,408	1,408	10,736	399,892	1,547,088	1,143.6	2	2	7,849,493	6,675,949.8	0.18	284.01	7.63	37.25	17.49	17.49
2002	1,847	1,847	12,418	514,020	1,744,383	1,466.0	1	1	7,994,395	6,770,040.2	0.23	278.30	6.72	41.39	6.82	6.82
2003	4,078	4,078	28,544	1,035,464	4,808,057	2,970.8	1	1	7,937,517	6,717,435.8	0.51	253.91	7.00	36.28	3.37	3.37
2004	4,864	4,864	30,345	1,103,952	5,577,118	3,172.5	5	5	8,494,638	6,923,928.2	0.57	226.96	6.24	36.38	15.76	15.76
2005	4,570	4,570	26,777	1,000,724	4,308,338	2,877.0	3	3	8,753,674	7,301,309.9	0.52	218.98	5.86	37.37	10.43	10.43
2006	6,904	6,904	50,631	1,896,852	7,511,037	5,409.4	15	15	19,680,949	12,094,175.8	0.35	274.75	7.33	37.46	27.73	27.73
2007	11,215	11,215	77,118	2,793,668	10,363,429	7,999.4	32	32	23,508,607	17,227,594.9	0.48	249.10	6.88	36.23	40.00	40.00
2008	21,404	21,404	128,975	4,550,631	15,679,472	13,111.8	56	64	44,766,382	28,437,836.5	0.48	212.61	6.03	35.28	42.71	48.81
2009	30,661	30,661	175,455	6,074,361	20,554,402	17,530.9	77	91	46,631,956	36,515,678.6	0.66	198.11	5.72	34.62	43.92	51.91
2010	30,403	30,403	159,868	5,509,076	18,096,543	15,967.0	60	70	44,847,821	35,278,819.4	0.68	181.20	5.26	34.46	37.58	43.84
2011	32,062	32,062	147,897	5,094,347	16,102,084	14,837.8	63	69	43,679,794	34,713,857.7	0.73	158.89	4.61	34.45	42.46	46.50
2012	33,069	33,069	119,014	3,900,804	12,078,200	11,499.5	64	73	42,577,533	33,528,874.7	0.78	117.96	3.60	32.78	55.65	63.48
2013	12,334	12,334	28,284	826,446	2,308,878	2,478.5	22	23	33,112,170	12,513,688.5	0.37	67.01	2.29	29.22	88.76	92.80

Table 4: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Year

	New Users	New Episodes	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Days Dispensing/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk	
183-day event washout																
Nonsecondary diagnosis																
2000	459	459	3,323	113,348	442,776	325.1	1	1	7,277,301	3,373,826.3	0.06	246.95	7.24	34.11	30.76	30.76
2001	1,407	1,407	10,735	399,883	1,547,070	1,143.6	2	2	7,849,415	6,675,573.0	0.18	284.21	7.63	37.25	17.49	17.49
2002	1,844	1,844	12,412	513,670	1,743,583	1,465.0	1	1	7,994,319	6,769,635.0	0.23	278.56	6.73	41.38	6.83	6.83
2003	4,073	4,073	28,527	1,034,969	4,806,827	2,969.3	1	1	7,937,451	6,717,071.9	0.51	254.10	7.00	36.28	3.37	3.37
2004	4,859	4,859	30,205	1,099,758	5,564,282	3,161.6	4	4	8,494,561	6,923,513.4	0.57	226.33	6.22	36.41	12.65	12.65
2005	4,569	4,569	26,776	1,000,694	4,308,248	2,876.9	3	3	8,753,606	7,300,881.3	0.52	219.02	5.86	37.37	10.43	10.43
2006	6,887	6,887	50,576	1,894,836	7,505,121	5,402.9	16	16	19,680,365	12,092,867.0	0.35	275.13	7.34	37.47	29.61	29.61
2007	11,173	11,173	76,829	2,784,359	10,335,466	7,972.9	30	31	23,507,859	17,225,366.4	0.48	249.20	6.88	36.24	37.63	38.88
2008	21,288	21,288	128,467	4,534,654	15,620,652	13,061.1	62	68	44,764,879	28,433,600.8	0.48	213.01	6.03	35.30	47.47	52.06
2009	30,494	30,494	174,741	6,052,699	20,480,167	17,460.6	106	123	46,630,588	36,510,039.0	0.65	198.49	5.73	34.64	60.71	70.44
2010	30,258	30,258	159,405	5,494,303	18,056,043	15,914.9	86	107	44,846,692	35,273,558.0	0.67	181.58	5.27	34.47	54.04	67.23
2011	31,916	31,916	147,425	5,080,577	16,056,551	14,794.1	89	99	43,678,648	34,708,653.7	0.73	159.19	4.62	34.46	60.16	66.92
2012	32,908	32,908	118,541	3,887,484	12,020,306	11,452.6	101	114	42,576,450	33,523,696.7	0.77	118.13	3.60	32.79	88.19	99.54
2013	12,283	12,283	28,189	823,984	2,303,514	2,469.6	34	38	33,110,390	12,511,718.9	0.37	67.08	2.29	29.23	137.68	153.87
Primary diagnosis																
2000	459	459	3,323	113,348	442,776	325.1	1	1	7,277,301	3,373,826.3	0.06	246.95	7.24	34.11	30.76	30.76
2001	1,407	1,407	10,735	399,883	1,547,070	1,143.6	2	2	7,849,415	6,675,573.4	0.18	284.21	7.63	37.25	17.49	17.49
2002	1,844	1,844	12,412	513,670	1,743,583	1,465.0	1	1	7,994,319	6,769,635.1	0.23	278.56	6.73	41.38	6.83	6.83
2003	4,073	4,073	28,527	1,034,969	4,806,827	2,969.3	1	1	7,937,451	6,717,071.9	0.51	254.10	7.00	36.28	3.37	3.37
2004	4,859	4,859	30,205	1,099,758	5,564,282	3,161.6	4	4	8,494,561	6,923,513.5	0.57	226.33	6.22	36.41	12.65	12.65
2005	4,569	4,569	26,776	1,000,694	4,308,248	2,876.9	3	3	8,753,609	7,300,901.4	0.52	219.02	5.86	37.37	10.43	10.43
2006	6,887	6,887	50,576	1,894,836	7,505,121	5,403.5	14	14	19,680,456	12,093,017.1	0.35	275.13	7.34	37.47	25.91	25.91
2007	11,178	11,178	76,850	2,784,953	10,337,152	7,976.8	24	24	23,507,910	17,225,632.7	0.48	249.15	6.88	36.24	30.09	30.09
2008	21,334	21,334	128,761	4,543,803	15,660,766	13,096.0	41	46	44,765,604	28,434,930.4	0.48	212.98	6.04	35.29	31.31	35.13
2009	30,560	30,560	175,003	6,060,471	20,510,708	17,493.8	64	76	46,631,206	36,512,267.0	0.66	198.31	5.73	34.63	36.58	43.44
2010	30,324	30,324	159,624	5,501,664	18,073,114	15,948.2	52	59	44,847,177	35,275,563.1	0.68	181.43	5.26	34.47	32.61	36.99
2011	31,983	31,983	147,645	5,087,035	16,072,481	14,819.0	55	59	43,679,076	34,710,469.2	0.73	159.05	4.62	34.45	37.11	39.81
2012	32,988	32,988	118,793	3,894,922	12,057,346	11,483.0	58	61	42,576,892	33,525,622.9	0.77	118.07	3.60	32.79	50.51	53.12
2013	12,320	12,320	28,266	825,991	2,307,838	2,477.1	19	20	33,111,096	12,512,530.9	0.37	67.04	2.29	29.22	76.70	80.74

Table 4: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Year

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk
Topiramate																
<i>7-day event washout</i>																
Nonsecondary diagnosis																
2000	1,920	1,920	9,678	365,683	1,035,400	1,059.2	0	0	7,275,228	3,372,428.0	0.26	190.46	5.04	37.78	0.00	0.00
2001	6,057	6,057	25,524	958,707	2,557,715	2,811.0	1	1	7,846,849	6,671,214.8	0.77	158.28	4.21	37.56	3.56	3.56
2002	9,062	9,062	40,008	1,595,759	4,271,442	4,650.8	1	1	7,987,674	6,760,809.4	1.13	176.09	4.41	39.89	2.15	2.15
2003	16,572	16,572	77,611	2,815,608	8,547,309	8,242.8	1	1	7,923,879	6,699,227.6	2.09	169.90	4.68	36.28	1.21	1.21
2004	16,813	16,813	65,848	2,345,915	10,087,441	6,949.1	1	1	8,468,959	6,895,172.4	1.99	139.53	3.92	35.63	1.44	1.44
2005	13,391	13,391	47,163	1,854,745	4,670,054	5,488.1	1	1	8,718,578	7,264,696.3	1.54	138.51	3.52	39.33	1.82	1.82
2006	24,736	24,736	94,323	3,656,699	8,811,458	10,777.1	3	3	19,622,891	12,046,076.7	1.26	147.83	3.81	38.77	2.78	2.78
2007	38,985	38,985	139,627	5,077,880	11,727,117	15,127.1	10	10	23,437,080	17,155,102.2	1.66	130.25	3.58	36.37	6.61	6.61
2008	66,815	66,815	210,992	7,329,655	16,595,096	22,133.1	13	13	44,633,633	28,319,667.4	1.50	109.70	3.16	34.74	5.87	5.87
2009	92,538	92,538	292,396	9,939,982	22,526,213	30,037.3	23	25	46,483,092	36,357,214.0	1.99	107.42	3.16	33.99	7.66	8.32
2010	89,739	89,739	271,805	9,204,922	20,897,670	27,922.3	22	24	44,674,260	35,101,714.3	2.01	102.57	3.03	33.87	7.88	8.60
2011	84,732	84,732	238,532	8,041,091	17,667,333	24,503.1	17	21	43,485,792	34,520,137.3	1.95	94.90	2.82	33.71	6.94	8.57
2012	92,802	92,802	230,214	7,517,368	15,942,628	23,158.4	14	15	42,373,133	33,326,533.3	2.19	81.00	2.48	32.65	6.05	6.48
2013	37,032	37,032	67,772	2,033,571	4,244,867	6,388.7	3	3	32,918,953	12,432,948.6	1.12	54.91	1.83	30.01	4.70	4.70
Primary diagnosis																
2000	1,920	1,920	9,678	365,683	1,035,400	1,059.2	0	0	7,275,228	3,372,428.0	0.26	190.46	5.04	37.78	0.00	0.00
2001	6,057	6,057	25,524	958,707	2,557,715	2,811.0	1	1	7,846,849	6,671,214.8	0.77	158.28	4.21	37.56	3.56	3.56
2002	9,062	9,062	40,008	1,595,759	4,271,442	4,650.8	1	1	7,987,674	6,760,809.4	1.13	176.09	4.41	39.89	2.15	2.15
2003	16,572	16,572	77,611	2,815,608	8,547,309	8,242.8	1	1	7,923,879	6,699,227.6	2.09	169.90	4.68	36.28	1.21	1.21
2004	16,813	16,813	65,848	2,345,915	10,087,441	6,949.1	1	1	8,468,959	6,895,172.4	1.99	139.53	3.92	35.63	1.44	1.44
2005	13,391	13,391	47,163	1,854,745	4,670,054	5,488.1	1	1	8,718,578	7,264,697.3	1.54	138.51	3.52	39.33	1.82	1.82
2006	24,736	24,736	94,323	3,656,699	8,811,458	10,777.1	2	2	19,622,892	12,046,083.5	1.26	147.83	3.81	38.77	1.86	1.86
2007	38,985	38,985	139,627	5,077,880	11,727,117	15,127.5	9	9	23,437,080	17,155,116.1	1.66	130.25	3.58	36.37	5.95	5.95
2008	66,817	66,817	210,995	7,329,745	16,595,276	22,135.6	8	8	44,633,637	28,319,730.1	1.50	109.70	3.16	34.74	3.61	3.61
2009	92,539	92,539	292,397	9,940,012	22,526,273	30,045.2	11	13	46,483,098	36,357,320.5	1.99	107.41	3.16	33.99	3.66	4.33
2010	89,742	89,742	271,808	9,205,013	20,897,821	27,924.0	14	16	44,674,260	35,101,806.7	2.01	102.57	3.03	33.87	5.01	5.73
2011	84,734	84,734	238,534	8,041,101	17,667,353	24,505.1	14	17	43,485,791	34,520,226.2	1.95	94.90	2.82	33.71	5.71	6.94
2012	92,806	92,806	230,220	7,517,542	15,943,129	23,159.7	11	12	42,373,131	33,326,627.3	2.19	81.00	2.48	32.65	4.75	5.18
2013	37,032	37,032	67,772	2,033,571	4,244,867	6,388.8	1	1	32,918,952	12,432,990.1	1.12	54.91	1.83	30.01	1.57	1.57

Table 4: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Year

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk
183-day event washout																
Nonsecondary diagnosis																
2000	1,919	1,919	9,675	365,613	1,035,260	1,059.0	0	0	7,275,141	3,372,237.7	0.26	190.52	5.04	37.79	0.00	0.00
2001	6,056	6,056	25,513	958,377	2,556,785	2,810.1	1	1	7,846,771	6,670,838.2	0.77	158.25	4.21	37.56	3.56	3.56
2002	9,058	9,058	39,946	1,593,932	4,266,424	4,645.7	1	1	7,987,598	6,760,406.2	1.13	175.97	4.41	39.90	2.15	2.15
2003	16,570	16,570	77,608	2,815,518	8,547,219	8,242.5	1	1	7,923,815	6,698,864.8	2.09	169.92	4.68	36.28	1.21	1.21
2004	16,811	16,811	65,845	2,345,795	10,087,221	6,948.7	1	1	8,468,883	6,894,758.7	1.99	139.54	3.92	35.63	1.44	1.44
2005	13,388	13,388	47,160	1,854,678	4,669,927	5,487.8	1	1	8,718,513	7,264,273.4	1.54	138.53	3.52	39.33	1.82	1.82
2006	24,725	24,725	94,303	3,655,922	8,809,588	10,774.6	3	3	19,622,304	12,044,778.4	1.26	147.86	3.81	38.77	2.78	2.78
2007	38,973	38,973	139,580	5,076,447	11,723,824	15,122.8	10	10	23,436,340	17,152,879.7	1.66	130.26	3.58	36.37	6.61	6.61
2008	66,785	66,785	210,879	7,325,557	16,588,192	22,121.2	11	11	44,632,116	28,315,434.3	1.50	109.69	3.16	34.74	4.97	4.97
2009	92,508	92,508	292,238	9,935,245	22,515,886	30,026.4	20	21	46,481,693	36,351,599.1	1.99	107.40	3.16	34.00	6.66	6.99
2010	89,712	89,712	271,738	9,202,496	20,892,569	27,915.0	21	21	44,673,055	35,096,458.2	2.01	102.58	3.03	33.87	7.52	7.52
2011	84,704	84,704	238,426	8,037,792	17,658,129	24,493.5	16	20	43,484,555	34,514,886.2	1.95	94.89	2.81	33.71	6.53	8.17
2012	92,780	92,780	230,138	7,515,106	15,936,488	23,152.5	13	13	42,371,947	33,321,293.6	2.19	81.00	2.48	32.65	5.61	5.61
2013	37,019	37,019	67,749	2,032,950	4,243,454	6,386.7	3	3	32,917,044	12,430,952.8	1.12	54.92	1.83	30.01	4.70	4.70
Primary diagnosis																
2000	1,919	1,919	9,675	365,613	1,035,260	1,059.0	0	0	7,275,141	3,372,237.7	0.26	190.52	5.04	37.79	0.00	0.00
2001	6,056	6,056	25,513	958,377	2,556,785	2,810.1	1	1	7,846,771	6,670,838.6	0.77	158.25	4.21	37.56	3.56	3.56
2002	9,058	9,058	39,946	1,593,932	4,266,424	4,645.7	1	1	7,987,598	6,760,406.3	1.13	175.97	4.41	39.90	2.15	2.15
2003	16,570	16,570	77,608	2,815,518	8,547,219	8,242.5	1	1	7,923,815	6,698,864.8	2.09	169.92	4.68	36.28	1.21	1.21
2004	16,811	16,811	65,845	2,345,795	10,087,221	6,948.7	1	1	8,468,883	6,894,758.8	1.99	139.54	3.92	35.63	1.44	1.44
2005	13,390	13,390	47,162	1,854,723	4,670,017	5,488.0	1	1	8,718,516	7,264,292.7	1.54	138.52	3.52	39.33	1.82	1.82
2006	24,731	24,731	94,314	3,656,309	8,810,588	10,775.9	2	2	19,622,398	12,044,925.6	1.26	147.84	3.81	38.77	1.86	1.86
2007	38,973	38,973	139,585	5,076,587	11,724,203	15,123.5	9	9	23,436,383	17,153,143.5	1.66	130.26	3.58	36.37	5.95	5.95
2008	66,799	66,799	210,940	7,327,398	16,591,954	22,128.8	7	7	44,632,840	28,316,778.5	1.50	109.69	3.16	34.74	3.16	3.16
2009	92,522	92,522	292,262	9,935,933	22,517,450	30,033.9	9	10	46,482,330	36,353,848.1	1.99	107.39	3.16	34.00	3.00	3.33
2010	89,729	89,729	271,771	9,203,494	20,894,532	27,919.4	14	16	44,673,555	35,098,488.8	2.01	102.57	3.03	33.86	5.01	5.73
2011	84,719	84,719	238,480	8,039,308	17,663,950	24,499.8	14	17	43,485,017	34,516,757.5	1.95	94.89	2.81	33.71	5.71	6.94
2012	92,797	92,797	230,186	7,516,540	15,941,592	23,157.4	10	10	42,372,426	33,323,288.2	2.19	81.00	2.48	32.65	4.32	4.32
2013	37,023	37,023	67,759	2,033,250	4,244,582	6,387.6	1	1	32,917,800	12,431,793.3	1.12	54.92	1.83	30.01	1.57	1.57

Table 4: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Year

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk
Clozapine																
<i>7-day event washout</i>																
Nonsecondary diagnosis																
2000	148	148	4,791	77,442	250,970	217.8	0	0	7,276,183	3,373,472.8	0.02	523.26	32.37	16.16	0.00	0.00
2001	326	326	10,472	170,899	887,212	482.6	0	0	7,848,753	6,675,642.3	0.04	524.23	32.12	16.32	0.00	0.00
2002	291	291	8,177	136,305	594,203	388.4	0	0	7,994,917	6,771,070.9	0.04	468.40	28.10	16.67	0.00	0.00
2003	266	266	5,799	100,922	421,821	288.5	0	0	7,939,629	6,720,821.7	0.03	379.41	21.80	17.40	0.00	0.00
2004	298	298	7,395	125,317	604,503	355.5	0	0	8,500,674	6,931,498.0	0.04	420.53	24.82	16.95	0.00	0.00
2005	269	269	5,490	88,489	310,470	251.6	1	1	8,763,789	7,312,447.0	0.03	328.96	20.41	16.12	39.74	39.74
2006	291	291	6,224	113,387	400,828	321.1	2	2	19,698,075	12,109,084.6	0.01	389.65	21.39	18.22	62.29	62.29
2007	363	363	7,824	141,210	436,869	399.5	0	0	23,533,345	17,251,657.6	0.02	389.01	21.55	18.05	0.00	0.00
2008	520	520	11,457	192,215	579,277	545.4	1	2	44,817,153	28,482,826.3	0.01	369.64	22.03	16.78	18.34	36.67
2009	639	639	12,167	185,325	577,625	529.9	0	0	46,696,909	36,583,412.0	0.01	290.02	19.04	15.23	0.00	0.00
2010	504	504	10,093	146,199	426,303	417.7	1	1	44,928,807	35,360,022.3	0.01	290.08	20.03	14.49	23.94	23.94
2011	560	560	8,916	119,619	342,631	345.3	1	1	43,774,548	34,808,400.7	0.01	213.61	15.92	13.42	28.96	28.96
2012	572	572	7,588	94,312	258,958	274.5	1	1	42,686,326	33,634,842.3	0.01	164.88	13.27	12.43	36.43	36.43
2013	199	199	1,433	15,378	41,005	46.3	1	1	33,208,777	12,552,847.6	0.01	77.28	7.20	10.73	216.02	216.02
Primary diagnosis																
2000	148	148	4,791	77,442	250,970	217.8	0	0	7,276,183	3,373,472.8	0.02	523.26	32.37	16.16	0.00	0.00
2001	326	326	10,472	170,899	887,212	482.6	0	0	7,848,753	6,675,642.3	0.04	524.23	32.12	16.32	0.00	0.00
2002	291	291	8,177	136,305	594,203	388.4	0	0	7,994,917	6,771,070.9	0.04	468.40	28.10	16.67	0.00	0.00
2003	266	266	5,799	100,922	421,821	288.5	0	0	7,939,629	6,720,821.7	0.03	379.41	21.80	17.40	0.00	0.00
2004	298	298	7,395	125,317	604,503	355.5	0	0	8,500,674	6,931,498.0	0.04	420.53	24.82	16.95	0.00	0.00
2005	269	269	5,490	88,489	310,470	251.6	1	1	8,763,789	7,312,448.0	0.03	328.96	20.41	16.12	39.74	39.74
2006	291	291	6,224	113,387	400,828	321.1	2	2	19,698,076	12,109,091.5	0.01	389.65	21.39	18.22	62.29	62.29
2007	363	363	7,824	141,210	436,869	399.5	0	0	23,533,345	17,251,671.5	0.02	389.01	21.55	18.05	0.00	0.00
2008	520	520	11,457	192,215	579,277	545.7	0	0	44,817,157	28,482,889.6	0.01	369.64	22.03	16.78	0.00	0.00
2009	639	639	12,167	185,325	577,625	529.9	0	0	46,696,916	36,583,521.1	0.01	290.02	19.04	15.23	0.00	0.00
2010	504	504	10,093	146,199	426,303	417.7	1	1	44,928,810	35,360,118.5	0.01	290.08	20.03	14.49	23.94	23.94
2011	560	560	8,916	119,619	342,631	345.3	1	1	43,774,551	34,808,494.7	0.01	213.61	15.92	13.42	28.96	28.96
2012	572	572	7,588	94,312	258,958	274.6	0	0	42,686,328	33,634,941.4	0.01	164.88	13.27	12.43	0.00	0.00
2013	199	199	1,433	15,378	41,005	46.3	1	1	33,208,779	12,552,890.7	0.01	77.28	7.20	10.73	216.02	216.02

Table 4: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Year

	New Users	New Episodes	New Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk
183-day event washout																
Nonsecondary diagnosis																
2000	148	148	4,791	77,442	250,970	217.8	0	0	7,276,096	3,373,282.4	0.02	523.26	32.37	16.16	0.00	0.00
2001	326	326	10,472	170,899	887,212	482.6	0	0	7,848,675	6,675,264.8	0.04	524.23	32.12	16.32	0.00	0.00
2002	291	291	8,177	136,305	594,203	388.4	0	0	7,994,841	6,770,662.8	0.04	468.40	28.10	16.67	0.00	0.00
2003	266	266	5,799	100,922	421,821	288.5	0	0	7,939,562	6,720,455.0	0.03	379.41	21.80	17.40	0.00	0.00
2004	298	298	7,395	125,317	604,503	355.5	0	0	8,500,593	6,931,076.1	0.04	420.53	24.82	16.95	0.00	0.00
2005	269	269	5,490	88,489	310,470	251.6	1	1	8,763,719	7,312,013.1	0.03	328.96	20.41	16.12	39.74	39.74
2006	290	290	6,197	113,186	400,488	320.5	2	2	19,697,482	12,107,767.2	0.01	390.30	21.37	18.26	62.40	62.40
2007	363	363	7,824	141,210	436,869	399.5	0	0	23,532,589	17,249,404.7	0.02	389.01	21.55	18.05	0.00	0.00
2008	520	520	11,457	192,215	579,277	545.4	1	2	44,815,624	28,478,536.8	0.01	369.64	22.03	16.78	18.34	36.67
2009	639	639	12,167	185,325	577,625	529.9	0	0	46,695,472	36,577,706.9	0.01	290.02	19.04	15.23	0.00	0.00
2010	502	502	10,026	144,990	424,153	414.4	1	1	44,927,561	35,354,651.6	0.01	288.82	19.97	14.46	24.13	24.13
2011	560	560	8,916	119,619	342,631	345.3	1	1	43,773,265	34,803,029.1	0.01	213.61	15.92	13.42	28.96	28.96
2012	570	570	7,576	94,128	258,470	274.0	0	0	42,685,090	33,629,482.8	0.01	165.14	13.29	12.42	0.00	0.00
2013	198	198	1,422	15,303	40,780	46.1	1	1	33,206,807	12,550,807.2	0.01	77.29	7.18	10.76	217.09	217.09
Primary diagnosis																
2000	148	148	4,791	77,442	250,970	217.8	0	0	7,276,096	3,373,282.4	0.02	523.26	32.37	16.16	0.00	0.00
2001	326	326	10,472	170,899	887,212	482.6	0	0	7,848,675	6,675,265.2	0.04	524.23	32.12	16.32	0.00	0.00
2002	291	291	8,177	136,305	594,203	388.4	0	0	7,994,841	6,770,662.9	0.04	468.40	28.10	16.67	0.00	0.00
2003	266	266	5,799	100,922	421,821	288.5	0	0	7,939,562	6,720,455.0	0.03	379.41	21.80	17.40	0.00	0.00
2004	298	298	7,395	125,317	604,503	355.5	0	0	8,500,593	6,931,076.2	0.04	420.53	24.82	16.95	0.00	0.00
2005	269	269	5,490	88,489	310,470	251.6	1	1	8,763,722	7,312,033.7	0.03	328.96	20.41	16.12	39.74	39.74
2006	291	291	6,224	113,387	400,828	321.1	2	2	19,697,576	12,107,918.3	0.01	389.65	21.39	18.22	62.29	62.29
2007	363	363	7,824	141,210	436,869	399.5	0	0	23,532,639	17,249,675.5	0.02	389.01	21.55	18.05	0.00	0.00
2008	520	520	11,457	192,215	579,277	545.7	0	0	44,816,349	28,479,899.6	0.01	369.64	22.03	16.78	0.00	0.00
2009	639	639	12,167	185,325	577,625	529.9	0	0	46,696,118	36,579,993.9	0.01	290.02	19.04	15.23	0.00	0.00
2010	503	503	10,079	146,101	426,130	417.4	1	1	44,928,077	35,356,731.0	0.01	290.46	20.04	14.50	23.96	23.96
2011	560	560	8,916	119,619	342,631	345.3	1	1	43,773,749	34,804,946.3	0.01	213.61	15.92	13.42	28.96	28.96
2012	572	572	7,588	94,312	258,958	274.6	0	0	42,685,595	33,631,533.8	0.01	164.88	13.27	12.43	0.00	0.00
2013	199	199	1,433	15,378	41,005	46.3	1	1	33,207,597	12,551,671.6	0.01	77.28	7.20	10.73	216.02	216.02

Table 4: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Year

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk
Olanzapine																
<i>7-day event washout</i>																
Nonsecondary diagnosis																
2000	10,901	10,901	56,651	1,780,300	2,441,780	5,225.6	2	2	7,260,105	3,362,241.6	1.50	163.32	5.20	31.43	3.83	3.83
2001	23,155	23,155	108,020	3,449,301	4,628,131	10,172.3	3	3	7,825,894	6,642,699.6	2.96	148.97	4.67	31.93	2.95	2.95
2002	25,820	25,820	106,721	3,420,956	4,695,988	10,162.5	4	4	7,953,101	6,720,164.5	3.25	132.49	4.13	32.06	3.94	3.94
2003	22,494	22,494	81,355	2,675,787	4,535,434	8,007.9	2	2	7,879,594	6,654,948.5	2.85	118.96	3.62	32.89	2.50	2.50
2004	16,583	16,583	57,309	1,872,122	5,756,284	5,597.4	4	4	8,425,526	6,854,470.7	1.97	112.89	3.46	32.67	7.15	7.15
2005	10,878	10,878	32,717	1,084,279	1,420,557	3,265.2	2	2	8,683,499	7,234,224.9	1.25	99.68	3.01	33.14	6.13	6.13
2006	10,495	10,495	36,301	1,283,374	1,673,527	3,805.5	8	8	19,631,457	12,048,542.3	0.53	122.28	3.46	35.35	21.02	21.02
2007	12,758	12,758	43,814	1,470,520	1,845,857	4,380.5	18	20	23,463,877	17,185,917.7	0.54	115.26	3.43	33.56	41.09	45.66
2008	20,424	20,424	67,739	2,167,519	2,580,782	6,499.3	16	17	44,733,059	28,403,863.8	0.46	106.13	3.32	32.00	24.62	26.16
2009	23,257	23,257	73,930	2,355,513	2,764,590	7,090.4	48	58	46,608,692	36,496,711.8	0.50	101.28	3.18	31.86	67.70	81.80
2010	21,746	21,746	69,285	2,199,690	2,616,768	6,622.6	25	28	44,838,557	35,271,794.9	0.48	101.15	3.19	31.75	37.75	42.28
2011	20,222	20,222	62,142	1,964,088	2,310,166	5,932.3	33	35	43,681,340	34,717,694.2	0.46	97.13	3.07	31.61	55.63	59.00
2012	21,499	21,499	60,716	1,861,097	2,191,313	5,646.9	34	42	42,591,051	33,543,017.8	0.50	86.57	2.82	30.65	60.21	74.38
2013	8,029	8,029	16,395	450,807	535,619	1,391.7	18	19	33,139,925	12,524,726.4	0.24	56.15	2.04	27.50	129.34	136.52
Primary diagnosis																
2000	10,901	10,901	56,651	1,780,300	2,441,780	5,225.6	2	2	7,260,105	3,362,241.6	1.50	163.32	5.20	31.43	3.83	3.83
2001	23,155	23,155	108,020	3,449,301	4,628,131	10,172.3	3	3	7,825,894	6,642,699.6	2.96	148.97	4.67	31.93	2.95	2.95
2002	25,820	25,820	106,721	3,420,956	4,695,988	10,162.5	4	4	7,953,101	6,720,164.5	3.25	132.49	4.13	32.06	3.94	3.94
2003	22,494	22,494	81,355	2,675,787	4,535,434	8,007.9	2	2	7,879,594	6,654,948.5	2.85	118.96	3.62	32.89	2.50	2.50
2004	16,583	16,583	57,309	1,872,122	5,756,284	5,597.4	3	3	8,425,526	6,854,470.7	1.97	112.89	3.46	32.67	5.36	5.36
2005	10,878	10,878	32,717	1,084,279	1,420,557	3,265.2	2	2	8,683,499	7,234,225.9	1.25	99.68	3.01	33.14	6.13	6.13
2006	10,496	10,496	36,302	1,283,434	1,673,707	3,805.8	7	7	19,631,458	12,048,549.0	0.53	122.28	3.46	35.35	18.39	18.39
2007	12,758	12,758	43,814	1,470,520	1,845,857	4,380.6	16	18	23,463,876	17,185,931.1	0.54	115.26	3.43	33.56	36.52	41.09
2008	20,425	20,425	67,740	2,167,549	2,580,812	6,499.6	15	15	44,733,062	28,403,926.7	0.46	106.12	3.32	32.00	23.08	23.08
2009	23,262	23,262	73,937	2,355,693	2,764,770	7,092.8	33	43	46,608,699	36,496,819.8	0.50	101.27	3.18	31.86	46.53	60.62
2010	21,749	21,749	69,294	2,199,998	2,617,099	6,623.7	20	21	44,838,557	35,271,888.3	0.49	101.15	3.19	31.75	30.19	31.70
2011	20,226	20,226	62,155	1,964,508	2,310,586	5,934.4	20	21	43,681,341	34,717,786.5	0.46	97.13	3.07	31.61	33.70	35.39
2012	21,503	21,503	60,724	1,861,291	2,191,542	5,648.1	24	28	42,591,051	33,543,114.6	0.50	86.56	2.82	30.65	42.49	49.57
2013	8,029	8,029	16,395	450,807	535,619	1,392.5	10	10	33,139,923	12,524,767.9	0.24	56.15	2.04	27.50	71.82	71.82

Table 4: Incident Drug Use (Incident to Drug of Interest Only) in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Drug Product, Event Washout Period, Primary Diagnosis Indicator, and Year

	New Users	New Episodes	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Number of Events	Eligible Members	Member-Years	New Users/ 1K Eligible Members	Days Supplied/ User	Days Dispensings/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	Total Number of Events / 10K Years at Risk	
183-day event washout																
Nonsecondary diagnosis																
2000	10,900	10,900	56,650	1,780,270	2,441,735	5,225.5	2	2	7,260,018	3,362,051.9	1.50	163.33	5.20	31.43	3.83	3.83
2001	23,151	23,151	108,007	3,449,000	4,627,596	10,171.3	3	3	7,825,816	6,642,324.3	2.96	148.98	4.67	31.93	2.95	2.95
2002	25,818	25,818	106,718	3,420,866	4,695,898	10,162.2	4	4	7,953,028	6,719,763.2	3.25	132.50	4.13	32.06	3.94	3.94
2003	22,492	22,492	81,352	2,675,711	4,535,338	8,007.7	2	2	7,879,532	6,654,589.3	2.85	118.96	3.62	32.89	2.50	2.50
2004	16,578	16,578	57,301	1,871,934	5,756,081	5,596.8	4	4	8,425,452	6,854,061.7	1.97	112.92	3.46	32.67	7.15	7.15
2005	10,869	10,869	32,688	1,083,294	1,419,238	3,262.2	2	2	8,683,431	7,233,803.1	1.25	99.67	3.01	33.14	6.13	6.13
2006	10,479	10,479	36,276	1,282,688	1,672,604	3,803.4	6	6	19,630,873	12,047,246.9	0.53	122.41	3.46	35.36	15.78	15.78
2007	12,715	12,715	43,710	1,467,833	1,841,883	4,372.4	12	12	23,463,132	17,183,699.8	0.54	115.44	3.44	33.58	27.45	27.45
2008	20,368	20,368	67,541	2,161,808	2,572,457	6,482.2	14	15	44,731,556	28,399,647.8	0.46	106.14	3.32	32.01	21.60	23.14
2009	23,201	23,201	73,819	2,352,273	2,760,015	7,080.8	39	47	46,607,319	36,491,111.5	0.50	101.39	3.18	31.87	55.08	66.38
2010	21,691	21,691	69,171	2,196,265	2,612,230	6,611.9	21	23	44,837,389	35,266,531.6	0.48	101.25	3.19	31.75	31.76	34.79
2011	20,156	20,156	62,040	1,961,052	2,306,615	5,923.0	22	22	43,680,130	34,712,443.8	0.46	97.29	3.08	31.61	37.14	37.14
2012	21,411	21,411	60,526	1,855,874	2,185,099	5,631.2	25	29	42,589,906	33,537,797.8	0.50	86.68	2.83	30.66	44.40	51.50
2013	7,994	7,994	16,351	449,718	534,494	1,388.5	14	14	33,138,048	12,522,742.4	0.24	56.26	2.05	27.50	100.83	100.83
Primary diagnosis																
2000	10,900	10,900	56,650	1,780,270	2,441,735	5,225.5	2	2	7,260,018	3,362,051.9	1.50	163.33	5.20	31.43	3.83	3.83
2001	23,151	23,151	108,007	3,449,000	4,627,596	10,171.3	3	3	7,825,816	6,642,324.7	2.96	148.98	4.67	31.93	2.95	2.95
2002	25,818	25,818	106,718	3,420,866	4,695,898	10,162.2	4	4	7,953,028	6,719,763.3	3.25	132.50	4.13	32.06	3.94	3.94
2003	22,492	22,492	81,352	2,675,711	4,535,338	8,007.7	2	2	7,879,532	6,654,589.3	2.85	118.96	3.62	32.89	2.50	2.50
2004	16,578	16,578	57,301	1,871,934	5,756,081	5,596.8	3	3	8,425,452	6,854,061.7	1.97	112.92	3.46	32.67	5.36	5.36
2005	10,869	10,869	32,688	1,083,294	1,419,238	3,262.2	2	2	8,683,434	7,233,823.5	1.25	99.67	3.01	33.14	6.13	6.13
2006	10,484	10,484	36,283	1,282,882	1,672,924	3,804.0	7	7	19,630,965	12,047,395.4	0.53	122.37	3.46	35.36	18.40	18.40
2007	12,718	12,718	43,714	1,467,923	1,842,063	4,372.8	10	10	23,463,179	17,183,965.9	0.54	115.42	3.44	33.58	22.87	22.87
2008	20,385	20,385	67,582	2,162,998	2,573,872	6,486.1	14	14	44,732,287	28,400,997.3	0.46	106.11	3.32	32.01	21.58	21.58
2009	23,234	23,234	73,885	2,354,095	2,762,297	7,088.2	26	34	46,607,958	36,493,373.4	0.50	101.32	3.18	31.86	36.68	47.97
2010	21,716	21,716	69,239	2,198,480	2,615,049	6,618.8	17	18	44,837,881	35,268,578.1	0.48	101.24	3.19	31.75	25.68	27.20
2011	20,181	20,181	62,084	1,962,418	2,308,102	5,927.8	17	17	43,680,586	34,714,322.3	0.46	97.24	3.08	31.61	28.68	28.68
2012	21,445	21,445	60,616	1,858,305	2,187,615	5,638.9	21	24	42,590,378	33,539,804.5	0.50	86.65	2.83	30.66	37.24	42.56
2013	8,013	8,013	16,372	450,235	535,012	1,390.7	8	8	33,138,809	12,523,586.4	0.24	56.19	2.04	27.50	57.53	57.53

Appendix A. Available Data in the Mini-Sentinel Distributed Database (MSDD) for Each Data Partner (DP) as of Request Send Date (April 11, 2014)

DP ID	Start Date	End Date
DP001	1/1/2000	5/31/2013
DP002	1/1/2000	5/31/2013
DP003	1/1/2000	5/31/2013
DP004	1/1/2000	5/31/2013
DP005	1/1/2000	5/31/2013
DP006	1/1/2000	5/31/2013
DP007	1/1/2000	5/31/2013
DP008	1/1/2000	5/31/2013
DP009	1/1/2000	5/31/2013
DP010	1/1/2000	5/31/2013
DP011	1/1/2000	5/31/2013
DP012	1/1/2000	5/31/2013
DP013	1/1/2000	5/31/2013
DP014	1/1/2000	5/31/2013
DP015	1/1/2000	5/31/2013

Appendix B: Group and Generic Names Used to Define Exposures in this Report

Group	Generic Name
Carbamazepine	CARBAMAZEPINE
Lamotrigine	LAMOTRIGINE
Levetiracetam	LEVETIRACETAM
Topiramate	TOPIRAMATE
Clozapine	CLOZAPINE
Olanzapine	OLANZAPINE/FLUOXETINE HCL
Olanzapine	OLANZAPINE

Appendix C: Generic Names Used to Assess Incidence of Exposures in this Report

Generic Name

ACETAZOLAMIDE
CARBAMAZEPINE
CLOBAZAM
CLONAZEPAM
DIAZEPAM
DIVALPROEX SODIUM
ETHOSUXIMIDE
EZOGABINE
FELBAMATE
GABAPENTIN
GABAPENTIN ENACARBIL
LACOSAMIDE
LORAZEPAM
PHENOBARB/HYOSCY/ATROPINE/SCOP
PHENOBARBITAL
PHENYTOIN
PHENYTOIN SODIUM
PHENYTOIN SODIUM EXTENDED
PREGABALIN
PRIMIDONE
RUFINAMIDE
THEOPHYLL/EPHED HCL/PHENOBARB
THEOPHYLL/EPHED HCL/PHENOBARB
VALPROIC ACID
VALPROIC ACID (AS SODIUM SALT)
VIGABATRIN
ZONISAMIDE

**Appendix D: International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)
Diagnosis Codes Used to Define Agranulocytosis Events in this Report**

Description	Code*
Diseases of white blood cells	288
Neutropenia	288.0
Neutropenia, unspecified	288.00
Congenital neutropenia	288.01
Cyclic neutropenia	288.02
Drug induced neutropenia	288.03
Neutropenia due to infection	288.04
Other neutropenia	288.09
Genetic anomalies of leukocytes	288.2
Hemophagocytic syndromes	288.4
Decreased white blood cell count	288.5
Leukocytopenia, unspecified	288.50
Other decreased white blood cell count	288.59
Unspecified disease of white blood cells	288.9

* exact match query

Appendix E. Specifications for Request to09y05_mpr_wp26_v01

Modular Program #3 was used to investigate diagnosis of agranulocytosis following new use of several anti-epileptic drugs (AEDs), as well as clozapine and olanzapine. Five runs of the program were required. In total, 40 different scenarios were examined in this request with differing exposures of interest, incidence criteria, event washout period, and event care setting. See below for a description of each of these scenarios. Report 1 presents scenarios 1-24 where the exposures are incident only to themselves.

		Coverage Requirement		Drug/Exposure		Event/Outcome							
		Coverage Requirement	Drug and Medical Coverage										
		Query Period	January 1, 2000 to May 31, 2013										
		Enrollment Gap	45 Days										
		Minimum Enrollment Days	183 Days										
		Age Stratifications	<18, 18-<45, 45-<65, 65+ Years										
Scenario	Incident exposure	Incident w/ respect to:	Washout (days)	Cohort Definition	Drug/Exposure					Event/Outcome			
					Episode Gap	Exposure Extension Period	Minimum Days Supplied	Minimum Episode Duration	Episode Truncation by Incident Exposure	Event/ Outcome	Washout Period	Event De-duplication	Care Setting/ PDX
1	Carbamazepine	Carbamazepine	183	01 (SING)	10	10	1	1	No	agranulocytosis	7	2	IP non-secondary
2	Levetiracetam	Levetiracetam	183	01 (SING)	10	10	1	1	No	agranulocytosis	7	2	IP non-secondary
3	Lamotrigine	Lamotrigine	183	01 (SING)	10	10	1	1	No	agranulocytosis	7	2	IP non-secondary
4	Topiramate	Topiramate	183	01 (SING)	10	10	1	1	No	agranulocytosis	7	2	IP non-secondary
5	Clozapine	Clozapine	183	01 (SING)	10	10	1	1	No	agranulocytosis	7	2	IP non-secondary
6	Olanzapine	Olanzapine	183	01 (SING)	10	10	1	1	No	agranulocytosis	7	2	IP non-secondary
7	Carbamazepine	Carbamazepine	183	01 (SING)	10	10	1	1	No	agranulocytosis	7	2	IPP
8	Levetiracetam	Levetiracetam	183	01 (SING)	10	10	1	1	No	agranulocytosis	7	2	IPP
9	Lamotrigine	Lamotrigine	183	01 (SING)	10	10	1	1	No	agranulocytosis	7	2	IPP
10	Topiramate	Topiramate	183	01 (SING)	10	10	1	1	No	agranulocytosis	7	2	IPP
11	Clozapine	Clozapine	183	01 (SING)	10	10	1	1	No	agranulocytosis	7	2	IPP
12	Olanzapine	Olanzapine	183	01 (SING)	10	10	1	1	No	agranulocytosis	7	2	IPP
13	Carbamazepine	Carbamazepine	183	01 (SING)	10	10	1	1	No	agranulocytosis	183	2	IP non-secondary
14	Levetiracetam	Levetiracetam	183	01 (SING)	10	10	1	1	No	agranulocytosis	183	2	IP non-secondary
15	Lamotrigine	Lamotrigine	183	01 (SING)	10	10	1	1	No	agranulocytosis	183	2	IP non-secondary
16	Topiramate	Topiramate	183	01 (SING)	10	10	1	1	No	agranulocytosis	183	2	IP non-secondary
17	Clozapine	Clozapine	183	01 (SING)	10	10	1	1	No	agranulocytosis	183	2	IP non-secondary

18	Olanzapine	Olanzapine	183	01 (SING)	10	10	1	1	No	agranulocytosis	183	2	IP non-secondary
19	Carbamazepine	Carbamazepine	183	01 (SING)	10	10	1	1	No	agranulocytosis	183	2	IPP
20	Levetiracetam	Levetiracetam	183	01 (SING)	10	10	1	1	No	agranulocytosis	183	2	IPP
21	Lamotrigine	Lamotrigine	183	01 (SING)	10	10	1	1	No	agranulocytosis	183	2	IPP
22	Topiramate	Topiramate	183	01 (SING)	10	10	1	1	No	agranulocytosis	183	2	IPP
23	Clozapine	Clozapine	183	01 (SING)	10	10	1	1	No	agranulocytosis	183	2	IPP
24	Olanzapine	Olanzapine	183	01 (SING)	10	10	1	1	No	agranulocytosis	183	2	IPP
25	<i>Carbamazepine</i>	<i>All Oral AEDs</i>	183	<i>01 (SING)</i>	<i>10</i>	<i>10</i>	<i>1</i>	<i>1</i>	YES	<i>agranulocytosis</i>	<i>7</i>	<i>2</i>	<i>IP non-secondary</i>
26	<i>Lamotrigine</i>	<i>All Oral AEDs</i>	183	<i>01 (SING)</i>	<i>10</i>	<i>10</i>	<i>1</i>	<i>1</i>	YES	<i>agranulocytosis</i>	<i>7</i>	<i>2</i>	<i>IP non-secondary</i>
27	<i>Levetiracetam</i>	<i>All Oral AEDs</i>	183	<i>01 (SING)</i>	<i>10</i>	<i>10</i>	<i>1</i>	<i>1</i>	YES	<i>agranulocytosis</i>	<i>7</i>	<i>2</i>	<i>IP non-secondary</i>
28	<i>Topiramate</i>	<i>All Oral AEDs</i>	183	<i>01 (SING)</i>	<i>10</i>	<i>10</i>	<i>1</i>	<i>1</i>	YES	<i>agranulocytosis</i>	<i>7</i>	<i>2</i>	<i>IP non-secondary</i>
29	<i>Carbamazepine</i>	<i>All Oral AEDs</i>	183	<i>01 (SING)</i>	<i>10</i>	<i>10</i>	<i>1</i>	<i>1</i>	YES	<i>agranulocytosis</i>	<i>7</i>	<i>2</i>	<i>IPP</i>
30	<i>Lamotrigine</i>	<i>All Oral AEDs</i>	183	<i>01 (SING)</i>	<i>10</i>	<i>10</i>	<i>1</i>	<i>1</i>	YES	<i>agranulocytosis</i>	<i>7</i>	<i>2</i>	<i>IPP</i>
31	<i>Levetiracetam</i>	<i>All Oral AEDs</i>	183	<i>01 (SING)</i>	<i>10</i>	<i>10</i>	<i>1</i>	<i>1</i>	YES	<i>agranulocytosis</i>	<i>7</i>	<i>2</i>	<i>IPP</i>
32	<i>Topiramate</i>	<i>All Oral AEDs</i>	183	<i>01 (SING)</i>	<i>10</i>	<i>10</i>	<i>1</i>	<i>1</i>	YES	<i>agranulocytosis</i>	<i>7</i>	<i>2</i>	<i>IPP</i>
33	<i>Carbamazepine</i>	<i>All Oral AEDs</i>	183	<i>01 (SING)</i>	<i>10</i>	<i>10</i>	<i>1</i>	<i>1</i>	YES	<i>agranulocytosis</i>	183	2	<i>IP non-secondary</i>
34	<i>Lamotrigine</i>	<i>All Oral AEDs</i>	183	<i>01 (SING)</i>	<i>10</i>	<i>10</i>	<i>1</i>	<i>1</i>	YES	<i>agranulocytosis</i>	183	2	<i>IP non-secondary</i>
35	<i>Levetiracetam</i>	<i>All Oral AEDs</i>	183	<i>01 (SING)</i>	<i>10</i>	<i>10</i>	<i>1</i>	<i>1</i>	YES	<i>agranulocytosis</i>	183	2	<i>IP non-secondary</i>
36	<i>Topiramate</i>	<i>All Oral AEDs</i>	183	<i>01 (SING)</i>	<i>10</i>	<i>10</i>	<i>1</i>	<i>1</i>	YES	<i>agranulocytosis</i>	183	2	<i>IP non-secondary</i>
37	<i>Carbamazepine</i>	<i>All Oral AEDs</i>	183	<i>01 (SING)</i>	<i>10</i>	<i>10</i>	<i>1</i>	<i>1</i>	YES	<i>agranulocytosis</i>	183	2	<i>IPP</i>
38	<i>Lamotrigine</i>	<i>All Oral AEDs</i>	183	<i>01 (SING)</i>	<i>10</i>	<i>10</i>	<i>1</i>	<i>1</i>	YES	<i>agranulocytosis</i>	183	2	<i>IPP</i>
39	<i>Levetiracetam</i>	<i>All Oral AEDs</i>	183	<i>01 (SING)</i>	<i>10</i>	<i>10</i>	<i>1</i>	<i>1</i>	YES	<i>agranulocytosis</i>	183	2	<i>IPP</i>
40	<i>Topiramate</i>	<i>All Oral AEDs</i>	183	<i>01 (SING)</i>	<i>10</i>	<i>10</i>	<i>1</i>	<i>1</i>	YES	<i>agranulocytosis</i>	183	2	<i>IPP</i>

Scenarios 25-40 (in italics) are presented in Report 2