

Disclaimer

The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

Data obtained through Mini-Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview for Request to09y05_mpr_wp57_v02

Request ID: to09y05_mpr_wp57_v02

Request Description: This report contains information on the availability of International Normalized Ratio (INR) laboratory test values and INR test procedures among incident warfarin brand and selected generic warfarin users.

Mini-Sentinel Analytic Tool Used: Cohort Identification and Descriptive Analysis (CIDA) tool, version 1.4

Data Source: Data from January 1, 2008 to October 31, 2013 from 12 Data Partners contributing to the Mini-Sentinel Distributed Database (MSDD) were included in this report. This request was distributed on October 17, 2014 to 12 Data Partners; this report contains data from 12 Data Partners. See Appendix A for a list of the dates of available data for each Data Partner.

Study Design: This request was a retrospective new user cohort study.

Exposure of Interest: The exposure of interest was warfarin use, which was defined using National Drug Codes (NDCs). See Appendix B for a list of generic and brand names used in this request.

Events of Interest: The events of interest were INR test procedures among incident warfarin brand and selected generic warfarin users. See Appendix C for a list of Healthcare Common Procedure Coding System (HCPCS) codes to define events of interest in this request.

Cohort Eligibility Criteria: Patients were required to be continuously enrolled in medical and prescription drug plans for at least 6 months (183 days) prior to their dispensing date, during which gaps in coverage of up to 45 days were allowed. Members were excluded if they had the exposure of interest in 6 months (183 days) prior to the dispensing date. The following age groups were included in the cohort: 20-44, 45-64, 65-74, 75-84, and 85+ years. See Appendix D for International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) and Healthcare Common Procedure Coding System (HCPCS) codes to assess inclusion and exclusion criteria in this request.

Limitations: Algorithms to define exposures and events are imperfect and, therefore, may be misclassified.

Please see Appendix E for the specifications of parameters used in the analyses for this request.

Notes: Results in this report are from a rerun of to09y05_cap_mpl1r_wp57_v01. An update was made to the CIDA package to modify the way in which denominator information was being calculated. This rerun utilized the updated program.

Please contact the Sentinel Operations Center (qf@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

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Glossary of Terms for Analyses Using Cohort Identification and Descriptive Analysis (CIDA) Tool*

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 during the blackout period, the episode is excluded.

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency department

Censor Episodes at Evidence of Death - indicates whether treatment episodes are truncated based on death date. A member has a death date if he or she has an encounter with a discharge status of "expired" in the Encounter Table, or if he

Cohort Definition (drug/exposure)- indicates how the cohort will be defined: (1): Cohort includes only the first valid incident treatment episode during the query period; (2): Cohort includes all valid incident treatment episodes during the query period; (3): Cohort includes all valid incident treatment episodes during the query period until an event occurs.

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

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

Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive

Event Deduplication - specifies how events are counted by the MP algorithm: (0): Counts all occurrences of an HOI during an exposure episode; (1): de-duplicates occurrences of the same HOI code and code type on the same day; (2): de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

Exposure Episode Length - number of days after exposure initiation that is considered "exposed time." (For Intent to Treat

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

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.

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 the first occurrence of an incident query code. A value of N indicates that the treatment episodes should not be truncated at

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

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

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

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

*all terms may not be used in this report

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

Table 1: Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Tests in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and October 31, 2013, by Warfarin Product and Event

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Days Supplied/ Dispensing	New Episodes w/ 10K Years at Risk	New Episodes w/ Events / New User
Brand warfarin														
<i>INR lab procedure</i>	14,344	14,344	14,344	450,107	584,991	748.2	10,016	1,435,753	1,801,503.6	9.99	31.38	31.38	133,862.59	0.70
<i>INR lab test result > 0</i>	14,344	14,344	14,344	450,107	584,991	1,478.5	1,804	1,435,753	1,801,503.6	9.99	31.38	31.38	12,201.15	0.13
Amneal generic warfarin														
<i>INR lab procedure</i>	123	123	123	2,969	3,049	7.5	77	1,452,635	1,874,744.9	0.08	24.14	24.14	102,680.72	0.63
<i>INR lab test result > 0</i>	123	123	123	2,969	3,049	12.9	14	1,452,635	1,874,744.9	0.08	24.14	24.14	10,865.92	0.11
BMS generic warfarin														
<i>INR lab procedure</i>	14,343	14,343	14,343	450,083	585,099	748.3	10,015	1,435,795	1,801,577.4	9.99	31.38	31.38	133,841.39	0.70
<i>INR lab test result > 0</i>	14,343	14,343	14,343	450,083	585,099	1,478.7	1,803	1,435,795	1,801,577.4	9.99	31.38	31.38	12,192.85	0.13
InvaGen generic warfarin														
<i>INR lab procedure</i>	2,912	2,912	2,912	91,319	116,741	171.0	1,975	1,452,246	1,872,535.0	2.01	31.36	31.36	115,516.96	0.68
<i>INR lab test result > 0</i>	2,912	2,912	2,912	91,319	116,741	302.1	359	1,452,246	1,872,535.0	2.01	31.36	31.36	11,881.87	0.12
Mylan generic warfarin														
<i>INR lab procedure</i>	349	349	349	10,872	14,128	20.9	236	1,452,613	1,874,231.9	0.24	31.15	31.15	113,151.75	0.68
<i>INR lab test result > 0</i>	349	349	349	10,872	14,128	36.1	51	1,452,613	1,874,231.9	0.24	31.15	31.15	14,111.93	0.15
Taro generic warfarin														
<i>INR lab procedure</i>	200,727	200,727	200,727	6,694,223	9,714,425	8,882.4	159,640	1,372,980	1,338,903.2	146.20	33.35	33.35	179,726.01	0.80
<i>INR lab test result > 0</i>	200,727	200,727	200,727	6,694,223	9,714,425	15,400.2	81,619	1,372,980	1,338,903.2	146.20	33.35	33.35	52,998.70	0.41
Teva generic warfarin														
<i>INR lab procedure</i>	110,319	110,319	110,319	3,367,278	4,250,839	5,275.0	81,625	1,379,470	1,470,141.4	79.97	30.52	30.52	154,738.51	0.74
<i>INR lab test result > 0</i>	110,319	110,319	110,319	3,367,278	4,250,839	10,708.6	20,678	1,379,470	1,470,141.4	79.97	30.52	30.52	19,309.68	0.19
USL generic warfarin														
<i>INR lab procedure</i>	18,025	18,025	18,025	548,000	670,569	919.3	13,115	1,444,653	1,831,126.2	12.48	30.40	30.40	142,666.01	0.73
<i>INR lab test result > 0</i>	18,025	18,025	18,025	548,000	670,569	1,763.6	3,403	1,444,653	1,831,126.2	12.48	30.40	30.40	19,295.64	0.19
Zydus generic warfarin														
<i>INR lab procedure</i>	65,949	65,949	65,949	2,193,921	2,771,829	3,572.1	47,316	1,431,367	1,730,173.4	46.07	33.27	33.27	132,460.66	0.72
<i>INR lab test result > 0</i>	65,949	65,949	65,949	2,193,921	2,771,829	6,716.2	9,888	1,431,367	1,730,173.4	46.07	33.27	33.27	14,722.53	0.15

Table 2: Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Tests in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and October 31, 2013, by Warfarin Product, Event, and Age Group

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	New Episodes w/ Events / New User
Brand warfarin														
<i>INR lab procedure</i>														
20-44 Years	256	256	256	7,465	10,386	7.9	220	65,113	42,258.0	3.93	29.16	29.16	276,895.24	0.86
45-64 Years	3,735	3,735	3,735	114,930	154,704	137.8	3,152	362,007	350,960.0	10.32	30.77	30.77	228,780.26	0.84
65-74 Years	4,041	4,041	4,041	128,191	164,834	215.1	2,804	427,348	476,048.6	9.46	31.72	31.72	130,373.36	0.69
75-84 Years	4,559	4,559	4,559	144,937	185,311	272.9	2,857	478,286	591,444.0	9.53	31.79	31.79	104,697.43	0.63
85+ Years	1,753	1,753	1,753	54,584	69,757	114.6	983	290,335	340,792.9	6.04	31.14	31.14	85,810.75	0.56
<i>INR lab test result > 0</i>														
20-44 Years	256	256	256	7,465	10,386	24.7	46	65,113	42,258.0	3.93	29.16	29.16	18,620.75	0.18
45-64 Years	3,735	3,735	3,735	114,930	154,704	379.9	504	362,007	350,960.0	10.32	30.77	30.77	13,265.64	0.13
65-74 Years	4,041	4,041	4,041	128,191	164,834	416.7	509	427,348	476,048.6	9.46	31.72	31.72	12,215.56	0.13
75-84 Years	4,559	4,559	4,559	144,937	185,311	475.6	534	478,286	591,444.0	9.53	31.79	31.79	11,229.02	0.12
85+ Years	1,753	1,753	1,753	54,584	69,757	181.7	211	290,335	340,792.9	6.04	31.14	31.14	11,613.76	0.12
Amneal generic warfarin														
<i>INR lab procedure</i>														
20-44 Years	0	0	0	0	0	0.0	0	65,517	42,910.7	0.00	---	---	---	---
45-64 Years	11	11	11	300	371	0.5	8	367,214	365,511.7	0.03	27.27	27.27	159,672.13	0.73
65-74 Years	18	18	18	521	673	0.8	16	434,417	495,899.5	0.04	28.94	28.94	209,462.37	0.89
75-84 Years	48	48	48	1,200	1,089	3.4	24	486,096	617,360.4	0.10	25.00	25.00	69,571.43	0.50
85+ Years	46	46	46	948	916	2.8	29	294,302	353,062.5	0.16	20.61	20.61	104,151.92	0.63
<i>INR lab test result > 0</i>														
20-44 Years	0	0	0	0	0	0.0	0	65,517	42,910.7	0.00	---	---	---	---
45-64 Years	11	11	11	300	371	1.1	2	367,214	365,511.7	0.03	27.27	27.27	17,773.72	0.18
65-74 Years	18	18	18	521	673	1.8	3	434,417	495,899.5	0.04	28.94	28.94	16,502.26	0.17
75-84 Years	48	48	48	1,200	1,089	5.0	6	486,096	617,360.4	0.10	25.00	25.00	11,936.27	0.13
85+ Years	46	46	46	948	916	4.9	3	294,302	353,062.5	0.16	20.61	20.61	6,104.46	0.07
BMS generic warfarin														
<i>INR lab procedure</i>														
20-44 Years	257	257	257	7,495	10,446	8.0	221	65,114	42,258.3	3.95	29.16	29.16	275,683.91	0.86
45-64 Years	3,727	3,727	3,727	114,716	154,461	136.8	3,154	362,025	350,995.4	10.29	30.78	30.78	230,547.25	0.85

Table 2: Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Tests in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and October 31, 2013, by Warfarin Product, Event, and Age Group

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	New Episodes w/ Events / New User
65-74 Years	4,041	4,041	4,041	128,166	164,768	215.1	2,803	427,358	476,063.5	9.46	31.72	31.72	130,290.38	0.69
75-84 Years	4,563	4,563	4,563	145,033	185,510	273.3	2,856	478,302	591,466.1	9.54	31.78	31.78	104,484.67	0.63
85+ Years	1,755	1,755	1,755	54,673	69,914	115.0	981	290,339	340,794.1	6.04	31.15	31.15	85,322.12	0.56
INR lab test result > 0														
20-44 Years	257	257	257	7,495	10,446	24.8	46	65,114	42,258.3	3.95	29.16	29.16	18,534.47	0.18
45-64 Years	3,727	3,727	3,727	114,716	154,461	379.2	504	362,025	350,995.4	10.29	30.78	30.78	13,291.22	0.14
65-74 Years	4,041	4,041	4,041	128,166	164,768	416.8	508	427,358	476,063.5	9.46	31.72	31.72	12,188.28	0.13
75-84 Years	4,563	4,563	4,563	145,033	185,510	476.0	534	478,302	591,466.1	9.54	31.78	31.78	11,218.16	0.12
85+ Years	1,755	1,755	1,755	54,673	69,914	181.9	211	290,339	340,794.1	6.04	31.15	31.15	11,599.08	0.12
InvaGen generic warfarin														
INR lab procedure														
20-44 Years	16	16	16	564	877	1.2	9	65,512	42,899.4	0.24	35.25	35.25	77,529.48	0.56
45-64 Years	351	351	351	10,806	14,983	18.1	266	367,142	365,245.2	0.96	30.79	30.79	147,117.66	0.76
65-74 Years	732	732	732	23,453	30,594	42.1	507	434,258	495,354.5	1.69	32.04	32.04	120,286.94	0.69
75-84 Years	1,164	1,164	1,164	37,388	47,479	68.6	783	485,850	616,474.5	2.40	32.12	32.12	114,195.32	0.67
85+ Years	649	649	649	19,108	22,808	41.0	410	294,134	352,561.4	2.21	29.44	29.44	99,968.29	0.63
INR lab test result > 0														
20-44 Years	16	16	16	564	877	1.8	0	65,512	42,899.4	0.24	35.25	35.25	0.00	0.00
45-64 Years	351	351	351	10,806	14,983	37.0	40	367,142	365,245.2	0.96	30.79	30.79	10,824.63	0.11
65-74 Years	732	732	732	23,453	30,594	76.5	91	434,258	495,354.5	1.69	32.04	32.04	11,900.80	0.12
75-84 Years	1,164	1,164	1,164	37,388	47,479	121.2	139	485,850	616,474.5	2.40	32.12	32.12	11,472.35	0.12
85+ Years	649	649	649	19,108	22,808	65.7	89	294,134	352,561.4	2.21	29.44	29.44	13,540.74	0.14
Mylan generic warfarin														
INR lab procedure														
20-44 Years	3	3	3	73	126	0.1	2	65,516	42,907.4	0.05	24.33	24.33	135,277.78	0.67
45-64 Years	45	45	45	1,375	1,855	2.3	33	367,206	365,444.7	0.12	30.56	30.56	142,137.38	0.73
65-74 Years	90	90	90	2,915	3,788	5.1	65	434,405	495,753.8	0.21	32.39	32.39	128,331.08	0.72
75-84 Years	135	135	135	4,157	5,550	8.7	89	486,076	617,159.2	0.28	30.79	30.79	102,320.59	0.66
85+ Years	76	76	76	2,352	2,810	4.6	47	294,279	352,966.8	0.26	30.95	30.95	101,638.54	0.62

Table 2: Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Tests in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and October 31, 2013, by Warfarin Product, Event, and Age Group

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	New Episodes w/ Events / New User
INR lab test result > 0														
20-44 Years	3	3	3	73	126	0.3	0	65,516	42,907.4	0.05	24.33	24.33	0.00	0.00
45-64 Years	45	45	45	1,375	1,855	4.8	5	367,206	365,444.7	0.12	30.56	30.56	10,471.62	0.11
65-74 Years	90	90	90	2,915	3,788	9.1	16	434,405	495,753.8	0.21	32.39	32.39	17,486.54	0.18
75-84 Years	135	135	135	4,157	5,550	14.0	18	486,076	617,159.2	0.28	30.79	30.79	12,813.29	0.13
85+ Years	76	76	76	2,352	2,810	7.8	12	294,279	352,966.8	0.26	30.95	30.95	15,341.27	0.16
Taro generic warfarin														
INR lab procedure														
20-44 Years	2,631	2,631	2,631	80,262	117,584	92.0	2,209	63,969	38,689.1	41.13	30.51	30.51	240,215.93	0.84
45-64 Years	38,820	38,820	38,820	1,247,991	1,871,526	1,450.1	32,857	348,405	282,955.1	111.42	32.15	32.15	226,579.25	0.85
65-74 Years	59,913	59,913	59,913	2,036,633	2,937,126	2,654.7	47,891	396,063	342,715.7	151.27	33.99	33.99	180,402.88	0.80
75-84 Years	70,669	70,669	70,669	2,394,662	3,444,687	3,241.1	55,622	437,699	416,155.8	161.46	33.89	33.89	171,616.14	0.79
85+ Years	28,694	28,694	28,694	934,675	1,343,501	1,444.6	21,061	264,314	258,387.5	108.56	32.57	32.57	145,793.47	0.73
INR lab test result > 0														
20-44 Years	2,631	2,631	2,631	80,262	117,584	202.8	974	63,969	38,689.1	41.13	30.51	30.51	48,020.29	0.37
45-64 Years	38,820	38,820	38,820	1,247,991	1,871,526	2,988.5	15,092	348,405	282,955.1	111.42	32.15	32.15	50,499.96	0.39
65-74 Years	59,913	59,913	59,913	2,036,633	2,937,126	4,657.8	23,794	396,063	342,715.7	151.27	33.99	33.99	51,084.61	0.40
75-84 Years	70,669	70,669	70,669	2,394,662	3,444,687	5,329.2	30,248	437,699	416,155.8	161.46	33.89	33.89	56,759.08	0.43
85+ Years	28,694	28,694	28,694	934,675	1,343,501	2,221.9	11,511	264,314	258,387.5	108.56	32.57	32.57	51,807.33	0.40
Teva generic warfarin														
INR lab procedure														
20-44 Years	1,973	1,973	1,973	57,162	75,755	66.3	1,669	63,568	38,695.7	31.04	28.97	28.97	251,631.41	0.85
45-64 Years	24,553	24,553	24,553	729,775	955,501	874.4	20,805	346,578	293,162.5	70.84	29.72	29.72	237,926.09	0.85
65-74 Years	31,452	31,452	31,452	978,331	1,234,725	1,507.2	23,378	403,946	387,100.6	77.86	31.11	31.11	155,111.85	0.74
75-84 Years	36,904	36,904	36,904	1,142,389	1,421,100	1,914.3	25,987	447,026	469,442.6	82.55	30.96	30.96	135,752.76	0.70
85+ Years	15,437	15,437	15,437	459,621	563,758	912.8	9,786	271,891	281,740.1	56.78	29.77	29.77	107,207.37	0.63
INR lab test result > 0														
20-44 Years	1,973	1,973	1,973	57,162	75,755	195.6	316	63,568	38,695.7	31.04	28.97	28.97	16,152.91	0.16
45-64 Years	24,553	24,553	24,553	729,775	955,501	2,404.9	4,224	346,578	293,162.5	70.84	29.72	29.72	17,564.17	0.17

Table 2: Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Tests in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and October 31, 2013, by Warfarin Product, Event, and Age Group

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	New Episodes w/ Events / New User
65-74 Years	31,452	31,452	31,452	978,331	1,234,725	3,066.3	5,878	403,946	387,100.6	77.86	31.11	31.11	19,169.98	0.19
75-84 Years	36,904	36,904	36,904	1,142,389	1,421,100	3,527.7	7,543	447,026	469,442.6	82.55	30.96	30.96	21,382.08	0.20
85+ Years	15,437	15,437	15,437	459,621	563,758	1,514.1	2,717	271,891	281,740.1	56.78	29.77	29.77	17,944.43	0.18
USL generic warfarin														
<i>INR lab procedure</i>														
20-44 Years	195	195	195	5,562	7,754	7.8	159	65,364	42,584.5	2.98	28.52	28.52	203,058.57	0.82
45-64 Years	3,082	3,082	3,082	93,612	123,313	124.6	2,543	365,494	359,021.6	8.43	30.37	30.37	204,111.71	0.83
65-74 Years	4,911	4,911	4,911	154,778	193,598	246.2	3,630	431,324	484,792.3	11.39	31.52	31.52	147,445.29	0.74
75-84 Years	6,534	6,534	6,534	200,625	238,538	347.3	4,645	481,685	600,837.1	13.56	30.70	30.70	133,737.95	0.71
85+ Years	3,303	3,303	3,303	93,423	107,366	193.3	2,138	291,340	343,890.7	11.34	28.28	28.28	110,578.38	0.65
<i>INR lab test result > 0</i>														
20-44 Years	195	195	195	5,562	7,754	19.1	33	65,364	42,584.5	2.98	28.52	28.52	17,290.56	0.17
45-64 Years	3,082	3,082	3,082	93,612	123,313	308.1	489	365,494	359,021.6	8.43	30.37	30.37	15,869.85	0.16
65-74 Years	4,911	4,911	4,911	154,778	193,598	484.6	893	431,324	484,792.3	11.39	31.52	31.52	18,425.71	0.18
75-84 Years	6,534	6,534	6,534	200,625	238,538	626.1	1,415	481,685	600,837.1	13.56	30.70	30.70	22,600.03	0.22
85+ Years	3,303	3,303	3,303	93,423	107,366	325.6	573	291,340	343,890.7	11.34	28.28	28.28	17,596.12	0.17
Zydus generic warfarin														
<i>INR lab procedure</i>														
20-44 Years	658	658	658	20,224	28,526	29.9	499	65,180	41,961.3	10.10	30.74	30.74	166,950.40	0.76
45-64 Years	12,360	12,360	12,360	403,478	542,743	590.3	9,749	361,920	343,242.6	34.15	32.64	32.64	165,164.86	0.79
65-74 Years	21,166	21,166	21,166	710,917	894,644	1,123.2	15,435	424,415	452,682.8	49.87	33.59	33.59	137,419.47	0.73
75-84 Years	23,053	23,053	23,053	775,363	957,208	1,293.6	16,082	473,229	562,948.8	48.71	33.63	33.63	124,323.52	0.70
85+ Years	8,712	8,712	8,712	283,939	348,709	535.2	5,551	286,891	329,337.8	30.37	32.59	32.59	103,724.50	0.64
<i>INR lab test result > 0</i>														
20-44 Years	658	658	658	20,224	28,526	66.8	79	65,180	41,961.3	10.10	30.74	30.74	11,821.84	0.12
45-64 Years	12,360	12,360	12,360	403,478	542,743	1,261.9	1,799	361,920	343,242.6	34.15	32.64	32.64	14,256.03	0.15
65-74 Years	21,166	21,166	21,166	710,917	894,644	2,150.2	3,258	424,415	452,682.8	49.87	33.59	33.59	15,152.17	0.15
75-84 Years	23,053	23,053	23,053	775,363	957,208	2,349.2	3,459	473,229	562,948.8	48.71	33.63	33.63	14,724.27	0.15
85+ Years	8,712	8,712	8,712	283,939	348,709	888.1	1,293	286,891	329,337.8	30.37	32.59	32.59	14,558.84	0.15

Table 3: Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Tests in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and October 31, 2013, by Warfarin Product, Event, and Sex

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	New Episodes w/ Events / New User
Brand warfarin														
<i>INR lab procedure</i>														
Female	5,854	5,854	5,854	183,147	233,148	319.7	3,945	640,053	786,749.3	9.15	31.29	31.29	123,413.24	0.67
Male	8,490	8,490	8,490	266,960	351,843	428.6	6,071	795,676	1,014,710.5	10.67	31.44	31.44	141,656.41	0.72
Unknown	0	0	0	0	0	0.0	0	24	43.7	0.00	---	---	---	---
<i>INR lab test result > 0</i>														
Female	5,854	5,854	5,854	183,147	233,148	601.4	765	640,053	786,749.3	9.15	31.29	31.29	12,720.17	0.13
Male	8,490	8,490	8,490	266,960	351,843	877.1	1,039	795,676	1,014,710.5	10.67	31.44	31.44	11,845.29	0.12
Unknown	0	0	0	0	0	0.0	0	24	43.7	0.00	---	---	---	---
Amneal generic warfarin														
<i>INR lab procedure</i>														
Female	72	72	72	1,651	1,622	4.8	39	647,429	818,196.2	0.11	22.93	22.93	81,398.57	0.54
Male	51	51	51	1,318	1,427	2.7	38	805,182	1,056,504.9	0.06	25.84	25.84	140,338.73	0.75
Unknown	0	0	0	0	0	0.0	0	24	43.7	0.00	---	---	---	---
<i>INR lab test result > 0</i>														
Female	72	72	72	1,651	1,622	7.5	8	647,429	818,196.2	0.11	22.93	22.93	10,613.88	0.11
Male	51	51	51	1,318	1,427	5.3	6	805,182	1,056,504.9	0.06	25.84	25.84	11,221.20	0.12
Unknown	0	0	0	0	0	0.0	0	24	43.7	0.00	---	---	---	---
BMS generic warfarin														
<i>INR lab procedure</i>														
Female	5,854	5,854	5,854	183,176	233,150	319.8	3,944	640,057	786,754.0	9.15	31.29	31.29	123,338.64	0.67
Male	8,489	8,489	8,489	266,907	351,949	428.5	6,071	795,714	1,014,779.7	10.67	31.44	31.44	141,679.04	0.72
Unknown	0	0	0	0	0	0.0	0	24	43.7	0.00	---	---	---	---
<i>INR lab test result > 0</i>														
Female	5,854	5,854	5,854	183,176	233,150	601.5	764	640,057	786,754.0	9.15	31.29	31.29	12,701.17	0.13
Male	8,489	8,489	8,489	266,907	351,949	877.2	1,039	795,714	1,014,779.7	10.67	31.44	31.44	11,844.29	0.12
Unknown	0	0	0	0	0	0.0	0	24	43.7	0.00	---	---	---	---
InvaGen generic warfarin														
<i>INR lab procedure</i>														
Female	1,407	1,407	1,407	43,484	54,332	85.0	936	647,246	817,143.3	2.17	30.91	30.91	110,114.99	0.67

Table 3: Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Tests in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and October 31, 2013, by Warfarin Product, Event, and Sex

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	New Episodes w/ Events / New User
Male	1,505	1,505	1,505	47,835	62,409	86.0	1,039	804,976	1,055,348.0	1.87	31.78	31.78	120,858.20	0.69
Unknown	0	0	0	0	0	0.0	0	24	43.7	0.00	---	---	---	---
INR lab test result > 0														
Female	1,407	1,407	1,407	43,484	54,332	147.9	153	647,246	817,143.3	2.17	30.91	30.91	10,344.54	0.11
Male	1,505	1,505	1,505	47,835	62,409	154.2	206	804,976	1,055,348.0	1.87	31.78	31.78	13,356.08	0.14
Unknown	0	0	0	0	0	0.0	0	24	43.7	0.00	---	---	---	---
Mylan generic warfarin														
INR lab procedure														
Female	145	145	145	4,303	5,658	9.5	86	647,415	817,989.8	0.22	29.68	29.68	90,262.93	0.59
Male	204	204	204	6,569	8,470	11.3	150	805,174	1,056,198.4	0.25	32.20	32.20	132,400.92	0.74
Unknown	0	0	0	0	0	0.0	0	24	43.7	0.00	---	---	---	---
INR lab test result > 0														
Female	145	145	145	4,303	5,658	14.9	21	647,415	817,989.8	0.22	29.68	29.68	14,141.32	0.14
Male	204	204	204	6,569	8,470	21.3	30	805,174	1,056,198.4	0.25	32.20	32.20	14,091.44	0.15
Unknown	0	0	0	0	0	0.0	0	24	43.7	0.00	---	---	---	---
Taro generic warfarin														
INR lab procedure														
Female	84,505	84,505	84,505	2,799,180	4,043,008	3,730.0	67,003	614,282	591,968.8	137.57	33.12	33.12	179,632.11	0.79
Male	116,216	116,216	116,216	3,894,815	5,671,037	5,152.2	92,631	758,675	746,909.7	153.18	33.51	33.51	179,789.79	0.80
Unknown	6	6	6	228	380	0.2	6	23	24.6	260.87	38.00	38.00	280,961.54	1.00
INR lab test result > 0														
Female	84,505	84,505	84,505	2,799,180	4,043,008	6,377.9	35,346	614,282	591,968.8	137.57	33.12	33.12	55,419.21	0.42
Male	116,216	116,216	116,216	3,894,815	5,671,037	9,022.0	46,269	758,675	746,909.7	153.18	33.51	33.51	51,284.85	0.40
Unknown	6	6	6	228	380	0.3	4	23	24.6	260.87	38.00	38.00	136,542.06	0.67
Teva generic warfarin														
INR lab procedure														
Female	45,812	45,812	45,812	1,385,109	1,720,846	2,265.9	33,164	616,649	646,831.5	74.29	30.23	30.23	146,361.09	0.72
Male	64,503	64,503	64,503	1,982,037	2,529,873	3,008.9	48,459	762,797	823,280.4	84.56	30.73	30.73	161,054.52	0.75
Unknown	4	4	4	132	120	0.3	2	24	29.5	166.67	33.00	33.00	74,540.82	0.50

Table 3: Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Tests in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and October 31, 2013, by Warfarin Product, Event, and Sex

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	New Episodes w/ Events / New User
INR lab test result > 0														
Female	45,812	45,812	45,812	1,385,109	1,720,846	4,425.1	8,811	616,649	646,831.5	74.29	30.23	30.23	19,911.31	0.19
Male	64,503	64,503	64,503	1,982,037	2,529,873	6,283.0	11,867	762,797	823,280.4	84.56	30.73	30.73	18,887.37	0.18
Unknown	4	4	4	132	120	0.5	0	24	29.5	166.67	33.00	33.00	0.00	0.00
USL generic warfarin														
INR lab procedure														
Female	7,944	7,944	7,944	237,065	283,287	413.3	5,661	643,939	798,953.6	12.34	29.84	29.84	136,956.96	0.71
Male	10,081	10,081	10,081	310,935	387,282	505.9	7,454	800,690	1,032,128.9	12.59	30.84	30.84	147,330.19	0.74
Unknown	0	0	0	0	0	0.0	0	24	43.7	0.00	---	---	---	---
INR lab test result > 0														
Female	7,944	7,944	7,944	237,065	283,287	770.2	1,569	643,939	798,953.6	12.34	29.84	29.84	20,370.87	0.20
Male	10,081	10,081	10,081	310,935	387,282	993.4	1,834	800,690	1,032,128.9	12.59	30.84	30.84	18,461.97	0.18
Unknown	0	0	0	0	0	0.0	0	24	43.7	0.00	---	---	---	---
Zydus generic warfarin														
INR lab procedure														
Female	26,840	26,840	26,840	876,835	1,095,635	1,444.2	19,199	638,809	759,119.5	42.02	32.67	32.67	132,941.94	0.72
Male	39,107	39,107	39,107	1,317,014	1,676,133	2,127.8	28,115	792,534	971,013.3	49.34	33.68	33.68	132,128.88	0.72
Unknown	2	2	2	72	60	0.1	2	24	40.7	83.33	36.00	36.00	292,200.00	1.00
INR lab test result > 0														
Female	26,840	26,840	26,840	876,835	1,095,635	2,729.8	4,056	638,809	759,119.5	42.02	32.67	32.67	14,858.34	0.15
Male	39,107	39,107	39,107	1,317,014	1,676,133	3,986.2	5,832	792,534	971,013.3	49.34	33.68	33.68	14,630.37	0.15
Unknown	2	2	2	72	60	0.2	0	24	40.7	83.33	36.00	36.00	0.00	0.00

Table 4: Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Tests in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and October 31, 2013, by Warfarin Product, Event, and Year

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	New Episodes w/ Events / New User
Brand warfarin														
<i>INR lab procedure</i>														
2008	4,296	4,296	4,296	135,004	179,956	230.6	2,930	480,536	240,840.9	8.94	31.43	31.43	127072.89	0.68
2009	4,132	4,132	4,132	128,873	168,901	213.6	2,875	526,846	284,320.2	7.84	31.19	31.19	134623.95	0.70
2010	2,710	2,710	2,710	85,385	110,567	133.9	1,955	557,722	303,452.0	4.86	31.51	31.51	145989.48	0.72
2011	1,534	1,534	1,534	48,591	61,493	82.2	1,067	581,405	323,864.7	2.64	31.68	31.68	129773.15	0.70
2012	1,064	1,064	1,064	33,142	41,384	55.4	766	617,670	346,779.8	1.72	31.15	31.15	138368.69	0.72
2013	608	608	608	19,112	22,691	32.6	423	606,965	302,246.0	1.00	31.43	31.43	129745.34	0.70
<i>INR lab test result > 0</i>														
2008	4,296	4,296	4,296	135,004	179,956	445.1	522	480,536	240,840.9	8.94	31.43	31.43	11728.98	0.12
2009	4,132	4,132	4,132	128,873	168,901	422.9	537	526,846	284,320.2	7.84	31.19	31.19	12697.15	0.13
2010	2,710	2,710	2,710	85,385	110,567	278.4	347	557,722	303,452.0	4.86	31.51	31.51	12462.56	0.13
2011	1,534	1,534	1,534	48,591	61,493	159.8	179	581,405	323,864.7	2.64	31.68	31.68	11204.95	0.12
2012	1,064	1,064	1,064	33,142	41,384	109.0	145	617,670	346,779.8	1.72	31.15	31.15	13302.17	0.14
2013	608	608	608	19,112	22,691	63.4	74	606,965	302,246.0	1.00	31.43	31.43	11675.88	0.12
Amneal generic warfarin														
<i>INR lab procedure</i>														
2008	0	0	0	0	0	0.0	0	499,660	255,520.6	0.00	---	---	---	---
2009	0	0	0	0	0	0.0	0	544,963	299,882.3	0.00	---	---	---	---
2010	0	0	0	0	0	0.0	0	574,742	317,571.9	0.00	---	---	---	---
2011	0	0	0	0	0	0.0	0	596,084	335,940.6	0.00	---	---	---	---
2012	0	0	0	0	0	0.0	0	629,995	356,671.8	0.00	---	---	---	---
2013	123	123	123	2,969	3,049	7.5	77	617,397	309,157.6	0.20	24.14	24.14	102680.72	0.63
<i>INR lab test result > 0</i>														
2008	0	0	0	0	0	0.0	0	499,660	255,520.6	0.00	---	---	---	---
2009	0	0	0	0	0	0.0	0	544,963	299,882.3	0.00	---	---	---	---
2010	0	0	0	0	0	0.0	0	574,742	317,571.9	0.00	---	---	---	---
2011	0	0	0	0	0	0.0	0	596,084	335,940.6	0.00	---	---	---	---
2012	0	0	0	0	0	0.0	0	629,995	356,671.8	0.00	---	---	---	---
2013	123	123	123	2,969	3,049	12.9	14	617,397	309,157.6	0.20	24.14	24.14	10865.92	0.11

Table 4: Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Tests in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and October 31, 2013, by Warfarin Product, Event, and Year

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	New Episodes w/ Events / New User
BMS generic warfarin														
<i>INR lab procedure</i>														
2008	4,296	4,296	4,296	134,981	179,802	230.5	2,930	480,574	240,860.6	8.94	31.42	31.42	127100.06	0.68
2009	4,131	4,131	4,131	128,884	169,134	213.8	2,874	526,896	284,349.1	7.84	31.20	31.20	134428.91	0.70
2010	2,710	2,710	2,710	85,373	110,565	133.8	1,955	557,740	303,477.1	4.86	31.50	31.50	146135.88	0.72
2011	1,533	1,533	1,533	48,561	61,463	82.2	1,066	581,404	323,863.6	2.64	31.68	31.68	129668.80	0.70
2012	1,065	1,065	1,065	33,172	41,444	55.4	767	617,670	346,778.6	1.72	31.15	31.15	138542.48	0.72
2013	608	608	608	19,112	22,691	32.6	423	606,970	302,248.5	1.00	31.43	31.43	129745.34	0.70
<i>INR lab test result > 0</i>														
2008	4,296	4,296	4,296	134,981	179,802	445.1	521	480,574	240,860.6	8.94	31.42	31.42	11704.35	0.12
2009	4,131	4,131	4,131	128,884	169,134	423.0	537	526,896	284,349.1	7.84	31.20	31.20	12694.03	0.13
2010	2,710	2,710	2,710	85,373	110,565	278.4	347	557,740	303,477.1	4.86	31.50	31.50	12462.56	0.13
2011	1,533	1,533	1,533	48,561	61,463	159.6	179	581,404	323,863.6	2.64	31.68	31.68	11213.02	0.12
2012	1,065	1,065	1,065	33,172	41,444	109.1	145	617,670	346,778.6	1.72	31.15	31.15	13288.15	0.14
2013	608	608	608	19,112	22,691	63.4	74	606,970	302,248.5	1.00	31.43	31.43	11675.88	0.12
InvaGen generic warfarin														
<i>INR lab procedure</i>														
2008	0	0	0	0	0	0.0	0	499,660	255,520.6	0.00	---	---	---	---
2009	0	0	0	0	0	0.0	0	544,963	299,882.3	0.00	---	---	---	---
2010	0	0	0	0	0	0.0	0	574,742	317,571.9	0.00	---	---	---	---
2011	1	1	1	30	30	0.1	0	596,084	335,940.6	0.00	30.00	30.00	0.00	---
2012	1,582	1,582	1,582	49,320	65,559	92.6	1,070	629,798	356,028.5	2.51	31.18	31.18	115500.04	0.68
2013	1,329	1,329	1,329	41,969	51,152	78.2	905	615,583	307,591.1	2.16	31.58	31.58	115706.82	0.68
<i>INR lab test result > 0</i>														
2008	0	0	0	0	0	0.0	0	499,660	255,520.6	0.00	---	---	---	---
2009	0	0	0	0	0	0.0	0	544,963	299,882.3	0.00	---	---	---	---
2010	0	0	0	0	0	0.0	0	574,742	317,571.9	0.00	---	---	---	---
2011	1	1	1	30	30	0.1	0	596,084	335,940.6	0.00	30.00	30.00	0.00	---
2012	1,582	1,582	1,582	49,320	65,559	163.6	192	629,798	356,028.5	2.51	31.18	31.18	11734.35	0.12

Table 4: Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Tests in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and October 31, 2013, by Warfarin Product, Event, and Year

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	New Episodes w/ Events / New User
2013	1,329	1,329	1,329	41,969	51,152	138.4	167	615,583	307,591.1	2.16	31.58	31.58	12066.14	0.13
Mylan generic warfarin														
<i>INR lab procedure</i>														
2008	0	0	0	0	0	0.0	0	499,660	255,520.6	0.00	---	---	---	---
2009	0	0	0	0	0	0.0	0	544,963	299,882.3	0.00	---	---	---	---
2010	1	1	1	1	1	0.1	0	574,742	317,571.9	0.00	1.00	1.00	0.00	0.00
2011	209	209	209	6,514	8,565	12.1	144	596,055	335,864.6	0.35	31.17	31.17	119157.23	0.69
2012	133	133	133	4,203	5,345	8.2	89	629,777	356,406.1	0.21	31.60	31.60	108213.22	0.67
2013	6	6	6	154	217	0.4	3	617,148	308,986.5	0.01	25.67	25.67	69351.27	0.50
<i>INR lab test result > 0</i>														
2008	0	0	0	0	0	0.0	0	499,660	255,520.6	0.00	---	---	---	---
2009	0	0	0	0	0	0.0	0	544,963	299,882.3	0.00	---	---	---	---
2010	1	1	1	1	1	0.1	0	574,742	317,571.9	0.00	1.00	1.00	0.00	0.00
2011	209	209	209	6,514	8,565	21.7	28	596,055	335,864.6	0.35	31.17	31.17	12880.35	0.13
2012	133	133	133	4,203	5,345	13.6	23	629,777	356,406.1	0.21	31.60	31.60	16885.93	0.17
2013	6	6	6	154	217	0.7	0	617,148	308,986.5	0.01	25.67	25.67	0.00	0.00
Taro generic warfarin														
<i>INR lab procedure</i>														
2008	39,673	39,673	39,673	1,376,852	2,424,056	1,739.1	32,842	460,866	213,763.9	86.08	34.71	34.71	188846.08	0.83
2009	49,506	49,506	49,506	1,641,929	2,290,079	2,413.3	37,979	468,119	227,920.6	105.76	33.17	33.17	157375.30	0.77
2010	30,932	30,932	30,932	1,015,809	1,382,581	1,331.5	24,197	459,411	221,743.5	67.33	32.84	32.84	181728.64	0.78
2011	28,347	28,347	28,347	945,192	1,303,506	1,212.7	22,608	464,997	230,247.2	60.96	33.34	33.34	186423.48	0.80
2012	31,433	31,433	31,433	1,033,044	1,383,272	1,373.1	24,907	484,900	238,254.5	64.82	32.86	32.86	181398.18	0.79
2013	20,836	20,836	20,836	681,397	930,931	812.8	17,107	462,552	206,973.5	45.05	32.70	32.70	210476.50	0.82
<i>INR lab test result > 0</i>														
2008	39,673	39,673	39,673	1,376,852	2,424,056	2,441.9	24,543	460,866	213,763.9	86.08	34.71	34.71	100509.49	0.62
2009	49,506	49,506	49,506	1,641,929	2,290,079	4,010.5	18,396	468,119	227,920.6	105.76	33.17	33.17	45869.31	0.37
2010	30,932	30,932	30,932	1,015,809	1,382,581	2,479.3	10,792	459,411	221,743.5	67.33	32.84	32.84	43528.86	0.35
2011	28,347	28,347	28,347	945,192	1,303,506	2,266.3	9,935	464,997	230,247.2	60.96	33.34	33.34	43837.82	0.35

Table 4: Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Tests in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and October 31, 2013, by Warfarin Product, Event, and Year

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	New Episodes w/ Events / New User
2012	31,433	31,433	31,433	1,033,044	1,383,272	2,607.0	10,076	484,900	238,254.5	64.82	32.86	32.86	38649.13	0.32
2013	20,836	20,836	20,836	681,397	930,931	1,595.2	7,877	462,552	206,973.5	45.05	32.70	32.70	49380.05	0.38
Teva generic warfarin														
<i>INR lab procedure</i>														
2008	28,640	28,640	28,640	872,300	1,152,405	1,321.8	21,329	401,879	169,491.5	71.27	30.46	30.46	161359.43	0.74
2009	25,508	25,508	25,508	778,625	975,134	1,212.6	18,805	455,439	219,128.0	56.01	30.52	30.52	155075.84	0.74
2010	19,477	19,477	19,477	590,689	735,341	900.8	14,725	498,060	250,226.2	39.11	30.33	30.33	163466.90	0.76
2011	15,170	15,170	15,170	465,526	571,773	755.5	11,074	520,009	271,890.3	29.17	30.69	30.69	146573.31	0.73
2012	13,020	13,020	13,020	400,916	504,024	662.7	9,426	557,830	296,157.9	23.34	30.79	30.79	142235.82	0.72
2013	8,504	8,504	8,504	259,222	312,161	421.5	6,266	550,648	263,247.5	15.44	30.48	30.48	148644.95	0.74
<i>INR lab test result > 0</i>														
2008	28,640	28,640	28,640	872,300	1,152,405	2,579.5	7,185	401,879	169,491.5	71.27	30.46	30.46	27854.01	0.25
2009	25,508	25,508	25,508	778,625	975,134	2,490.4	4,723	455,439	219,128.0	56.01	30.52	30.52	18964.46	0.19
2010	19,477	19,477	19,477	590,689	735,341	1,911.0	3,459	498,060	250,226.2	39.11	30.33	30.33	18100.62	0.18
2011	15,170	15,170	15,170	465,526	571,773	1,533.0	2,228	520,009	271,890.3	29.17	30.69	30.69	14534.02	0.15
2012	13,020	13,020	13,020	400,916	504,024	1,328.3	1,819	557,830	296,157.9	23.34	30.79	30.79	13694.30	0.14
2013	8,504	8,504	8,504	259,222	312,161	866.4	1,264	550,648	263,247.5	15.44	30.48	30.48	14588.76	0.15
USL generic warfarin														
<i>INR lab procedure</i>														
2008	2,282	2,282	2,282	66,144	81,591	121.3	1,548	494,056	250,493.3	4.62	28.99	28.99	127568.02	0.68
2009	2,791	2,791	2,791	83,114	103,789	143.9	1,975	538,783	294,046.2	5.18	29.78	29.78	137202.34	0.71
2010	3,259	3,259	3,259	97,228	119,536	160.2	2,431	567,107	310,528.8	5.75	29.83	29.83	151779.07	0.75
2011	2,639	2,639	2,639	80,389	98,809	134.2	1,911	587,172	328,065.9	4.49	30.46	30.46	142432.97	0.72
2012	3,546	3,546	3,546	109,289	134,093	181.0	2,591	619,894	347,597.5	5.72	30.82	30.82	143145.38	0.73
2013	3,508	3,508	3,508	111,836	132,750	178.6	2,659	605,703	300,394.6	5.79	31.88	31.88	148842.87	0.76
<i>INR lab test result > 0</i>														
2008	2,282	2,282	2,282	66,144	81,591	216.7	480	494,056	250,493.3	4.62	28.99	28.99	22155.11	0.21
2009	2,791	2,791	2,791	83,114	103,789	265.1	617	538,783	294,046.2	5.18	29.78	29.78	23272.26	0.22
2010	3,259	3,259	3,259	97,228	119,536	303.8	798	567,107	310,528.8	5.75	29.83	29.83	26266.56	0.24

Table 4: Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Tests in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and October 31, 2013, by Warfarin Product, Event, and Year

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Days Supplied/ Dispensing	New Episodes w/ Events / 10K Years at Risk	New Episodes w/ Events / New User
2011	2,639	2,639	2,639	80,389	98,809	259.4	469	587,172	328,065.9	4.49	30.46	30.46	18079.77	0.18
2012	3,546	3,546	3,546	109,289	134,093	348.8	661	619,894	347,597.5	5.72	30.82	30.82	18952.65	0.19
2013	3,508	3,508	3,508	111,836	132,750	369.9	378	605,703	300,394.6	5.79	31.88	31.88	10220.19	0.11
Zydus generic warfarin														
<i>INR lab procedure</i>														
2008	2,252	2,252	2,252	68,942	90,158	127.3	1,512	495,699	251,593.4	4.54	30.61	30.61	118737.07	0.67
2009	24,096	24,096	24,096	851,630	1,114,436	1,479.7	16,359	537,686	286,172.5	44.81	35.34	35.34	110553.62	0.68
2010	11,484	11,484	11,484	372,740	470,250	568.6	8,480	541,833	289,262.1	21.19	32.46	32.46	149146.96	0.74
2011	10,561	10,561	10,561	341,401	425,138	537.8	7,765	559,018	303,979.4	18.89	32.33	32.33	144381.92	0.74
2012	10,298	10,298	10,298	330,494	401,976	511.5	7,663	587,389	320,440.1	17.53	32.09	32.09	149828.21	0.74
2013	7,258	7,258	7,258	228,714	269,871	347.2	5,537	573,386	278,725.8	12.66	31.51	31.51	159486.87	0.76
<i>INR lab test result > 0</i>														
2008	2,252	2,252	2,252	68,942	90,158	227.3	350	495,699	251,593.4	4.54	30.61	30.61	15398.58	0.16
2009	24,096	24,096	24,096	851,630	1,114,436	2,455.4	3,828	537,686	286,172.5	44.81	35.34	35.34	15590.07	0.16
2010	11,484	11,484	11,484	372,740	470,250	1,154.3	1,769	541,833	289,262.1	21.19	32.46	32.46	15325.34	0.15
2011	10,561	10,561	10,561	341,401	425,138	1,080.6	1,456	559,018	303,979.4	18.89	32.33	32.33	13474.38	0.14
2012	10,298	10,298	10,298	330,494	401,976	1,052.6	1,477	587,389	320,440.1	17.53	32.09	32.09	14032.22	0.14
2013	7,258	7,258	7,258	228,714	269,871	746.1	1,008	573,386	278,725.8	12.66	31.51	31.51	13510.40	0.14

Appendix A: Dates of Available Data for Each Data Partner as of Request Send Date (October 17, 2014)

Data Partner ID	Start Date	End Date
DP001	1/1/2008	10/31/2013
DP002	1/1/2008	10/31/2013
DP003	1/1/2008	10/31/2013
DP004	1/1/2008	10/31/2013
DP005	1/1/2008	6/30/2012
DP006	1/1/2008	10/31/2013
DP007	1/1/2008	10/31/2013
DP008	1/31/2008	10/31/2013
DP009	1/1/2008	6/30/2012
DP010	1/1/2008	10/31/2013
DP011	1/1/2008	10/31/2013
DP012	1/1/2008	10/31/2013

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

Generic Name	Brand Name
Warfarin sodium	
Warfarin sodium	Coumadin
Warfarin sodium	Jantoven

Appendix C: Healthcare Common Procedure Coding System (HCPCS) Diagnosis Codes Used to Define International Normalized Ratio (INR) Procedure Events in this Report

Code	Code Type	Description
3555F	HCPCS Level 1	PT HAD INR MEASUREMENT PERFORMED
85610	HCPCS Level 1	PROTHROMBIN TIME

Appendix D: International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) and Healthcare Common Procedure Coding System (HCPCS) Diagnosis and Procedure Codes Used to Assess Inclusions and Exclusions in this Report

Group	Code	Code Type	Care Setting	Principal Discharge Diagnosis Restrictions
AFib	427.3	ICD-9-CM Diagnosis	Any	Any
AFib	427.31	ICD-9-CM Diagnosis	Any	Any
AFib	427.32	ICD-9-CM Diagnosis	Any	Any
DVT	453.4	ICD-9-CM Diagnosis	Any	Any
DVT	453.40	ICD-9-CM Diagnosis	Any	Any
DVT	453.41	ICD-9-CM Diagnosis	Any	Any
DVT	453.42	ICD-9-CM Diagnosis	Any	Any
DVT	451.1	ICD-9-CM Diagnosis	Any	Any
DVT	451.11	ICD-9-CM Diagnosis	Any	Any
DVT	451.19	ICD-9-CM Diagnosis	Any	Any
DVT	451.2	ICD-9-CM Diagnosis	Any	Any
DVT	451.81	ICD-9-CM Diagnosis	Any	Any
DVT	451.83	ICD-9-CM Diagnosis	Any	Any
DVT	453.84	ICD-9-CM Diagnosis	Any	Any
PE	415.1	ICD-9-CM Diagnosis	Any	Any
PE	415.11	ICD-9-CM Diagnosis	Any	Any
PE	415.12	ICD-9-CM Diagnosis	Any	Any
PE	415.19	ICD-9-CM Diagnosis	Any	Any
Joint replacement	V436	ICD-9-CM Diagnosis	Any	Any
Joint replacement	V4360	ICD-9-CM Diagnosis	Any	Any
Joint replacement	V4361	ICD-9-CM Diagnosis	Any	Any
Joint replacement	V4362	ICD-9-CM Diagnosis	Any	Any
Joint replacement	V4363	ICD-9-CM Diagnosis	Any	Any
Joint replacement	V4364	ICD-9-CM Diagnosis	Any	Any
Joint replacement	V4365	ICD-9-CM Diagnosis	Any	Any
Joint replacement	V4366	ICD-9-CM Diagnosis	Any	Any
Joint replacement	V4369	ICD-9-CM Diagnosis	Any	Any
Joint replacement	81.5	ICD-9-CM Procedure	Any	N/A
Joint replacement	81.51	ICD-9-CM Procedure	Any	N/A
Joint replacement	81.52	ICD-9-CM Procedure	Any	N/A
Joint replacement	81.53	ICD-9-CM Procedure	Any	N/A
Joint replacement	81.54	ICD-9-CM Procedure	Any	N/A
Joint replacement	81.55	ICD-9-CM Procedure	Any	N/A
Joint replacement	81.56	ICD-9-CM Procedure	Any	N/A
Joint replacement	81.57	ICD-9-CM Procedure	Any	N/A
Joint replacement	81.59	ICD-9-CM Procedure	Any	N/A
Joint replacement	81.8	ICD-9-CM Procedure	Any	N/A
Joint replacement	81.80	ICD-9-CM Procedure	Any	N/A
Joint replacement	81.81	ICD-9-CM Procedure	Any	N/A
Joint replacement	81.82	ICD-9-CM Procedure	Any	N/A
Joint replacement	81.83	ICD-9-CM Procedure	Any	N/A
Joint replacement	81.84	ICD-9-CM Procedure	Any	N/A
Joint replacement	81.85	ICD-9-CM Procedure	Any	N/A
Joint replacement	24363	HCPCS Level 1	Any	N/A
Joint replacement	27130	HCPCS Level 1	Any	N/A
Joint replacement	27132	HCPCS Level 1	Any	N/A
Joint replacement	27134	HCPCS Level 1	Any	N/A
Joint replacement	27137	HCPCS Level 1	Any	N/A

Joint replacement	27138	HCPCS Level 1	Any	N/A
Joint replacement	27447	HCPCS Level 1	Any	N/A
mitral stenosis	394	ICD-9-CM Diagnosis	Any	Any
mitral stenosis	394.0	ICD-9-CM Diagnosis	Any	Any
mitral stenosis	394.1	ICD-9-CM Diagnosis	Any	Any
mitral stenosis	394.2	ICD-9-CM Diagnosis	Any	Any
mitral stenosis	394.9	ICD-9-CM Diagnosis	Any	Any
mitral stenosis	396.0	ICD-9-CM Diagnosis	Any	Any
mitral stenosis	396.1	ICD-9-CM Diagnosis	Any	Any
mitral stenosis	396.8	ICD-9-CM Diagnosis	Any	Any
valve replacement	V422	ICD-9-CM Diagnosis	Any	Any
valve replacement	V433	ICD-9-CM Diagnosis	Any	Any
valve replacement	35.2	ICD-9-CM Procedure	Any	N/A
valve replacement	35.20	ICD-9-CM Procedure	Any	N/A
valve replacement	35.21	ICD-9-CM Procedure	Any	N/A
valve replacement	35.22	ICD-9-CM Procedure	Any	N/A
valve replacement	35.23	ICD-9-CM Procedure	Any	N/A
valve replacement	35.24	ICD-9-CM Procedure	Any	N/A
valve replacement	35.25	ICD-9-CM Procedure	Any	N/A
valve replacement	35.26	ICD-9-CM Procedure	Any	N/A
valve replacement	35.27	ICD-9-CM Procedure	Any	N/A
valve replacement	35.28	ICD-9-CM Procedure	Any	N/A
valve replacement	33405	HCPCS Level 1	Any	N/A
valve replacement	33406	HCPCS Level 1	Any	N/A
valve replacement	33410	HCPCS Level 1	Any	N/A
valve replacement	33411	HCPCS Level 1	Any	N/A
valve replacement	33412	HCPCS Level 1	Any	N/A
valve replacement	33413	HCPCS Level 1	Any	N/A
valve replacement	33430	HCPCS Level 1	Any	N/A
valve replacement	33465	HCPCS Level 1	Any	N/A
valve replacement	33475	HCPCS Level 1	Any	N/A
valve replacement	33496	HCPCS Level 1	Any	N/A
valve repair	33400	HCPCS Level 1	Any	N/A
valve repair	33401	HCPCS Level 1	Any	N/A
valve repair	33403	HCPCS Level 1	Any	N/A
valve repair	33420	HCPCS Level 1	Any	N/A
valve repair	33422	HCPCS Level 1	Any	N/A
valve repair	33425	HCPCS Level 1	Any	N/A
valve repair	33426	HCPCS Level 1	Any	N/A
valve repair	33427	HCPCS Level 1	Any	N/A
valve repair	33463	HCPCS Level 1	Any	N/A
valve repair	33464	HCPCS Level 1	Any	N/A
valve repair	33465	HCPCS Level 1	Any	N/A
valve repair	33470	HCPCS Level 1	Any	N/A
valve repair	33471	HCPCS Level 1	Any	N/A
valve repair	33472	HCPCS Level 1	Any	N/A
valve repair	33474	HCPCS Level 1	Any	N/A
valve repair	92986	HCPCS Level 1	Any	N/A
valve repair	92987	HCPCS Level 1	Any	N/A
valve repair	92990	HCPCS Level 1	Any	N/A
Kidney transplant	996.81	ICD-9-CM Diagnosis	Any	Any
Kidney transplant	V42	ICD-9-CM Diagnosis	Any	Any
Kidney transplant	V420	ICD-9-CM Diagnosis	Any	Any
Kidney transplant	55.6	ICD-9-CM Procedure	Any	Any
Kidney transplant	55.61	ICD-9-CM Procedure	Any	Any



Kidney transplant	55.69	ICD-9-CM Procedure	Any	Any
Dialysis	0505F	HCPCS Level 1	Outpatient	N/A
Dialysis	0507F	HCPCS Level 1	Outpatient	N/A
Dialysis	4053F	HCPCS Level 1	Outpatient	N/A
Dialysis	4054F	HCPCS Level 1	Outpatient	N/A
Dialysis	4055F	HCPCS Level 1	Outpatient	N/A
Dialysis	90935	HCPCS Level 1	Outpatient	N/A
Dialysis	90937	HCPCS Level 1	Outpatient	N/A
Dialysis	90940	HCPCS Level 1	Outpatient	N/A
Dialysis	90963	HCPCS Level 1	Outpatient	N/A
Dialysis	90964	HCPCS Level 1	Outpatient	N/A
Dialysis	90965	HCPCS Level 1	Outpatient	N/A
Dialysis	90966	HCPCS Level 1	Outpatient	N/A
Dialysis	90989	HCPCS Level 1	Outpatient	N/A
Dialysis	90993	HCPCS Level 1	Outpatient	N/A
Dialysis	90999	HCPCS Level 1	Outpatient	N/A
Dialysis	93990	HCPCS Level 1	Outpatient	N/A
Dialysis	99512	HCPCS Level 1	Outpatient	N/A
Dialysis	99559	HCPCS Level 1	Outpatient	N/A
Dialysis	A4653	HCPCS Level 2	Outpatient	N/A
Dialysis	A4671	HCPCS Level 2	Outpatient	N/A
Dialysis	A4672	HCPCS Level 2	Outpatient	N/A
Dialysis	A4673	HCPCS Level 2	Outpatient	N/A
Dialysis	A4680	HCPCS Level 2	Outpatient	N/A
Dialysis	A4690	HCPCS Level 2	Outpatient	N/A
Dialysis	A4714	HCPCS Level 2	Outpatient	N/A
Dialysis	A4719	HCPCS Level 2	Outpatient	N/A
Dialysis	A4730	HCPCS Level 2	Outpatient	N/A
Dialysis	A4736	HCPCS Level 2	Outpatient	N/A
Dialysis	A4737	HCPCS Level 2	Outpatient	N/A
Dialysis	A4740	HCPCS Level 2	Outpatient	N/A
Dialysis	A4750	HCPCS Level 2	Outpatient	N/A
Dialysis	A4755	HCPCS Level 2	Outpatient	N/A
Dialysis	A4760	HCPCS Level 2	Outpatient	N/A
Dialysis	A4765	HCPCS Level 2	Outpatient	N/A
Dialysis	A4766	HCPCS Level 2	Outpatient	N/A
Dialysis	A4770	HCPCS Level 2	Outpatient	N/A
Dialysis	A4771	HCPCS Level 2	Outpatient	N/A
Dialysis	A4772	HCPCS Level 2	Outpatient	N/A
Dialysis	A4773	HCPCS Level 2	Outpatient	N/A
Dialysis	A4774	HCPCS Level 2	Outpatient	N/A
Dialysis	A4780	HCPCS Level 2	Outpatient	N/A
Dialysis	A4801	HCPCS Level 2	Outpatient	N/A
Dialysis	A4802	HCPCS Level 2	Outpatient	N/A
Dialysis	A4860	HCPCS Level 2	Outpatient	N/A
Dialysis	A4880	HCPCS Level 2	Outpatient	N/A
Dialysis	A4900	HCPCS Level 2	Outpatient	N/A
Dialysis	A4901	HCPCS Level 2	Outpatient	N/A
Dialysis	A4905	HCPCS Level 2	Outpatient	N/A
Dialysis	A4910	HCPCS Level 2	Outpatient	N/A
Dialysis	A4911	HCPCS Level 2	Outpatient	N/A
Dialysis	A4913	HCPCS Level 2	Outpatient	N/A
Dialysis	A4918	HCPCS Level 2	Outpatient	N/A
Dialysis	A4929	HCPCS Level 2	Outpatient	N/A
Dialysis	C1037	HCPCS Level 2	Outpatient	N/A

Dialysis	C1152	HCPCS Level 2	Outpatient	N/A
Dialysis	C1752	HCPCS Level 2	Outpatient	N/A
Dialysis	C1881	HCPCS Level 2	Outpatient	N/A
Dialysis	E1500	HCPCS Level 2	Outpatient	N/A
Dialysis	E1520	HCPCS Level 2	Outpatient	N/A
Dialysis	E1530	HCPCS Level 2	Outpatient	N/A
Dialysis	E1540	HCPCS Level 2	Outpatient	N/A
Dialysis	E1550	HCPCS Level 2	Outpatient	N/A
Dialysis	E1560	HCPCS Level 2	Outpatient	N/A
Dialysis	E1580	HCPCS Level 2	Outpatient	N/A
Dialysis	E1590	HCPCS Level 2	Outpatient	N/A
Dialysis	E1592	HCPCS Level 2	Outpatient	N/A
Dialysis	E1594	HCPCS Level 2	Outpatient	N/A
Dialysis	E1615	HCPCS Level 2	Outpatient	N/A
Dialysis	E1620	HCPCS Level 2	Outpatient	N/A
Dialysis	E1625	HCPCS Level 2	Outpatient	N/A
Dialysis	E1630	HCPCS Level 2	Outpatient	N/A
Dialysis	E1634	HCPCS Level 2	Outpatient	N/A
Dialysis	E1636	HCPCS Level 2	Outpatient	N/A
Dialysis	E1638	HCPCS Level 2	Outpatient	N/A
Dialysis	E1640	HCPCS Level 2	Outpatient	N/A
Dialysis	E1699	HCPCS Level 2	Outpatient	N/A
Dialysis	G0257	HCPCS Level 2	Outpatient	N/A
Dialysis	G0320	HCPCS Level 2	Outpatient	N/A
Dialysis	G0321	HCPCS Level 2	Outpatient	N/A
Dialysis	G0322	HCPCS Level 2	Outpatient	N/A
Dialysis	G0323	HCPCS Level 2	Outpatient	N/A
Dialysis	G0324	HCPCS Level 2	Outpatient	N/A
Dialysis	G0325	HCPCS Level 2	Outpatient	N/A
Dialysis	G0326	HCPCS Level 2	Outpatient	N/A
Dialysis	G0327	HCPCS Level 2	Outpatient	N/A
Dialysis	G0365	HCPCS Level 2	Outpatient	N/A
Dialysis	G8075	HCPCS Level 2	Outpatient	N/A
Dialysis	G8076	HCPCS Level 2	Outpatient	N/A
Dialysis	G8575	HCPCS Level 2	Outpatient	N/A
Dialysis	G8714	HCPCS Level 2	Outpatient	N/A
Dialysis	G8956	HCPCS Level 2	Outpatient	N/A
Dialysis	G8957	HCPCS Level 2	Outpatient	N/A
Dialysis	G9231	HCPCS Level 2	Outpatient	N/A
Dialysis	J0882	HCPCS Level 2	Outpatient	N/A
Dialysis	J0886	HCPCS Level 2	Outpatient	N/A
Dialysis	K0610	HCPCS Level 2	Outpatient	N/A
Dialysis	K0611	HCPCS Level 2	Outpatient	N/A
Dialysis	K0612	HCPCS Level 2	Outpatient	N/A
Dialysis	K0613	HCPCS Level 2	Outpatient	N/A
Dialysis	K0614	HCPCS Level 2	Outpatient	N/A
Dialysis	Q4054	HCPCS Level 2	Outpatient	N/A
Dialysis	Q4055	HCPCS Level 2	Outpatient	N/A
Dialysis	Q4081	HCPCS Level 2	Outpatient	N/A
Dialysis	S0194	HCPCS Level 2	Outpatient	N/A
Dialysis	S9339	HCPCS Level 2	Outpatient	N/A
Dialysis	V56	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	7925	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	V563	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	V560	ICD-9-CM Diagnosis	Outpatient	Any

Dialysis	V568	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	V562	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	V561	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	V451	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	E8791	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	E8702	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	V5632	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	V5631	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	E8722	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	E8712	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	45821	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	99668	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	36476	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	99656	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	V4512	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	99673	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	36104	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	V4511	ICD-9-CM Diagnosis	Outpatient	Any
Dialysis	3927	ICD-9-CM Procedure	Outpatient	N/A
Dialysis	1255	ICD-9-CM Procedure	Outpatient	N/A
Dialysis	3995	ICD-9-CM Procedure	Outpatient	N/A
Dialysis	5498	ICD-9-CM Procedure	Outpatient	N/A
Dialysis	3943	ICD-9-CM Procedure	Outpatient	N/A
Dialysis	3942	ICD-9-CM Procedure	Outpatient	N/A
Dialysis	3895	ICD-9-CM Procedure	Outpatient	N/A

Appendix E: Specifications for Request ID: to09y05_cap_mpl1r_wp57_v02

FDA requested use of the Level 1 Cohort Identification and Descriptive Analysis (CIDA) tool to examine availability of International Normalized Ratio (INR) laboratory test values* and INR test procedures* among incident warfarin brand and selected generic warfarin users. In total, 18 different scenarios were examined in this report with varying exposures of interest and event definitions. See below for a description of each of these scenarios.

Enrollment Gap 45 days Age Groups 20-44, 45-64, 65-74, 75-84, 85+ years Query Period January 1, 2008 - October 31, 2013 Coverage Requirement Medical and Drug Coverage Enrollment Requirement 183 days															
Scenario	Drug/Exposure				Pre-Existing Condition				Event/Outcome						
	Incident exposure	Incident w/ respect to:	Washout (days)	Cohort Definition	Exposed time duration (days)	Episode Truncation by Incident Exposure	Pre-Existing Condition	Include or Exclude	Lookback Start	Lookback End	Event/ Outcome	Care Setting /PDX	Washout (days)	Event De-duplication	Blackout Period
1	Brand Warfarin	Brand Warfarin	183	01	42	No	Atrial fibrillation DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Include	-183	+3	INR lab test result \geq 0	Any	0	2	0
2	Generic Warfarin (USL)	Generic Warfarin (USL)	183	01	42	No	Atrial fibrillation DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Include	-183	+3	INR lab test result \geq 0	Any	0	2	0
3	Generic Warfarin (Amneal)	Generic Warfarin (Amneal)	183	01	42	No	Atrial fibrillation DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Include	-183	+3	INR lab test result \geq 0	Any	0	2	0
4	Generic Warfarin (BMS)	Generic Warfarin (BMS)	183	01	42	No	Atrial fibrillation DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Include	-183	+3	INR lab test result \geq 0	Any	0	2	0
5	Generic Warfarin (Teva)	Generic Warfarin (Teva)	183	01	42	No	Atrial fibrillation DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Include	-183	+3	INR lab test result \geq 0	Any	0	2	0

6	Generic Warfarin (Mylan)	Generic Warfarin (Mylan)	183	01	42	No	Atrial fibrillation	Include	-183	+3	INR lab test result \geq 0	Any	0	2	0
							DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Exclude	-183	-1					
7	Generic Warfarin (Zydus)	Generic Warfarin (Zydus)	183	01	42	No	Atrial fibrillation	Include	-183	+3	INR lab test result \geq 0	Any	0	2	0
							DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Exclude	-183	-1					
8	Generic Warfarin (InvaGen)	Generic Warfarin (InvaGen)	183	01	42	No	Atrial fibrillation	Include	-183	+3	INR lab test result \geq 0	Any	0	2	0
							DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Exclude	-183	-1					
9	Generic Warfarin (Taro)	Generic Warfarin (Taro)	183	01	42	No	Atrial fibrillation	Include	-183	+3	INR lab test result \geq 0	Any	0	2	0
							DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Exclude	-183	-1					
10	Brand Warfarin	Brand Warfarin	183	01	42	No	Atrial fibrillation	Include	-183	+3	INR lab test performed	Any	0	2	0
							DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Exclude	-183	-1					
11	Generic Warfarin (USL)	Generic Warfarin (USL)	183	01	42	No	Atrial fibrillation	Include	-183	+3	INR lab test performed	Any	0	2	0
							DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Exclude	-183	-1					
12	Generic Warfarin (Amneal)	Generic Warfarin (Amneal)	183	01	42	No	Atrial fibrillation	Include	-183	+3	INR lab test performed	Any	0	2	0
							DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Exclude	-183	-1					
13	Generic Warfarin (BMS)	Generic Warfarin (BMS)	183	01	42	No	Atrial fibrillation	Include	-183	+3	INR lab test performed	Any	0	2	0
							DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Exclude	-183	-1					

14	Generic Warfarin (Teva)	Generic Warfarin (Teva)	183	01	42	No	Atrial fibrillation	Include	-183	+3	INR lab test performed	Any	0	2	0
							DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Exclude	-183	-1					
15	Generic Warfarin (Mylan)	Generic Warfarin (Mylan)	183	01	42	No	Atrial fibrillation	Include	-183	+3	INR lab test performed	Any	0	2	0
							DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Exclude	-183	-1					
16	Generic Warfarin (Zydus)	Generic Warfarin (Zydus)	183	01	42	No	Atrial fibrillation	Include	-183	+3	INR lab test performed	Any	0	2	0
							DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Exclude	-183	-1					
17	Generic Warfarin (InvaGen)	Generic Warfarin (InvaGen)	183	01	42	No	Atrial fibrillation	Include	-183	+3	INR lab test performed	Any	0	2	0
							DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Exclude	-183	-1					
18	Generic Warfarin (Taro)	Generic Warfarin (Taro)	183	01	42	No	Atrial fibrillation	Include	-183	+3	INR lab test performed	Any	0	2	0
							DVT, PE, Joint Replacement, mitral stenosis, valve replacement, kidney transplant, dialysis	Exclude	-183	-1					

*Based on preliminary investigation performed by the Mini-Sentinel Common Data Model (MSCDM) Clinical Data Elements Workgroup, there may be overlap between users who have an INR lab procedure and users who have an INR lab result value. However, events in these groups may also be mutually exclusive (i.e., some lab procedures may not have an associated lab result in the MSDD, and some results may not have an associated procedure).

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

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

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

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