

## 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 to16\_cap\_mpl1r\_wp019

**Request ID:** to16\_cap\_mpl1r\_wp019

**Request Description:** This request examined the availability of international normalized ratio (INR) laboratory test values and INR test procedures among incident warfarin users in the Mini-Sentinel Distributed Database (MSDD).

**Mini-Sentinel Modular Program Tool Used:** Modular Program #6 (MP6)

**Data Source:** Data from January 1, 2008 to December 31, 2014 from 11 Data Partners contributing to the MSDD were included in this report. This request was distributed to Data Partners on March 10, 2015. Please see Appendix A for the dates of available data for each Data Partner.

**Study Design:** This request examined the availability of INR laboratory test values and INR test procedures among incident warfarin users.

**Events of Interest:** The events of interest were INR laboratory test results and INR test procedures among incident warfarin users. Procedures were defined using Healthcare Common Procedure Coding System (HCPCS) procedure codes and Current Procedural Terminology, Fourth Edition (CPT-4) procedure codes. All qualifying events that occurred between January 1, 2008 and December 31, 2014 were included. Please see Appendix B for a list of HCPCS and CPT-4 procedure codes used to define INR in this request.

**Cohort Eligibility Criteria:** Patients were required to be continuously enrolled in health plans with medical and drug coverage for at least 183 days prior to their first qualifying warfarin dispensing date (index), during which gaps in coverage of up to 45 days were allowed. Individuals 40 years of age or older were included in the cohort. Please see Appendix C for a list of generic and brand drug names used to define warfarin in this request.

**Please see Appendix D for the specifications of parameters used in this request.**

**Limitations:** Algorithms used to define exposures and inclusion criteria are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind.

**Notes:** Please contact the Sentinel Operations Center Query Fulfillment Team ([qf@sentinelssystem.org](mailto:qf@sentinelssystem.org)) for questions and to provide comments/suggestions for future enhancements to this document.

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## Glossary of Terms in Modular Program 6\*

**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).

**Claims** - number of exposure event claims experienced by new patients.

**Code Count** - this parameter instructs the program to de-duplicate multiple occurrences of the same post-diagnosis treatment on the same day. If codecount = 1, the program will only count one code per member per day. If codecount = 0, the program will include all occurrences of each code in output metrics.

**Eligible Members** - number of members eligible for an incident exposure/lookup period (defined by the exposure and event washout periods and any pre-existing inclusions or exclusions) with drug and medical coverage during the query period.

**Member-Years** - sum of all days a member is eligible for an incident exposure/lookup period (i.e., days that the member meets all inclusion criteria such as incidence, pre-existing condition, and enrollment requirements) divided by 365.25.

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

**Inclusion/Exclusion Indicator** - indicates whether condition(s) of interest are used for inclusion or exclusion criteria. A value of 1 instructs the program that members must have the condition of interest (inclusion criteria); a value of 0 instructs the program that members must not have the condition of interest (exclusion criteria).

**Lookback Period Start and End** - range of days relative to index that the program looks for inclusion/exclusion conditions of interest. For example, if the Inclusion/Exclusion Indicator = 1, Lookback Period Start = -183 and Lookback Period End = 0, the cohort will only include members with the condition of interest present in the 183 days prior to and including the index date (the index date is day 0).

**Lookup Period Duration** - fixed period of time following an incident exposure that the MP6 program searches for events of interest.

**Minimum Lookup Period Duration** - minimum number of enrollment days required after an incident exposure/lookup period start. For example, if the minimum duration = 10, a member must have 10 or more days of continuous enrollment in drug and medical benefit coverage following the exposure/lookup period start in order for the lookup period to be included in output metrics.

**New Patients** - number of members with incident exposure/lookup period during the query period. A user may only be counted once in a query period.

**New Patients with Post-Exposure Event** - number of patients who have an incident claim for the post-exposure event of interest.

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

**Query Period** - period in which the modular program evaluates exposures of interest.

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

**Washout Period (post-diagnosis treatment)** - number of days before diagnosis a user is required to have no evidence of a prior post-diagnosis treatment and continuous drug and medical coverage prior to an incident claim.

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

**Incidence Type (post-diagnosis treatment)**- *Minimum Incidence type* considers the first post-diagnosis exposure episode as long as it is the first in the user's entire available history. *Multiple Incidence type* uses the washout period to establish incidence and considers all qualifying post-diagnosis exposures.

**Time-to-Event (tte)/Time-to-Treatment** - number of days between the start of an exposure lookup period (index date) and the first event claim.

\*all terms may not be used in this report

**Table 1a. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and INR Procedures in Any Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition and Event Frequency Categories**

	Event Frequency Category	New Users	Eligible Members	Member-Years	New Users with Events	Percent of New Users who have Event	Percent of New Users with an Event who have Specified Number of Events
<b>INR Laboratory Result</b>		667,148	29,667,295	77,128,091	199,558	29.91%	100.00%
	0				467,590	70.09%	N/A
	1				35,857	5.37%	17.97%
	2-3				43,805	6.57%	21.95%
	4+				119,896	17.97%	60.08%
<b>INR Procedure</b>		667,148	29,667,290	77,128,089	487,521	73.08%	100.00%
	0				179,627	26.92%	N/A
	1				96,813	14.51%	19.86%
	2-3				142,429	21.35%	29.21%
	4+				248,279	37.21%	50.93%

**Table 1b. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and INR Procedures in the Outpatient\* Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition and Event Frequency Categories**

	Event Frequency Category	New Users	Eligible Members	Member-Years	New Users with Events	Percent of New Users who have Event	Percent of New Users with an Event who have Specified Number of Events
<b>INR Laboratory Result</b>		667,148	29,667,301	77,128,092	193,798	29.05%	100.00%
	0				473,350	70.95%	N/A
	1				36,870	5.53%	19.02%
	2-3				46,214	6.93%	23.85%
	4+				110,714	16.60%	57.13%
<b>INR Procedure</b>		667,148	29,667,294	77,128,089	472,140	70.77%	100.00%
	0				195,008	29.23%	N/A
	1				95,565	14.32%	20.24%
	2-3				139,206	20.87%	29.48%
	4+				237,369	35.58%	50.28%

\*For this request, laboratory results with a patient location of "Unknown" were included in the outpatient care setting.

**Table 1c. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and INR Procedures in the Inpatient Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition and Event Frequency Categories**

	Event Frequency Category	New Users	Eligible Members	Member-Years	New Users with Events	Percent of New Users who have Event	Percent of New Users with an Event who have Specified Number of Events
<b>INR Laboratory Result</b>		667,148	29,667,309	77,128,096	48,324	7.24%	100.00%
	0				618,824	92.76%	N/A
	1				35,401	5.31%	73.26%
	2-3				6,031	0.90%	12.48%
	4+				6,892	1.03%	14.26%
<b>INR Procedure</b>		667,148	29,667,311	77,128,097	22,217	3.33%	100.00%
	0				644,931	96.67%	N/A
	1				16,849	2.53%	75.84%
	2-3				4,785	0.72%	21.54%
	4+				583	0.09%	2.62%

**Table 2a. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and INR Procedures in Any Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition, Year, and Event Frequency Categories**

Year	Event Frequency Category	New Users	Eligible Members	Member-Years	New Users with Events	Percent of New Users who have Event	Percent of New Users with an Event who have Specified Number of Events
<b>INR Laboratory Result</b>							
<b>2008</b>		107,411	15,186,444	11,002,431.0	30,378	28.28%	100.00%
	0				77,033	71.72%	N/A
	1				5,493	5.11%	18.08%
	2-3				6,891	6.42%	22.68%
	4+				17,994	16.75%	59.23%
<b>2009</b>		120,599	15,514,295	12,662,143.0	33,674	27.92%	100.00%
	0				86,925	72.08%	N/A
	1				6,296	5.22%	18.70%
	2-3				8,211	6.81%	24.38%
	4+				19,167	15.89%	56.92%
<b>2010</b>		116,768	15,117,315	12,333,011.0	33,807	28.95%	100.00%
	0				82,961	71.05%	N/A
	1				6,239	5.34%	18.45%
	2-3				8,115	6.95%	24.00%
	4+				19,453	16.66%	57.54%
<b>2011</b>		103,188	14,604,814	12,054,455.0	30,500	29.56%	100.00%
	0				72,688	70.44%	N/A
	1				5,280	5.12%	17.31%
	2-3				6,266	6.07%	20.54%
	4+				18,954	18.37%	62.14%



**Table 2a. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and INR Procedures in Any Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition, Year, and Event Frequency Categories**

Year	Event Frequency Category	New Users	Eligible Members	Member-Years	New Users with Events	Percent of New Users who have Event	Percent of New Users with an Event who have Specified Number of Events
<b>INR Laboratory Result</b>							
<b>2012</b>		98,928	14,375,356	11,864,219.0	30,142	30.47%	100.00%
	0				68,786	69.53%	N/A
	1				5,406	5.46%	17.94%
	2-3				6,242	6.31%	20.71%
	4+				18,494	18.69%	61.36%
<b>2013</b>		86,941	14,395,960	11,840,800.0	28,270	32.52%	100.00%
	0				58,671	67.48%	N/A
	1				4,994	5.74%	17.67%
	2-3				5,544	6.38%	19.61%
	4+				17,732	20.40%	62.72%
<b>2014</b>		33,313	12,106,888	5,371,031.0	12,787	38.38%	100.00%
	0				20,526	61.62%	N/A
	1				2,149	6.45%	16.81%
	2-3				2,536	7.61%	19.83%
	4+				8,102	24.32%	63.36%

**Table 2a. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and INR Procedures in Any Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition, Year, and Event Frequency Categories**

Year	Event Frequency Category	New Users	Eligible Members	Member-Years	New Users with Events	Percent of New Users who have Event	Percent of New Users with an Event who have Specified Number of Events
<b>INR Procedure</b>							
<b>2008</b>		107,411	15,186,439	11,002,429.0	76,575	71.29%	100.00%
	0				30,836	28.71%	N/A
	1				15,377	14.32%	20.08%
	2-3				23,135	21.54%	30.21%
	4+				38,063	35.44%	49.71%
<b>2009</b>		120,599	15,514,294	12,662,143.0	87,534	72.58%	100.00%
	0				33,065	27.42%	N/A
	1				17,365	14.40%	19.84%
	2-3				26,560	22.02%	30.34%
	4+				43,609	36.16%	49.82%
<b>2010</b>		116,768	15,117,315	12,333,011.0	85,236	73.00%	100.00%
	0				31,532	27.00%	N/A
	1				16,622	14.24%	19.50%
	2-3				25,188	21.57%	29.55%
	4+				43,426	37.19%	50.95%
<b>2011</b>		103,188	14,604,814	12,054,455.0	75,488	73.16%	100.00%
	0				27,700	26.84%	N/A
	1				14,885	14.43%	19.72%
	2-3				21,529	20.86%	28.52%
	4+				39,074	37.87%	51.76%

**Table 2a. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and INR Procedures in Any Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition, Year, and Event Frequency Categories**

Year	Event Frequency Category	New Users	Eligible Members	Member-Years	New Users with Events	Percent of New Users who have Event	Percent of New Users with an Event who have Specified Number of Events
<b>INR Procedure</b>							
<b>2012</b>		98,928	14,375,356	11,864,219.0	73,659	74.46%	100.00%
	0				25,269	25.54%	N/A
	1				14,595	14.75%	19.81%
	2-3				21,117	21.35%	28.67%
	4+				37,947	38.36%	51.52%
<b>2013</b>		86,941	14,395,960	11,840,800.0	64,559	74.26%	100.00%
	0				22,382	25.74%	N/A
	1				12,921	14.86%	20.01%
	2-3				18,333	21.09%	28.40%
	4+				33,305	38.31%	51.59%
<b>2014</b>		33,313	12,106,888	5,371,031.0	24,470	73.45%	100.00%
	0				8,843	26.55%	N/A
	1				5,048	15.15%	20.63%
	2-3				6,567	19.71%	26.84%
	4+				12,855	38.59%	52.53%

**Table 2b. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and INR Procedures in the Outpatient\* Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition, Year, and Event Frequency Categories**

Year	Event Frequency Category	New Users	Eligible Members	Member-Years	New Users with Events	Percent of New Users who have Event	Percent of New Users with an Event who have Specified Number of Events
<b>INR Laboratory Result</b>							
<b>2008</b>		107,411	15,186,449	11,002,432.0	29,530	27.49%	100.00%
	0				77,881	72.51%	N/A
	1				5,634	5.25%	19.08%
	2-3				7,096	6.61%	24.03%
	4+				16,800	15.64%	56.89%
<b>2009</b>		120,599	15,514,295	12,662,143.0	33,035	27.39%	100.00%
	0				87,564	72.61%	N/A
	1				6,492	5.38%	19.65%
	2-3				8,534	7.08%	25.83%
	4+				18,009	14.93%	54.51%
<b>2010</b>		116,768	15,117,315	12,333,011.0	33,021	28.28%	100.00%
	0				83,747	71.72%	N/A
	1				6,407	5.49%	19.40%
	2-3				8,532	7.31%	25.84%
	4+				18,082	15.49%	54.76%
<b>2011</b>		103,188	14,604,814	12,054,455.0	29,557	28.64%	100.00%
	0				73,631	71.36%	N/A
	1				5,409	5.24%	18.30%
	2-3				6,751	6.54%	22.84%
	4+				17,397	16.86%	58.86%

**Table 2b. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and INR Procedures in the Outpatient\* Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition, Year, and Event Frequency Categories**

Year	Event Frequency Category	New Users	Eligible Members	Member-Years	New Users with Events	Percent of New Users who have Event	Percent of New Users with an Event who have Specified Number of Events
<b>INR Laboratory Result</b>							
<b>2012</b>		98,928	14,375,356	11,864,219.0	29,046	29.36%	100.00%
	0				69,882	70.64%	N/A
	1				5,550	5.61%	19.11%
	2-3				6,633	6.70%	22.84%
	4+				16,863	17.05%	58.06%
<b>2013</b>		86,941	14,395,961	11,840,800.0	27,261	31.36%	100.00%
	0				59,680	68.64%	N/A
	1				5,118	5.89%	18.77%
	2-3				5,944	6.84%	21.80%
	4+				16,199	18.63%	59.42%
<b>2014</b>		33,313	12,106,888	5,371,031.0	12,348	37.07%	100.00%
	0				20,965	62.93%	N/A
	1				2,260	6.78%	18.30%
	2-3				2,724	8.18%	22.06%
	4+				7,364	22.11%	59.64%

**Table 2b. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and INR Procedures in the Outpatient\* Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition, Year, and Event Frequency Categories**

Year	Event Frequency Category	New Users	Eligible Members	Member-Years	New Users with Events	Percent of New Users who have Event	Percent of New Users with an Event who have Specified Number of Events
<b>INR Procedure</b>							
<b>2008</b>		107,411	15,186,442	11,002,430.0	74,284	69.16%	100.00%
	0				33,127	30.84%	N/A
	1				15,114	14.07%	20.35%
	2-3				22,743	21.17%	30.62%
	4+				36,427	33.91%	49.04%
<b>2009</b>		120,599	15,514,294	12,662,143.0	84,993	70.48%	100.00%
	0				35,606	29.52%	N/A
	1				17,118	14.19%	20.14%
	2-3				26,080	21.63%	30.68%
	4+				41,795	34.66%	49.17%
<b>2010</b>		116,768	15,117,315	12,333,011.0	82,644	70.78%	100.00%
	0				34,124	29.22%	N/A
	1				16,375	14.02%	19.81%
	2-3				24,648	21.11%	29.82%
	4+				41,621	35.64%	50.36%
<b>2011</b>		103,188	14,604,814	12,054,455.0	73,132	70.87%	100.00%
	0				30,056	29.13%	N/A
	1				14,639	14.19%	20.02%
	2-3				21,141	20.49%	28.91%
	4+				37,352	36.20%	51.07%

**Table 2b. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and INR Procedures in the Outpatient\* Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition, Year, and Event Frequency Categories**

Year	Event Frequency Category	New Users	Eligible Members	Member-Years	New Users with Events	Percent of New Users who have Event	Percent of New Users with an Event who have Specified Number of Events
<b>INR Procedure</b>							
<b>2012</b>		98,928	14,375,356	11,864,219.0	71,161	71.93%	100.00%
	0				27,767	28.07%	N/A
	1				14,469	14.63%	20.33%
	2-3				20,547	20.77%	28.87%
	4+				36,145	36.54%	50.79%
<b>2013</b>		86,941	14,395,961	11,840,800.0	62,210	71.55%	100.00%
	0				24,731	28.45%	N/A
	1				12,835	14.76%	20.63%
	2-3				17,587	20.23%	28.27%
	4+				31,788	36.56%	51.10%
<b>2014</b>		33,313	12,106,888	5,371,031.0	23,716	71.19%	100.00%
	0				9,597	28.81%	N/A
	1				5,015	15.05%	21.15%
	2-3				6,460	19.39%	27.24%
	4+				12,241	36.75%	51.61%

\*For this request, laboratory results with a patient location of "Unknown" were included in the outpatient care setting.

**Table 2c. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and INR Procedures in the Inpatient Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition, Year, and Event Frequency Categories**

Year	Event Frequency Category	New Users	Eligible Members	Member-Years	New Users with Events	Percent of New Users who have Event	Percent of New Users with an Event who have Specified Number of Events
<b>INR Laboratory Result</b>							
<b>2008</b>		107,411	15,186,465	11,002,437.0	6,235	5.80%	100.00%
	0				101,176	94.20%	N/A
	1				4,518	4.21%	72.46%
	2-3				731	0.68%	11.72%
	4+				986	0.92%	15.81%
<b>2009</b>		120,599	15,514,295	12,662,143.0	6,445	5.34%	100.00%
	0				114,154	94.66%	N/A
	1				4,705	3.90%	73.00%
	2-3				778	0.65%	12.07%
	4+				962	0.80%	14.93%
<b>2010</b>		116,768	15,117,315	12,333,011.0	7,102	6.08%	100.00%
	0				109,666	93.92%	N/A
	1				5,024	4.30%	70.74%
	2-3				885	0.76%	12.46%
	4+				1,193	1.02%	16.80%
<b>2011</b>		103,188	14,604,814	12,054,455.0	8,543	8.28%	100.00%
	0				94,645	91.72%	N/A
	1				6,254	6.06%	73.21%
	2-3				1,041	1.01%	12.19%
	4+				1,248	1.21%	14.61%



**Table 2c. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and INR Procedures in the Inpatient Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition, Year, and Event Frequency Categories**

Year	Event Frequency Category	New Users	Eligible Members	Member-Years	New Users with Events	Percent of New Users who have Event	Percent of New Users with an Event who have Specified Number of Events
<b>INR Laboratory Result</b>							
<b>2012</b>		98,928	14,375,356	11,864,219.0	8,264	8.35%	100.00%
	0				90,664	91.65%	N/A
	1				6,083	6.15%	73.61%
	2-3				1,094	1.11%	13.24%
	4+				1,087	1.10%	13.15%
<b>2013</b>		86,941	14,395,960	11,840,800.0	7,918	9.11%	100.00%
	0				79,023	90.89%	N/A
	1				5,872	6.75%	74.16%
	2-3				1,044	1.20%	13.19%
	4+				1,002	1.15%	12.65%
<b>2014</b>		33,313	12,106,888	5,371,031.0	3,817	11.46%	100.00%
	0				29,496	88.54%	N/A
	1				2,945	8.84%	77.15%
	2-3				458	1.37%	12.00%
	4+				414	1.24%	10.85%

**Table 2c. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and INR Procedures in the Inpatient Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition, Year, and Event Frequency Categories**

Year	Event Frequency Category	New Users	Eligible Members	Member-Years	New Users with Events	Percent of New Users who have Event	Percent of New Users with an Event who have Specified Number of Events
<b>INR Procedure</b>							
<b>2008</b>		107,411	15,186,466	11,002,437.0	3,489	3.25%	100.00%
	0				103,922	96.75%	N/A
	1				2,686	2.50%	76.98%
	2-3				737	0.69%	21.12%
	4+				66	0.06%	1.89%
<b>2009</b>		120,599	15,514,295	12,662,143.0	3,974	3.30%	100.00%
	0				116,625	96.70%	N/A
	1				3,152	2.61%	79.32%
	2-3				742	0.62%	18.67%
	4+				80	0.07%	2.01%
<b>2010</b>		116,768	15,117,315	12,333,011.0	3,840	3.29%	100.00%
	0				112,928	96.71%	N/A
	1				2,878	2.46%	74.95%
	2-3				793	0.68%	20.65%
	4+				169	0.14%	4.40%
<b>2011</b>		103,188	14,604,814	12,054,455.0	3,545	3.44%	100.00%
	0				99,643	96.56%	N/A
	1				2,680	2.60%	75.60%
	2-3				771	0.75%	21.75%
	4+				94	0.09%	2.65%

**Table 2c. Summary of Incident Warfarin Use and International Normalized Ratio (INR) Laboratory Results and INR Procedures in the Inpatient Care Setting in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2008 and December 31, 2014, by Event Definition, Year, and Event Frequency Categories**

Year	Event Frequency Category	New Users	Eligible Members	Member-Years	New Users with Events	Percent of New Users who have Event	Percent of New Users with an Event who have Specified Number of Events
<b>INR Procedure</b>							
<b>2012</b>		98,928	14,375,356	11,864,219.0	3,174	3.21%	100.00%
	0				95,754	96.79%	N/A
	1				2,392	2.42%	75.36%
	2-3				710	0.72%	22.37%
	4+				72	0.07%	2.27%
<b>2013</b>		86,941	14,395,961	11,840,800.0	3,045	3.50%	100.00%
	0				83,896	96.50%	N/A
	1				2,244	2.58%	73.69%
	2-3				731	0.84%	24.01%
	4+				70	0.08%	2.30%
<b>2014</b>		33,313	12,106,888	5,371,031.0	1,150	3.45%	100.00%
	0				32,163	96.55%	N/A
	1				817	2.45%	71.04%
	2-3				301	0.90%	26.17%
	4+				32	0.10%	2.78%

**Appendix A. Dates of Available Data for Each Data Partner (DP) in the Mini-Sentinel Distributed Database (MSDD) as of Request End Date (December 31, 2014)**

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<b>DP ID</b>	<b>Start Date</b>	<b>End Date</b>
DP01	1/1/2008	3/31/2014
DP02	1/1/2008	4/30/2014
DP03	1/1/2008	7/31/2014
DP04	1/1/2008	6/30/2014
DP05	1/1/2008	10/31/2014
DP06	1/1/2008	7/31/2014
DP07	1/1/2008	6/30/2012
DP08	1/1/2008	6/30/2012
DP09	1/1/2008	4/30/2014
DP10	1/1/2008	9/30/2014
DP11	1/1/2008	4/30/2014

**Appendix B. List of Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology, Fourth Edition (CPT-4) Codes Used to Define International Normalized Ratio (INR) Procedures in this Request**

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<b>Code</b>	<b>Description</b>	<b>CodeType</b>
3555F	PT HAD INR MEASUREMENT PERFORMED	HCPCS
85610	PROTHROMBIN TIME	CPT-4

**Appendix C. Generic and Brand Drug Names Used to Define Warfarin Exposure in this Request**

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<b>Generic Name</b>	<b>Brand Name</b>
WARFARIN SODIUM	WARFARIN SODIUM
WARFARIN SODIUM	JANTOVEN
WARFARIN SODIUM	COUMADIN

**Appendix D. Specifications for Parameters in this Request**

This requested utilized Modular Program #6 to examine availability of International Normalized Ratio (INR) laboratory test values and INR test procedures among incident warfarin users.

**Query Period:** January 1, 2008 to December 31, 2014  
**Enrollment Gap:** 45 days  
**Age Groups:** 40+ years  
**Coverage Requirement:** Medical and Drug Coverage  
**Enrollment Requirement:** 183 days  
**Lab Date Algorithm:** lab date, result date, order date

Scenario	Drug/Exposure							Event/Outcome					
	Exposure of Interest	Incident with Respect to:	Washout (days)	Washout Type*	Lookup Period Duration (days)	Min Lookup Duration (days)	Care Setting	Event	Washout (days)	Washout Type**	Frequency Categories	Care Setting	Episode Gap (days)
1	Warfarin	Warfarin	183	Single	30	0	Any	INR lab test result $\geq 0$	0	Multiple	0, 1, 2-3, $\geq 4$	Any	0
2	Warfarin	Warfarin	183	Single	30	0	Any	INR procedure	0	Multiple	0, 1, 2-3, $\geq 4$	Any	0
3	Warfarin	Warfarin	183	Single	30	0	Any	INR lab test result $\geq 0$	0	Multiple	0, 1, 2-3, $\geq 4$	Outpatient or Unknown	0
4	Warfarin	Warfarin	183	Single	30	0	Any	INR procedure	0	Multiple	0, 1, 2-3, $\geq 4$	Outpatient or Unknown	0
5	Warfarin	Warfarin	183	Single	30	0	Any	INR lab test result $\geq 0$	0	Multiple	0, 1, 2-3, $\geq 4$	Inpatient	0
6	Warfarin	Warfarin	183	Single	30	0	Any	INR procedure	0	Multiple	0, 1, 2-3, $\geq 4$	Inpatient	0

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

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

Current Procedural Terminology, Fourth Edition (CPT-4) codes were checked against "Optum 2012 Current Procedure Codes & Relative Values Data File" provided by OptumInsight

\*A "single" washout type will consider only the first event for every lookup period that satisfies the washout period criteria.

\*\*A "multiple" washout type will consider all events for every lookup period that satisfies the washout period criteria.