

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

Request Description FDA requested use of Modular Program #3 (MP3) to investigate gastrointestinal hemorrhage (GIH) or intracerebral hemorrhage (ICH) events following new use of dabigatran or warfarin among all patients as well as those with a pre-existing condition of atrial fibrillation. This is a re-run of MSY3_MPR41. This required one run of MP3. The time window for the request was October 19, 2010 to June 30, 2013. The package was distributed to 15 Data Partners on June 26, 2014. Please see the Specifications tab for more details on each scenario.

This report contains results for all patients. A second report (to09y05_mpr_wp37_v01 - report 1 of 2) contains results for patients with a pre-existing condition of atrial fibrillation only.

Request ID to09y05_mpr_wp37_v01 - report 2 of 2

Specifications Program parameter inputs and scenarios

Glossary List of Terms found in this Report and their Definitions

Table 1 Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, New Episodes with Events, Years at Risk, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and New Episodes with Events per 10,000 Years at Risk by Drug, Incidence Criteria, Washout Period, and Outcome.

Table 2 Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, New Episodes with Events, Years at Risk, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and New Episodes with Events per 10,000 Years at Risk by Drug, Incidence Criteria, Washout Period, Outcome, and Age Group.

Table 3 Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, New Episodes with Events, Years at Risk, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and New Episodes with Events per 10,000 Years at Risk by Drug, Incidence Criteria, Washout Period, Outcome, and Sex.

Table 4 Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, New Episodes with Events, Years at Risk, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and New Episodes with Events per 10,000 Years at Risk by Drug, Incidence Criteria, Washout Period, Outcome, and Year.

Appendix A List of exposure drug and procedure codes

Appendix B List of event diagnosis codes

Notes: Please contact the Mini-Sentinel Operations Center (MSOC_Requests@harvardpilgrim.org) for questions and to provide comments/suggestions for future enhancements to this document.

Modular Program Specifications for to09y05_mpr_wp37_v01

Modular Program 3, version 7.2, was used to investigate gastrointestinal hemorrhage (GIH) or intracerebral hemorrhage (ICH) events (see Appendix B) following new use of dabigatran or warfarin among all patients and among patients with a pre-existing condition of atrial fibrillation (ICD-9-CM 427.31). In total, 48 scenarios were examined in this report with differing exposures of interest, incidence criteria, pre-existing condition criteria, and event/outcome. See below for a description of each of these scenarios. **This report contains results for all patients (scenarios 25-48) only.** A second report contains results for patients with a pre-existing condition of atrial fibrillation (scenarios 1-24).

Enrollment Gap 45 days
 Age Groups 00-40, 41-54, 55-64, 65-74, 75-84, 85+
 Query Period October 19, 2010 - June 30, 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	Exposure Episode Gap	Exposure Extension Period	Min Episode Duration	Min Days Supplied	Episode Truncation by Incident Exposure	Pre-Existing Condition	Include or Exclude	Lookback Start	Lookback End	Care Setting/PDX	Event/Outcome	Care Setting/PDX	Incident w/ respect to:	Washout (days)	Event De-duplication	Blackout Period
1	Dabigatran	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH	ED*, IP*	ICH	183	0	0
2	Dabigatran	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	GIH	ED*, IP*	GIH	183	0	0
3	Dabigatran	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
4	Warfarin	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH	ED*, IP*	ICH	183	0	0
5	Warfarin	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	GIH	ED*, IP*	GIH	183	0	0
6	Warfarin	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
7	Dabigatran	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH	ED*, IP*	ICH	183	0	0
8	Dabigatran	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	GIH	ED*, IP*	GIH	183	0	0
9	Dabigatran	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
10	Warfarin	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH	ED*, IP*	ICH	183	0	0
11	Warfarin	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	GIH	ED*, IP*	GIH	183	0	0
12	Warfarin	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
13	Dabigatran	Dabigatran	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH	ED*, IP*	ICH	183	0	0
14	Dabigatran	Dabigatran	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	GIH	ED*, IP*	GIH	183	0	0
15	Dabigatran	Dabigatran	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
16	Warfarin	Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH	ED*, IP*	ICH	183	0	0
17	Warfarin	Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	GIH	ED*, IP*	GIH	183	0	0
18	Warfarin	Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
19	Dabigatran	Dabigatran	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH	ED*, IP*	ICH	183	0	0
20	Dabigatran	Dabigatran	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	GIH	ED*, IP*	GIH	183	0	0
21	Dabigatran	Dabigatran	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
22	Warfarin	Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH	ED*, IP*	ICH	183	0	0
23	Warfarin	Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	GIH	ED*, IP*	GIH	183	0	0
24	Warfarin	Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0

25	Dabigatran	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH	ED*, IP*	ICH	183	0	0
26	Dabigatran	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	GIH	ED*, IP*	GIH	183	0	0
27	Dabigatran	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
28	Warfarin	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH	ED*, IP*	ICH	183	0	0
29	Warfarin	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	GIH	ED*, IP*	GIH	183	0	0
30	Warfarin	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
31	Dabigatran	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH	ED*, IP*	ICH	183	0	0
32	Dabigatran	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	GIH	ED*, IP*	GIH	183	0	0
33	Dabigatran	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
34	Warfarin	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH	ED*, IP*	ICH	183	0	0
35	Warfarin	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	GIH	ED*, IP*	GIH	183	0	0
36	Warfarin	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
37	Dabigatran	Dabigatran	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH	ED*, IP*	ICH	183	0	0
38	Dabigatran	Dabigatran	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	GIH	ED*, IP*	GIH	183	0	0
39	Dabigatran	Dabigatran	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
40	Warfarin	Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH	ED*, IP*	ICH	183	0	0
41	Warfarin	Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	GIH	ED*, IP*	GIH	183	0	0
42	Warfarin	Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
43	Dabigatran	Dabigatran	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH	ED*, IP*	ICH	183	0	0
44	Dabigatran	Dabigatran	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	GIH	ED*, IP*	GIH	183	0	0
45	Dabigatran	Dabigatran	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
46	Warfarin	Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH	ED*, IP*	ICH	183	0	0
47	Warfarin	Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	GIH	ED*, IP*	GIH	183	0	0
48	Warfarin	Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0

NDC codes checked against First Data Bank's "National Drug Data File (NDDF®) Plus"
 ICD-9-CM diagnosis and procedure codes checked against "Ingenix 2012 ICD-9-CM Data File" provided by OptumInsight
 HCPCS codes checked against "Optum 2012 HCPCS Level II Data File" provided by OptumInsight
 CPT codes checked against "Optum 2012 Current Procedure Codes & Relative Values Data File" provided by OptumInsight

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 the "RxAmt"
- 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). Along with the Principal Diagnosis Indicator, forms the Caresetting/PDX parameter.
- Principal Diagnosis (PDX)** - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the
- 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 query period; (3) 03: 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.
- Years at Risk** - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.23.
- Eligible Members** - Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.
- Enrollment Gap** - number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled"
- Episode Gap** - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same
- Event De-duplication** - specifies how events are counted by the MP algorithm. '0' counts all occurrences of an event group code of interest. '1' de-duplicates occurrences of the same event code on the same day (i.e., de-duplicates at the exact match code level), '2' de-duplicates occurrences of the same event group code on the same day (e.g., de-duplicates at the GROUP level).
- Exposure Extension Period** - number of days post treatment period in which the outcomes/events are counted for a treatment episode.
- Lookback Period (pre-existing condition)** - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).
- Member-Years** - sum of all days of enrollment with medical and drug coverage** in the query period preceded by an exposure washout
- Minimum Days Supplied** - specifies a minimum number of days in length of the days supplied for the episode to be considered
- Minimum Episode Duration** - specifies a minimum number of days in length of the episode for it to be considered
- New Episodes** - new treatment episodes; length of episode is determined by days supplied in one dispensing (or consecutive dispensings
- New Users** - number of members with incident exposure during the query period. Member must have no evidence of exposure (s) of interest (defined by incidence criteria) in the prior washout period. A user may only be counted once in a query period.
- 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 the occurrence of the incident query code.
- Washout Period (drug/exposure)**** - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.
- Washout Period (event/outcome)**** - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

*all terms may not be used in this report

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

Table 1. Summary of Incident Dabigatran and Warfarin Use in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, and Outcome

	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	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
Dabigatran (Incident with respect to Dabigatran)														
<i>GIH</i>														
183-Day Washout Period	66,339	66,339	320,667	11,885,939	23,721,118	34,675.9	102	58,411,656	89,726,784.8	1.14	179.17	4.83	37.07	0.81
365-Day Washout Period	60,598	60,598	295,996	11,017,868	21,989,666	32,119.0	96	50,230,063	78,091,118.3	1.21	181.82	4.88	37.22	0.82
<i>ICH</i>														
183-Day Washout Period	66,238	66,238	319,812	11,855,452	23,659,966	34,588.5	107	58,411,995	89,732,420.1	1.13	178.98	4.83	37.07	0.85
365-Day Washout Period	60,511	60,511	295,221	10,989,874	21,933,500	32,041.1	97	50,230,247	78,095,698.2	1.20	181.62	4.88	37.23	0.83
<i>GIH or ICH</i>														
183-Day Washout Period	66,153	66,153	319,429	11,843,088	23,635,696	34,537.3	206	58,409,802	89,710,715.2	1.13	179.03	4.83	37.08	1.63
365-Day Washout Period	60,426	60,426	294,835	10,977,297	21,908,804	31,990.1	191	50,228,274	78,076,589.3	1.20	181.67	4.88	37.23	1.63
Dabigatran (Incident with respect to Dabigatran and Warfarin)														
<i>GIH</i>														
183-Day Washout Period	40,696	40,696	171,931	6,105,165	12,185,614	17,934.0	50	58,028,833	88,692,685.6	0.70	150.02	4.22	35.51	0.76
365-Day Washout Period	34,865	34,865	149,218	5,315,444	10,611,595	15,596.8	45	49,803,112	77,003,573.5	0.70	152.46	4.28	35.62	0.79
<i>ICH</i>														
183-Day Washout Period	40,642	40,642	171,486	6,089,515	12,153,927	17,887.7	60	58,029,212	88,698,634.6	0.70	149.83	4.22	35.51	0.92
365-Day Washout Period	34,816	34,816	148,822	5,301,253	10,582,826	15,556.8	50	49,803,358	77,008,470.1	0.70	152.26	4.27	35.62	0.88
<i>GIH or ICH</i>														
183-Day Washout Period	40,603	40,603	171,338	6,084,641	12,144,479	17,867.5	108	58,027,034	88,678,835.1	0.70	149.86	4.22	35.51	1.65
365-Day Washout Period	34,782	34,782	148,688	5,296,859	10,574,338	15,538.3	94	49,801,478	76,991,273.3	0.70	152.29	4.27	35.62	1.66
Warfarin (Incident with respect to Warfarin)														
<i>GIH</i>														
183-Day Washout Period	384,724	384,724	1,322,783	48,504,671	66,396,457	142,566.9	938	58,046,602	88,645,939.0	6.63	126.08	3.44	36.67	1.80
365-Day Washout Period	322,132	322,132	1,125,319	40,617,155	55,789,803	119,373.4	812	49,821,804	77,010,045.4	6.47	126.09	3.49	36.09	1.86
<i>ICH</i>														
183-Day Washout Period	384,047	384,047	1,318,455	48,359,921	66,201,498	142,224.6	1,058	58,046,989	88,651,937.2	6.62	125.92	3.43	36.68	2.04
365-Day Washout Period	321,547	321,547	1,121,633	40,494,338	55,623,933	119,092.5	904	49,822,062	77,014,953.3	6.45	125.94	3.49	36.10	2.08
<i>GIH or ICH</i>														
183-Day Washout Period	382,980	382,980	1,313,970	48,212,478	66,013,032	141,574.4	1,966	58,044,808	88,632,370.2	6.60	125.89	3.43	36.69	3.80
365-Day Washout Period	320,606	320,606	1,117,626	40,362,798	55,455,454	118,514.0	1,692	49,820,180	76,997,824.1	6.44	125.90	3.49	36.11	3.91

Table 1. Summary of Incident Dabigatran and Warfarin Use in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, and Outcome

	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	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
Warfarin (Incident with respect to Dabigatran and Warfarin)														
<i>GIH</i>														
183-Day Washout Period	379,180	379,180	1,297,770	47,455,943	65,099,707	139,463.7	924	58,028,833	88,590,970.0	6.53	125.15	3.42	36.57	1.81
365-Day Washout Period	317,323	317,323	1,103,717	39,725,381	54,681,211	116,735.6	800	49,803,112	76,958,918.5	6.37	125.19	3.48	35.99	1.88
<i>ICH</i>														
183-Day Washout Period	378,501	378,501	1,293,460	47,312,918	64,908,116	139,130.5	1,031	58,029,212	88,596,971.2	6.52	125.00	3.42	36.58	2.03
365-Day Washout Period	316,741	316,741	1,100,038	39,604,004	54,517,437	116,461.6	884	49,803,358	76,963,831.8	6.36	125.04	3.47	36.00	2.08
<i>GIH or ICH</i>														
183-Day Washout Period	377,458	377,458	1,289,141	47,170,391	64,724,367	138,498.4	1,925	58,027,034	88,577,456.0	6.50	124.97	3.42	36.59	3.81
365-Day Washout Period	315,816	315,816	1,096,164	39,476,028	54,352,549	115,896.8	1,660	49,801,478	76,946,752.8	6.34	125.00	3.47	36.01	3.92

Table 2. Summary of Incident Dabigatran and Warfarin Use among Patients in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, 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	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
Dabigatran (Incident with respect to Dabigatran)														
<i>GIH</i>														
183-Day Washout Period														
00 to 40 Years	1,244	1,244	3,444	106,233	212,026	330.7	0	33,011,683	45,856,340.0	0.04	85.40	2.77	30.85	0.00
41 to 54 Years	7,560	7,560	30,337	1,002,916	2,004,068	2,999.6	3	14,291,212	20,528,490.8	0.53	132.66	4.01	33.06	0.27
55 to 64 Years	17,390	17,390	86,744	3,051,545	6,098,016	8,919.0	21	8,425,846	12,482,564.5	2.06	175.48	4.99	35.18	0.64
65 to 74 Years	18,517	18,517	92,055	3,566,165	7,119,087	10,350.5	24	4,113,783	6,328,717.1	4.50	192.59	4.97	38.74	0.63
75 to 84 Years	16,140	16,140	80,755	3,155,781	6,294,970	9,159.2	37	1,970,580	3,285,816.9	8.19	195.53	5.00	39.08	1.11
85+ Years	5,488	5,488	27,332	1,003,299	1,992,950	2,917.0	17	767,149	1,244,855.5	7.15	182.82	4.98	36.71	1.60
365-Day Washout Period														
00 to 40 Years	1,030	1,030	2,796	87,006	173,546	271.1	0	27,350,076	38,592,187.0	0.04	84.47	2.71	31.12	0.00
41 to 54 Years	6,631	6,631	27,166	900,264	1,799,159	2,689.5	2	12,553,097	18,148,844.5	0.53	135.77	4.10	33.14	0.20
55 to 64 Years	15,700	15,700	78,990	2,784,462	5,564,987	8,134.4	20	7,645,050	11,328,854.5	2.05	177.35	5.03	35.25	0.67
65 to 74 Years	16,773	16,773	84,552	3,288,987	6,566,104	9,537.7	23	3,788,532	5,725,151.6	4.43	196.09	5.04	38.90	0.66
75 to 84 Years	15,244	15,244	76,508	3,000,672	5,985,675	8,705.4	35	1,891,862	3,105,719.2	8.06	196.84	5.02	39.22	1.10
85+ Years	5,220	5,220	25,984	956,477	1,900,195	2,780.9	16	743,118	1,190,361.4	7.02	183.23	4.98	36.81	1.58
<i>ICH</i>														
183-Day Washout Period														
00 to 40 Years	1,246	1,246	3,446	106,353	212,176	331.1	0	33,012,207	45,860,562.0	0.04	85.36	2.77	30.86	0.00
41 to 54 Years	7,553	7,553	30,237	999,698	1,997,502	2,990.3	4	14,291,336	20,529,708.8	0.53	132.36	4.00	33.06	0.37
55 to 64 Years	17,367	17,367	86,577	3,045,406	6,085,636	8,900.0	20	8,425,876	12,483,070.4	2.06	175.36	4.99	35.18	0.62
65 to 74 Years	18,486	18,486	91,760	3,554,744	7,096,378	10,316.5	29	4,113,660	6,328,700.4	4.49	192.29	4.96	38.74	0.77
75 to 84 Years	16,103	16,103	80,468	3,147,311	6,278,189	9,134.0	40	1,970,497	3,285,473.4	8.17	195.45	5.00	39.11	1.20
85+ Years	5,483	5,483	27,324	1,001,940	1,990,084	2,916.6	14	767,049	1,244,905.0	7.15	182.74	4.98	36.67	1.31
365-Day Washout Period														
00 to 40 Years	1,032	1,032	2,798	87,126	173,696	271.5	0	27,350,472	38,595,635.1	0.04	84.42	2.71	31.14	0.00
41 to 54 Years	6,625	6,625	27,067	897,076	1,792,653	2,680.5	3	12,553,151	18,149,866.0	0.53	135.41	4.09	33.14	0.31
55 to 64 Years	15,681	15,681	78,847	2,779,118	5,554,197	8,120.0	18	7,645,097	11,329,275.1	2.05	177.23	5.03	35.25	0.61
65 to 74 Years	16,746	16,746	84,312	3,279,145	6,546,553	9,508.6	26	3,788,425	5,725,122.7	4.42	195.82	5.03	38.89	0.75
75 to 84 Years	15,211	15,211	76,233	2,992,651	5,969,792	8,681.5	38	1,891,763	3,105,385.6	8.04	196.74	5.01	39.26	1.20
85+ Years	5,216	5,216	25,964	954,758	1,896,609	2,779.0	12	743,017	1,190,413.7	7.02	183.04	4.98	36.77	1.18

Table 2. Summary of Incident Dabigatran and Warfarin Use among Patients in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, 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	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
GIH or ICH														
183-Day Washout Period														
00 to 40 Years	1,244	1,244	3,444	106,233	212,026	330.7	0	33,011,399	45,854,366.3	0.04	85.40	2.77	30.85	0.00
41 to 54 Years	7,545	7,545	30,222	999,208	1,996,532	2,988.4	7	14,290,828	20,525,897.1	0.53	132.43	4.01	33.06	0.64
55 to 64 Years	17,349	17,349	86,496	3,042,918	6,080,840	8,889.5	39	8,425,438	12,479,479.9	2.06	175.39	4.99	35.18	1.20
65 to 74 Years	18,469	18,469	91,701	3,552,749	7,092,418	10,308.1	53	4,113,306	6,325,484.4	4.49	192.36	4.97	38.74	1.41
75 to 84 Years	16,082	16,082	80,361	3,143,489	6,270,545	9,118.6	76	1,970,151	3,282,452.2	8.16	195.47	5.00	39.12	2.28
85+ Years	5,464	5,464	27,205	998,491	1,983,334	2,901.9	31	766,838	1,243,035.3	7.13	182.74	4.98	36.70	2.92
365-Day Washout Period														
00 to 40 Years	1,030	1,030	2,796	87,006	173,546	271.1	0	27,349,858	38,590,571.8	0.04	84.47	2.71	31.12	0.00
41 to 54 Years	6,617	6,617	27,052	896,586	1,791,683	2,678.6	5	12,552,746	18,146,569.9	0.53	135.50	4.09	33.14	0.51
55 to 64 Years	15,663	15,663	78,766	2,776,630	5,549,401	8,109.6	36	7,644,662	11,326,064.3	2.05	177.27	5.03	35.25	1.22
65 to 74 Years	16,730	16,730	84,254	3,277,180	6,542,653	9,500.3	49	3,788,058	5,722,213.7	4.42	195.89	5.04	38.90	1.41
75 to 84 Years	15,189	15,189	76,124	2,988,646	5,961,782	8,665.6	73	1,891,402	3,102,544.0	8.03	196.76	5.01	39.26	2.31
85+ Years	5,197	5,197	25,843	951,249	1,889,739	2,764.8	28	742,798	1,188,625.7	7.00	183.04	4.97	36.81	2.77
Dabigatran (Incident with respect to Dabigatran and Warfarin)														
GIH														
183-Day Washout Period														
00 to 40 Years	953	953	2,279	67,914	135,482	214.9	0	32,995,855	45,817,693.6	0.03	71.26	2.39	29.80	0.00
41 to 54 Years	5,367	5,367	18,257	585,284	1,168,952	1,770.4	1	14,239,013	20,406,534.8	0.38	109.05	3.40	32.06	0.15
55 to 64 Years	11,290	11,290	48,366	1,648,146	3,294,089	4,853.9	11	8,336,248	12,281,646.5	1.35	145.98	4.28	34.08	0.62
65 to 74 Years	11,204	11,204	49,151	1,807,532	3,610,316	5,277.8	15	3,994,497	6,065,818.2	2.80	161.33	4.39	36.78	0.78
75 to 84 Years	8,953	8,953	40,520	1,522,748	3,036,620	4,434.5	18	1,844,300	3,002,342.6	4.85	170.08	4.53	37.58	1.11
85+ Years	2,929	2,929	13,358	473,541	940,155	1,382.5	5	706,545	1,118,649.9	4.15	161.67	4.56	35.45	0.99
365-Day Washout Period														
00 to 40 Years	753	753	1,711	51,230	102,083	163.0	0	27,331,893	38,551,293.1	0.03	68.03	2.27	29.94	0.00
41 to 54 Years	4,451	4,451	15,456	494,998	988,502	1,495.2	0	12,494,340	18,018,083.3	0.36	111.21	3.47	32.03	0.00
55 to 64 Years	9,519	9,519	41,073	1,400,627	2,799,461	4,122.2	9	7,544,782	11,111,427.0	1.26	147.14	4.31	34.10	0.60
65 to 74 Years	9,520	9,520	42,614	1,569,596	3,136,544	4,577.2	14	3,657,965	5,452,393.9	2.60	164.87	4.48	36.83	0.84
75 to 84 Years	7,979	7,979	36,358	1,370,902	2,734,658	3,989.8	17	1,753,072	2,812,050.7	4.55	171.81	4.56	37.71	1.17
85+ Years	2,643	2,643	12,006	428,091	850,347	1,249.4	5	675,499	1,058,325.4	3.91	161.97	4.54	35.66	1.10

Table 2. Summary of Incident Dabigatran and Warfarin Use among Patients in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, 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	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
ICH														
183-Day Washout Period														
00 to 40 Years	955	955	2,281	68,034	135,632	215.3	0	32,996,379	45,821,905.5	0.03	71.24	2.39	29.83	0.00
41 to 54 Years	5,366	5,366	18,220	583,979	1,166,222	1,766.6	2	14,239,131	20,407,750.5	0.38	108.83	3.40	32.05	0.31
55 to 64 Years	11,278	11,278	48,273	1,644,524	3,286,608	4,841.5	12	8,336,276	12,282,197.2	1.35	145.82	4.28	34.07	0.68
65 to 74 Years	11,182	11,182	48,989	1,801,259	3,597,740	5,260.7	14	3,994,378	6,065,849.7	2.80	161.09	4.38	36.77	0.73
75 to 84 Years	8,938	8,938	40,396	1,519,759	3,030,732	4,425.9	23	1,844,229	3,002,169.5	4.85	170.03	4.52	37.62	1.42
85+ Years	2,923	2,923	13,327	471,960	936,993	1,377.6	9	706,459	1,118,762.2	4.14	161.46	4.56	35.41	1.79
365-Day Washout Period														
00 to 40 Years	755	755	1,713	51,350	102,233	163.3	0	27,332,288	38,554,722.6	0.03	68.01	2.27	29.98	0.00
41 to 54 Years	4,449	4,449	15,415	493,573	985,532	1,491.1	1	12,494,403	18,019,097.5	0.36	110.94	3.46	32.02	0.18
55 to 64 Years	9,508	9,508	40,978	1,397,044	2,792,058	4,111.7	11	7,544,800	11,111,885.2	1.26	146.93	4.31	34.09	0.73
65 to 74 Years	9,501	9,501	42,492	1,564,498	3,126,318	4,563.6	10	3,657,875	5,452,417.7	2.60	164.67	4.47	36.82	0.60
75 to 84 Years	7,965	7,965	36,263	1,368,698	2,730,340	3,983.6	20	1,753,002	2,811,898.7	4.54	171.84	4.55	37.74	1.37
85+ Years	2,638	2,638	11,961	426,090	846,345	1,243.5	8	675,427	1,058,448.4	3.91	161.52	4.53	35.62	1.76
GIH or ICH														
183-Day Washout Period														
00 to 40 Years	953	953	2,279	67,914	135,482	214.9	0	32,995,575	45,815,817.8	0.03	71.26	2.39	29.80	0.00
41 to 54 Years	5,360	5,360	18,207	583,614	1,165,492	1,765.4	3	14,238,639	20,404,158.5	0.38	108.88	3.40	32.05	0.47
55 to 64 Years	11,267	11,267	48,213	1,642,786	3,283,312	4,834.8	22	8,335,840	12,278,936.2	1.35	145.81	4.28	34.07	1.25
65 to 74 Years	11,178	11,178	48,972	1,800,773	3,596,798	5,257.6	29	3,994,046	6,063,098.8	2.80	161.10	4.38	36.77	1.51
75 to 84 Years	8,929	8,929	40,357	1,518,039	3,027,292	4,418.8	40	1,843,895	2,999,670.3	4.84	170.01	4.52	37.62	2.48
85+ Years	2,916	2,916	13,310	471,515	936,103	1,375.9	14	706,264	1,117,153.5	4.13	161.70	4.56	35.43	2.79
365-Day Washout Period														
00 to 40 Years	753	753	1,711	51,230	102,083	163.0	0	27,331,674	38,549,759.9	0.03	68.03	2.27	29.94	0.00
41 to 54 Years	4,444	4,444	15,406	493,328	985,042	1,490.3	1	12,494,015	18,016,015.4	0.36	111.01	3.47	32.02	0.18
55 to 64 Years	9,498	9,498	40,925	1,395,516	2,789,182	4,105.8	19	7,544,405	11,109,002.5	1.26	146.93	4.31	34.10	1.27
65 to 74 Years	9,498	9,498	42,476	1,564,042	3,125,436	4,560.6	24	3,657,545	5,449,973.1	2.60	164.67	4.47	36.82	1.44
75 to 84 Years	7,958	7,958	36,226	1,367,098	2,727,140	3,976.8	37	1,752,673	2,809,590.9	4.54	171.79	4.55	37.74	2.55
85+ Years	2,631	2,631	11,944	425,645	845,455	1,241.8	13	675,233	1,056,931.7	3.90	161.78	4.54	35.64	2.87

Table 2. Summary of Incident Dabigatran and Warfarin Use among Patients in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, 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	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
Warfarin (Incident with respect to Warfarin)														
<i>GIH</i>														
183-Day Washout Period														
00 to 40 Years	22,884	22,884	86,782	2,854,917	4,259,962	8,408.3	47	32,996,074	45,813,136.2	0.69	124.76	3.79	32.90	1.53
41 to 54 Years	62,137	62,137	214,820	7,185,319	10,596,785	21,316.3	122	14,239,359	20,395,386.2	4.36	115.64	3.46	33.45	1.57
55 to 64 Years	95,108	95,108	290,597	10,035,459	14,398,855	29,953.6	175	8,337,147	12,266,643.6	11.41	105.52	3.06	34.53	1.60
65 to 74 Years	95,806	95,806	312,079	12,381,327	16,646,348	36,301.5	237	3,996,223	6,055,701.3	23.97	129.23	3.26	39.67	1.79
75 to 84 Years	79,601	79,601	295,173	11,690,292	15,109,202	33,966.6	255	1,845,484	2,997,910.0	43.13	146.86	3.71	39.60	2.06
85+ Years	29,188	29,188	123,332	4,357,357	5,385,306	12,620.6	102	706,255	1,117,161.6	41.33	149.29	4.23	35.33	2.21
365-Day Washout Period														
00 to 40 Years	17,991	17,991	69,569	2,287,461	3,419,327	6,726.9	39	27,332,176	38,550,116.6	0.66	127.14	3.87	32.88	1.59
41 to 54 Years	51,152	51,152	179,425	5,960,865	8,837,172	17,674.5	99	12,495,411	18,016,707.6	4.09	116.53	3.51	33.22	1.53
55 to 64 Years	79,749	79,749	245,182	8,357,029	12,070,989	24,959.2	149	7,547,428	11,111,901.9	10.57	104.79	3.07	34.09	1.63
65 to 74 Years	80,248	80,248	263,750	10,257,327	13,872,275	30,101.0	208	3,661,565	5,455,176.2	21.92	127.82	3.29	38.89	1.89
75 to 84 Years	68,026	68,026	258,330	9,997,885	12,953,420	29,040.1	229	1,755,884	2,816,181.1	38.74	146.97	3.80	38.70	2.16
85+ Years	24,966	24,966	109,063	3,756,588	4,636,620	10,871.7	88	676,280	1,059,961.9	36.92	150.47	4.37	34.44	2.22
<i>ICH</i>														
183-Day Washout Period														
00 to 40 Years	22,804	22,804	86,257	2,837,450	4,234,870	8,363.9	25	32,996,597	45,817,358.6	0.69	124.43	3.78	32.90	0.82
41 to 54 Years	61,973	61,973	213,963	7,157,692	10,553,812	21,250.5	89	14,239,483	20,396,625.6	4.35	115.50	3.45	33.45	1.15
55 to 64 Years	94,915	94,915	289,270	9,995,475	14,347,874	29,849.7	175	8,337,181	12,267,213.2	11.38	105.31	3.05	34.55	1.61
65 to 74 Years	95,699	95,699	311,350	12,358,144	16,615,031	36,255.0	271	3,996,104	6,055,731.5	23.95	129.14	3.25	39.69	2.05
75 to 84 Years	79,478	79,478	294,342	11,656,584	15,069,868	33,893.4	340	1,845,412	2,997,735.1	43.07	146.66	3.70	39.60	2.75
85+ Years	29,178	29,178	123,273	4,354,576	5,380,044	12,612.0	158	706,171	1,117,273.1	41.32	149.24	4.22	35.32	3.43
365-Day Washout Period														
00 to 40 Years	17,932	17,932	69,159	2,273,981	3,399,897	6,693.2	20	27,332,572	38,553,550.2	0.66	126.81	3.86	32.88	0.82
41 to 54 Years	51,011	51,011	178,676	5,936,708	8,801,249	17,615.8	75	12,495,476	18,017,730.1	4.08	116.38	3.50	33.23	1.17
55 to 64 Years	79,586	79,586	244,022	8,320,671	12,025,223	24,867.1	157	7,547,450	11,112,368.7	10.54	104.55	3.07	34.10	1.73
65 to 74 Years	80,151	80,151	263,101	10,237,641	13,845,944	30,060.6	227	3,661,476	5,455,197.4	21.89	127.73	3.28	38.91	2.07
75 to 84 Years	67,912	67,912	257,675	9,970,273	12,919,629	28,988.6	284	1,755,818	2,816,022.7	38.68	146.81	3.79	38.69	2.68
85+ Years	24,955	24,955	109,000	3,755,064	4,631,991	10,867.1	141	676,210	1,060,084.1	36.90	150.47	4.37	34.45	3.55

Table 2. Summary of Incident Dabigatran and Warfarin Use among Patients in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, 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	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
GIH or ICH														
183-Day Washout Period														
00 to 40 Years	22,700	22,700	85,871	2,824,776	4,214,170	8,316.5	72	32,995,794	45,811,290.6	0.69	124.44	3.78	32.90	2.37
41 to 54 Years	61,809	61,809	213,272	7,135,130	10,524,159	21,160.4	205	14,238,993	20,393,067.2	4.34	115.44	3.45	33.46	2.65
55 to 64 Years	94,701	94,701	288,571	9,970,800	14,314,649	29,738.5	345	8,336,753	12,264,000.3	11.36	105.29	3.05	34.55	3.18
65 to 74 Years	95,432	95,432	310,268	12,319,355	16,567,917	36,085.3	499	3,995,782	6,053,042.3	23.88	129.09	3.25	39.71	3.79
75 to 84 Years	79,251	79,251	293,207	11,623,186	15,028,343	33,725.4	589	1,845,089	2,995,290.3	42.95	146.66	3.70	39.64	4.78
85+ Years	29,087	29,087	122,781	4,339,231	5,363,795	12,548.3	256	705,982	1,115,679.5	41.20	149.18	4.22	35.34	5.59
365-Day Washout Period														
00 to 40 Years	17,842	17,842	68,816	2,262,455	3,381,101	6,650.7	59	27,331,957	38,548,593.3	0.65	126.81	3.86	32.88	2.43
41 to 54 Years	50,868	50,868	178,069	5,917,207	8,775,434	17,539.4	168	12,495,089	18,014,659.1	4.07	116.32	3.50	33.23	2.62
55 to 64 Years	79,400	79,400	243,412	8,299,952	11,996,569	24,769.5	303	7,547,056	11,109,497.6	10.52	104.53	3.07	34.10	3.35
65 to 74 Years	79,915	79,915	262,145	10,202,367	13,803,234	29,911.7	428	3,661,154	5,452,771.9	21.83	127.67	3.28	38.92	3.92
75 to 84 Years	67,708	67,708	256,628	9,939,877	12,881,357	28,833.7	508	1,755,497	2,813,733.1	38.57	146.81	3.79	38.73	4.82
85+ Years	24,873	24,873	108,556	3,740,940	4,617,759	10,808.9	226	676,020	1,058,569.2	36.79	150.40	4.36	34.46	5.72
Warfarin (Incident with respect to Dabigatran and Warfarin)														
GIH														
183-Day Washout Period														
00 to 40 Years	22,817	22,817	86,468	2,842,868	4,242,988	8,371.9	47	32,995,855	45,812,370.9	0.69	124.59	3.79	32.88	1.54
41 to 54 Years	61,694	61,694	212,672	7,105,851	10,490,660	21,075.1	122	14,237,726	20,389,973.0	4.33	115.18	3.45	33.41	1.58
55 to 64 Years	93,935	93,935	285,618	9,842,141	14,149,412	29,370.9	171	8,331,759	12,252,349.9	11.27	104.78	3.04	34.46	1.59
65 to 74 Years	94,182	94,182	304,980	12,064,340	16,254,916	35,367.7	231	3,989,686	6,039,940.7	23.61	128.10	3.24	39.56	1.79
75 to 84 Years	77,887	77,887	287,253	11,346,339	14,695,312	32,959.0	251	1,839,781	2,984,108.1	42.33	145.68	3.69	39.50	2.09
85+ Years	28,665	28,665	120,779	4,254,404	5,266,419	12,319.2	102	703,950	1,112,227.4	40.72	148.42	4.21	35.22	2.27
365-Day Washout Period														
00 to 40 Years	17,936	17,936	69,315	2,277,695	3,404,987	6,697.4	39	27,331,893	38,549,309.4	0.66	126.99	3.86	32.86	1.59
41 to 54 Years	50,738	50,738	177,461	5,890,205	8,744,070	17,460.8	99	12,493,588	18,011,332.6	4.06	116.09	3.50	33.19	1.55
55 to 64 Years	78,731	78,731	240,897	8,191,450	11,857,903	24,460.8	145	7,541,923	11,098,530.5	10.44	104.04	3.06	34.00	1.62
65 to 74 Years	78,857	78,857	257,607	9,985,936	13,535,342	29,303.1	203	3,654,804	5,440,852.1	21.58	126.63	3.27	38.76	1.90
75 to 84 Years	66,549	66,549	251,668	9,713,129	12,609,179	28,203.6	226	1,750,054	2,803,550.2	38.03	145.95	3.78	38.60	2.19
85+ Years	24,512	24,512	106,769	3,666,966	4,529,730	10,609.8	88	673,851	1,055,343.6	36.38	149.60	4.36	34.34	2.27

Table 2. Summary of Incident Dabigatran and Warfarin Use among Patients in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, 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	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
ICH														
183-Day Washout Period														
00 to 40 Years	22,737	22,737	85,943	2,825,401	4,217,895	8,327.5	25	32,996,379	45,816,591.8	0.69	124.26	3.78	32.88	0.82
41 to 54 Years	61,528	61,528	211,813	7,078,136	10,447,550	21,009.0	89	14,237,851	20,391,213.1	4.32	115.04	3.44	33.42	1.16
55 to 64 Years	93,741	93,741	284,333	9,803,678	14,100,575	29,269.8	173	8,331,789	12,252,922.5	11.25	104.58	3.03	34.48	1.62
65 to 74 Years	94,074	94,074	304,245	12,040,916	16,223,637	35,322.6	261	3,989,561	6,039,973.8	23.58	127.99	3.23	39.58	2.02
75 to 84 Years	77,766	77,766	286,405	11,313,482	14,657,615	32,891.5	328	1,839,704	2,983,930.7	42.27	145.48	3.68	39.50	2.73
85+ Years	28,655	28,655	120,721	4,251,305	5,260,846	12,310.1	155	703,867	1,112,339.2	40.71	148.36	4.21	35.22	3.45
365-Day Washout Period														
00 to 40 Years	17,877	17,877	68,905	2,264,215	3,385,557	6,663.7	20	27,332,288	38,552,741.0	0.65	126.66	3.85	32.86	0.82
41 to 54 Years	50,595	50,595	176,711	5,866,028	8,708,078	17,402.1	75	12,493,652	18,012,354.9	4.05	115.94	3.49	33.20	1.18
55 to 64 Years	78,566	78,566	239,764	8,156,133	11,813,290	24,370.1	153	7,541,941	11,098,999.4	10.42	103.81	3.05	34.02	1.72
65 to 74 Years	78,761	78,761	256,977	9,966,941	13,509,673	29,265.6	221	3,654,713	5,440,879.5	21.55	126.55	3.26	38.79	2.07
75 to 84 Years	66,440	66,440	250,970	9,685,465	12,575,950	28,155.1	277	1,749,983	2,803,389.9	37.97	145.78	3.78	38.59	2.69
85+ Years	24,502	24,502	106,711	3,665,222	4,524,888	10,605.0	138	673,780	1,055,467.1	36.36	149.59	4.36	34.35	3.56
GIH or ICH														
183-Day Washout Period														
00 to 40 Years	22,633	22,633	85,557	2,812,727	4,197,196	8,280.0	72	32,995,575	45,810,525.4	0.69	124.28	3.78	32.88	2.38
41 to 54 Years	61,367	61,367	211,128	7,055,812	10,418,305	20,919.6	205	14,237,360	20,387,658.0	4.31	114.98	3.44	33.42	2.68
55 to 64 Years	93,531	93,531	283,642	9,779,333	14,067,739	29,161.4	339	8,331,362	12,249,718.7	11.23	104.56	3.03	34.48	3.18
65 to 74 Years	93,813	93,813	303,200	12,003,771	16,178,206	35,159.2	483	3,989,241	6,037,292.2	23.52	127.95	3.23	39.59	3.76
75 to 84 Years	77,546	77,546	285,359	11,281,750	14,617,302	32,728.7	573	1,839,386	2,981,507.3	42.16	145.48	3.68	39.54	4.79
85+ Years	28,568	28,568	120,255	4,236,998	5,245,619	12,249.4	253	703,677	1,110,754.5	40.60	148.31	4.21	35.23	5.65
365-Day Washout Period														
00 to 40 Years	17,787	17,787	68,562	2,252,689	3,366,761	6,621.2	59	27,331,674	38,547,786.1	0.65	126.65	3.85	32.86	2.44
41 to 54 Years	50,454	50,454	176,107	5,846,683	8,682,589	17,326.2	168	12,493,265	18,009,286.6	4.04	115.88	3.49	33.20	2.65
55 to 64 Years	78,384	78,384	239,161	8,135,624	11,784,906	24,275.0	295	7,541,549	11,096,138.2	10.39	103.79	3.05	34.02	3.33
65 to 74 Years	78,529	78,529	256,046	9,932,662	13,468,108	29,120.9	417	3,654,388	5,438,461.6	21.49	126.48	3.26	38.79	3.92
75 to 84 Years	66,238	66,238	249,995	9,656,234	12,538,506	28,003.8	498	1,749,664	2,801,119.7	37.86	145.78	3.77	38.63	4.87
85+ Years	24,424	24,424	106,293	3,652,136	4,511,679	10,549.7	223	673,591	1,053,960.6	36.26	149.53	4.35	34.36	5.79

Table 3. Summary of Incident Dabigatran and Warfarin Use among Patients in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, 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	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
Dabigatran (Incident with respect to Dabigatran)														
<i>GIH</i>														
183-Day Washout Period														
Female	23,982	23,982	118,346	4,340,380	8,656,632	12,649.1	43	29,670,846	45,928,112.8	0.81	180.98	4.93	36.68	0.93
Male	42,337	42,337	202,248	7,543,309	15,059,986	22,020.1	59	28,723,559	43,777,219.5	1.47	178.17	4.78	37.30	0.73
Unknown	20	20	73	2,250	4,500	6.6	0	17,251	21,452.5	1.16	112.50	3.65	30.82	0.00
365-Day Washout Period														
Female	22,034	22,034	109,835	4,041,345	8,061,060	11,768.6	40	25,577,848	40,091,947.1	0.86	183.41	4.98	36.79	0.93
Male	38,544	38,544	186,088	6,974,273	13,924,106	20,343.8	56	24,636,526	37,984,111.0	1.56	180.94	4.83	37.48	0.75
Unknown	20	20	73	2,250	4,500	6.6	0	15,689	15,060.2	1.27	112.50	3.65	30.82	0.00
<i>ICH</i>														
183-Day Washout Period														
Female	23,945	23,945	118,150	4,332,573	8,641,218	12,627.4	39	29,670,962	45,930,642.4	0.81	180.94	4.93	36.67	0.85
Male	42,273	42,273	201,589	7,520,629	15,014,248	21,954.5	68	28,723,783	43,780,323.6	1.47	177.91	4.77	37.31	0.85
Unknown	20	20	73	2,250	4,500	6.6	0	17,250	21,454.1	1.16	112.50	3.65	30.82	0.00
365-Day Washout Period														
Female	22,003	22,003	109,665	4,034,257	8,047,084	11,748.6	35	25,577,891	40,094,006.3	0.86	183.35	4.98	36.79	0.82
Male	38,488	38,488	185,483	6,953,367	13,881,916	20,285.9	62	24,636,669	37,986,632.6	1.56	180.66	4.82	37.49	0.84
Unknown	20	20	73	2,250	4,500	6.6	0	15,687	15,059.3	1.27	112.50	3.65	30.82	0.00
<i>GIH or ICH</i>														
183-Day Washout Period														
Female	23,908	23,908	117,934	4,326,039	8,628,178	12,600.9	81	29,669,977	45,920,461.1	0.81	180.95	4.93	36.68	1.76
Male	42,225	42,225	201,422	7,514,799	15,003,018	21,929.8	125	28,722,575	43,768,809.2	1.47	177.97	4.77	37.31	1.56
Unknown	20	20	73	2,250	4,500	6.6	0	17,250	21,444.9	1.16	112.50	3.65	30.82	0.00
365-Day Washout Period														
Female	21,966	21,966	109,452	4,027,836	8,034,270	11,723.2	74	25,576,985	40,084,983.6	0.86	183.37	4.98	36.80	1.73
Male	38,440	38,440	185,310	6,947,211	13,870,034	20,260.3	117	24,635,602	37,976,552.1	1.56	180.73	4.82	37.49	1.58
Unknown	20	20	73	2,250	4,500	6.6	0	15,687	15,053.5	1.27	112.50	3.65	30.82	0.00

Table 3. Summary of Incident Dabigatran and Warfarin Use among Patients in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, 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	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
Dabigatran (Incident with respect to Dabigatran and Warfarin)														
<i>GIH</i>														
183-Day Washout Period														
Female	14,098	14,098	62,217	2,189,991	4,370,255	6,410.9	20	29,506,274	45,464,002.5	0.48	155.34	4.41	35.20	0.85
Male	26,583	26,583	109,677	3,913,981	7,812,973	11,519.6	30	28,505,347	43,207,340.8	0.93	147.24	4.13	35.69	0.71
Unknown	15	15	37	1,193	2,386	3.5	0	17,212	21,342.3	0.87	79.53	2.47	32.24	0.00
365-Day Washout Period														
Female	12,191	12,191	54,754	1,929,648	3,852,150	5,641.3	18	25,393,059	39,596,945.4	0.48	158.28	4.49	35.24	0.87
Male	22,659	22,659	94,427	3,384,603	6,757,059	9,952.0	27	24,394,409	37,391,685.2	0.93	149.37	4.17	35.84	0.74
Unknown	15	15	37	1,193	2,386	3.5	0	15,644	14,942.8	0.96	79.53	2.47	32.24	0.00
<i>ICH</i>														
183-Day Washout Period														
Female	14,080	14,080	62,097	2,185,851	4,362,038	6,399.6	17	29,506,386	45,466,696.0	0.48	155.25	4.41	35.20	0.73
Male	26,547	26,547	109,352	3,902,471	7,789,503	11,484.5	43	28,505,615	43,210,594.7	0.93	147.00	4.12	35.69	1.03
Unknown	15	15	37	1,193	2,386	3.5	0	17,211	21,343.9	0.87	79.53	2.47	32.24	0.00
365-Day Washout Period														
Female	12,175	12,175	54,649	1,925,873	3,844,663	5,631.3	14	25,393,124	39,599,174.6	0.48	158.18	4.49	35.24	0.68
Male	22,626	22,626	94,136	3,374,187	6,735,777	9,922.0	36	24,394,592	37,394,353.6	0.93	149.13	4.16	35.84	0.99
Unknown	15	15	37	1,193	2,386	3.5	0	15,642	14,941.9	0.96	79.53	2.47	32.24	0.00
<i>GIH or ICH</i>														
183-Day Washout Period														
Female	14,062	14,062	62,033	2,183,866	4,358,098	6,391.5	37	29,505,420	45,457,406.7	0.48	155.30	4.41	35.20	1.58
Male	26,526	26,526	109,268	3,899,582	7,783,995	11,472.4	71	28,504,403	43,200,093.6	0.93	147.01	4.12	35.69	1.69
Unknown	15	15	37	1,193	2,386	3.5	0	17,211	21,334.8	0.87	79.53	2.47	32.24	0.00
365-Day Washout Period														
Female	12,158	12,158	54,586	1,923,978	3,840,903	5,623.6	32	25,392,268	39,591,045.7	0.48	158.25	4.49	35.25	1.56
Male	22,609	22,609	94,065	3,371,688	6,731,049	9,911.2	62	24,393,568	37,385,291.4	0.93	149.13	4.16	35.84	1.71
Unknown	15	15	37	1,193	2,386	3.5	0	15,642	14,936.2	0.96	79.53	2.47	32.24	0.00

Table 3. Summary of Incident Dabigatran and Warfarin Use among Patients in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, 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	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
Warfarin (Incident with respect to Warfarin)														
<i>GIH</i>														
183-Day Washout Period														
Female	185,716	185,716	629,476	22,449,136	30,320,401	66,164.5	460	29,512,560	45,427,727.8	6.29	120.88	3.39	35.66	1.90
Male	198,824	198,824	692,956	26,044,573	36,061,021	76,370.2	478	28,516,825	43,196,869.7	6.97	130.99	3.49	37.58	1.71
Unknown	184	184	351	10,962	15,035	32.1	0	17,217	21,341.5	10.69	59.58	1.91	31.23	0.00
365-Day Washout Period														
Female	157,468	157,468	540,614	18,997,487	25,725,983	55,997.7	395	25,399,638	39,590,070.4	6.20	120.64	3.43	35.14	1.93
Male	164,489	164,489	584,375	21,609,377	30,049,674	63,345.5	417	24,406,520	37,405,029.0	6.74	131.37	3.55	36.98	1.80
Unknown	175	175	330	10,291	14,146	30.1	0	15,646	14,946.0	11.18	58.81	1.89	31.18	0.00
<i>ICH</i>														
183-Day Washout Period														
Female	185,386	185,386	627,233	22,377,925	30,231,528	66,000.6	518	29,512,673	45,430,451.3	6.28	120.71	3.38	35.68	2.15
Male	198,478	198,478	690,872	25,971,046	35,954,947	76,191.9	540	28,517,100	43,200,142.7	6.96	130.85	3.48	37.59	1.94
Unknown	183	183	350	10,950	15,023	32.1	0	17,216	21,343.2	10.63	59.84	1.91	31.29	0.00
365-Day Washout Period														
Female	157,166	157,166	538,539	18,931,859	25,642,899	55,850.1	444	25,399,708	39,592,309.5	6.19	120.46	3.43	35.15	2.18
Male	164,207	164,207	582,765	21,552,200	29,966,900	63,212.3	460	24,406,710	37,407,698.7	6.73	131.25	3.55	36.98	1.99
Unknown	174	174	329	10,279	14,134	30.1	0	15,644	14,945.1	11.12	59.07	1.89	31.24	0.00
<i>GIH or ICH</i>														
183-Day Washout Period														
Female	184,911	184,911	625,203	22,312,418	30,145,604	65,700.1	962	29,511,706	45,421,285.1	6.27	120.67	3.38	35.69	4.01
Male	197,886	197,886	688,417	25,889,110	35,852,406	75,842.2	1,004	28,515,886	43,189,751.1	6.94	130.83	3.48	37.61	3.62
Unknown	183	183	350	10,950	15,023	32.1	0	17,216	21,334.0	10.63	59.84	1.91	31.29	0.00
365-Day Washout Period														
Female	156,753	156,753	536,746	18,874,080	25,567,020	55,582.8	827	25,398,852	39,584,224.0	6.17	120.41	3.42	35.16	4.07
Male	163,679	163,679	580,551	21,478,439	29,874,300	62,901.1	865	24,405,684	37,398,660.7	6.71	131.22	3.55	37.00	3.77
Unknown	174	174	329	10,279	14,134	30.1	0	15,644	14,939.4	11.12	59.07	1.89	31.24	0.00

Table 3. Summary of Incident Dabigatran and Warfarin Use among Patients in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, 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	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
Warfarin (Incident with respect to Dabigatran and Warfarin)														
GIH														
183-Day Washout Period														
Female	183,468	183,468	618,761	22,000,815	29,782,645	64,843.8	454	29,506,274	45,408,598.3	6.22	119.92	3.37	35.56	1.92
Male	195,528	195,528	678,658	25,444,166	35,302,027	74,587.8	470	28,505,347	43,161,038.6	6.86	130.13	3.47	37.49	1.73
Unknown	184	184	351	10,962	15,035	32.1	0	17,212	21,333.1	10.69	59.58	1.91	31.23	0.00
365-Day Washout Period														
Female	155,527	155,527	531,299	18,616,076	25,264,398	54,873.9	390	25,393,059	39,572,389.3	6.12	119.70	3.42	35.04	1.95
Male	161,621	161,621	572,088	21,099,014	29,402,667	61,831.6	410	24,394,409	37,371,590.5	6.63	130.55	3.54	36.88	1.82
Unknown	175	175	330	10,291	14,146	30.1	0	15,644	14,938.6	11.19	58.81	1.89	31.18	0.00
ICH														
183-Day Washout Period														
Female	183,137	183,137	616,488	21,929,869	29,694,655	64,683.3	503	29,506,386	45,411,323.0	6.21	119.75	3.37	35.57	2.13
Male	195,181	195,181	676,622	25,372,099	35,198,439	74,415.1	528	28,505,615	43,164,313.5	6.85	129.99	3.47	37.50	1.94
Unknown	183	183	350	10,950	15,023	32.1	0	17,211	21,334.7	10.63	59.84	1.91	31.29	0.00
365-Day Washout Period														
Female	155,227	155,227	529,212	18,551,302	25,182,627	54,730.5	436	25,393,124	39,574,630.3	6.11	119.51	3.41	35.05	2.18
Male	161,340	161,340	570,497	21,042,423	29,320,676	61,701.1	448	24,394,592	37,374,263.8	6.61	130.42	3.54	36.88	1.99
Unknown	174	174	329	10,279	14,134	30.1	0	15,642	14,937.6	11.12	59.07	1.89	31.24	0.00
GIH or ICH														
183-Day Washout Period														
Female	182,673	182,673	614,577	21,867,281	29,611,249	64,391.8	941	29,505,420	45,402,177.9	6.19	119.71	3.36	35.58	4.00
Male	194,602	194,602	674,214	25,292,160	35,098,095	74,074.4	984	28,504,403	43,153,952.6	6.83	129.97	3.46	37.51	3.64
Unknown	183	183	350	10,950	15,023	32.1	0	17,211	21,325.5	10.63	59.84	1.91	31.29	0.00
365-Day Washout Period														
Female	154,822	154,822	527,511	18,495,437	25,108,303	54,469.1	814	25,392,268	39,566,564.9	6.10	119.46	3.41	35.06	4.09
Male	160,820	160,820	568,324	20,970,312	29,230,112	61,397.6	846	24,393,568	37,365,256.0	6.59	130.40	3.53	36.90	3.77
Unknown	174	174	329	10,279	14,134	30.1	0	15,642	14,931.9	11.12	59.07	1.89	31.24	0.00

Table 4. Summary of Incident Dabigatran and Warfarin Use among Patients in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, 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	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
Dabigatran (Incident with respect to Dabigatran)														
<i>GIH</i>														
183-Day Washout Period														
2010	4,153	4,153	26,373	999,741	1,995,115	2,876.1	10	37,378,917	7,168,982.6	0.11	240.73	6.35	37.91	0.95
2011	38,172	38,172	208,186	7,839,339	15,649,074	22,778.2	60	42,532,178	33,822,444.3	0.90	205.37	5.45	37.66	0.72
2012	18,643	18,643	72,333	2,587,818	5,163,276	7,649.1	30	41,514,891	33,155,436.5	0.45	138.81	3.88	35.78	1.07
2013	5,371	5,371	13,775	459,041	913,652	1,372.6	2	34,281,522	15,579,921.4	0.16	85.47	2.56	33.32	0.40
365-Day Washout Period														
2010	3,699	3,699	23,547	898,737	1,793,198	2,583.9	8	30,624,427	6,037,543.5	0.12	242.97	6.37	38.17	0.85
2011	34,931	34,931	192,401	7,280,602	14,532,910	21,140.8	58	34,853,857	29,319,779.9	1.00	208.43	5.51	37.84	0.75
2012	16,982	16,982	67,159	2,409,899	4,810,032	7,113.5	28	36,902,422	28,832,591.3	0.46	141.91	3.95	35.88	1.08
2013	4,986	4,986	12,889	428,630	853,526	1,280.8	2	30,306,646	13,901,203.5	0.16	85.97	2.59	33.26	0.43
<i>ICH</i>														
183-Day Washout Period														
2010	4,136	4,136	26,228	995,018	1,985,698	2,864.2	10	37,380,088	7,169,369.1	0.11	240.57	6.34	37.94	0.96
2011	38,125	38,125	207,580	7,818,209	15,606,594	22,714.7	68	42,532,431	33,824,565.3	0.90	205.07	5.44	37.66	0.82
2012	18,616	18,616	72,265	2,584,507	5,156,667	7,640.6	27	41,515,159	33,157,522.3	0.45	138.83	3.88	35.76	0.97
2013	5,361	5,361	13,739	457,718	911,006	1,369.1	2	34,281,795	15,580,963.4	0.16	85.38	2.56	33.32	0.40
365-Day Washout Period														
2010	3,684	3,684	23,404	894,056	1,783,865	2,573.3	9	30,625,238	6,037,842.1	0.12	242.69	6.35	38.20	0.96
2011	34,889	34,889	191,875	7,261,836	14,495,158	21,085.1	60	34,853,988	29,321,509.1	1.00	208.14	5.50	37.85	0.78
2012	16,962	16,962	67,089	2,406,675	4,803,597	7,105.3	26	36,902,834	28,834,260.5	0.46	141.89	3.96	35.87	1.00
2013	4,976	4,976	12,853	427,307	850,880	1,277.4	2	30,306,779	13,902,086.5	0.16	85.87	2.58	33.25	0.43
<i>GIH or ICH</i>														
183-Day Washout Period														
2010	4,133	4,133	26,205	994,270	1,984,202	2,857.3	19	37,374,622	7,167,739.0	0.11	240.57	6.34	37.94	1.82
2011	38,073	38,073	207,342	7,810,287	15,591,118	22,685.4	127	42,530,995	33,816,590.6	0.90	205.14	5.45	37.67	1.53
2012	18,591	18,591	72,149	2,581,017	5,149,777	7,626.7	56	41,513,810	33,149,389.1	0.45	138.83	3.88	35.77	2.01
2013	5,356	5,356	13,733	457,514	910,598	1,367.8	4	34,280,425	15,576,996.5	0.16	85.42	2.56	33.31	0.80
365-Day Washout Period														
2010	3,681	3,681	23,381	893,308	1,782,369	2,567.2	16	30,620,837	6,036,479.0	0.12	242.68	6.35	38.21	1.71
2011	34,839	34,839	191,637	7,253,888	14,479,630	21,055.8	117	34,852,971	29,314,511.7	1.00	208.21	5.50	37.85	1.52
2012	16,935	16,935	66,970	2,402,998	4,796,333	7,091.0	54	36,901,035	28,827,146.5	0.46	141.90	3.95	35.88	2.08
2013	4,971	4,971	12,847	427,103	850,472	1,276.1	4	30,305,646	13,898,452.0	0.16	85.92	2.58	33.25	0.86

Table 4. Summary of Incident Dabigatran and Warfarin Use among Patients in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, 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	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
Dabigatran (Incident with respect to Dabigatran and Warfarin)														
<i>GIH</i>														
183-Day Washout Period														
2010	1,392	1,392	7,920	282,403	563,810	818.5	3	36,981,727	7,085,742.1	0.04	202.88	5.69	35.66	1.00
2011	20,365	20,365	98,540	3,560,391	7,109,152	10,410.6	22	42,185,609	33,432,293.3	0.48	174.83	4.84	36.13	0.58
2012	14,437	14,437	54,007	1,883,599	3,759,209	5,573.4	24	41,180,622	32,772,622.1	0.35	130.47	3.74	34.88	1.18
2013	4,502	4,502	11,464	378,772	753,442	1,131.5	1	33,961,572	15,402,028.1	0.13	84.13	2.55	33.04	0.24
365-Day Washout Period														
2010	1,125	1,125	6,279	223,585	446,259	648.5	2	30,218,949	5,952,938.9	0.04	198.74	5.58	35.61	0.84
2011	17,332	17,332	84,767	3,080,631	6,151,470	9,000.5	21	34,494,982	28,910,475.5	0.50	177.74	4.89	36.34	0.64
2012	12,453	12,453	47,912	1,673,655	3,341,614	4,941.5	21	36,521,519	28,431,357.4	0.34	134.40	3.85	34.93	1.16
2013	3,955	3,955	10,260	337,573	672,251	1,006.2	1	29,946,176	13,708,801.6	0.13	85.35	2.59	32.90	0.27
<i>ICH</i>														
183-Day Washout Period														
2010	1,385	1,385	7,855	280,507	560,018	810.6	5	36,983,022	7,086,156.4	0.04	202.53	5.67	35.71	1.69
2011	20,337	20,337	98,230	3,549,574	7,087,341	10,379.0	34	42,185,858	33,434,513.1	0.48	174.54	4.83	36.14	0.90
2012	14,423	14,423	53,965	1,881,648	3,755,097	5,568.7	20	41,180,888	32,774,846.0	0.35	130.46	3.74	34.87	0.98
2013	4,497	4,497	11,436	377,786	751,470	1,129.3	1	33,961,843	15,403,119.2	0.13	84.01	2.54	33.03	0.24
365-Day Washout Period														
2010	1,119	1,119	6,215	221,701	442,491	642.5	4	30,219,897	5,953,265.6	0.04	198.12	5.55	35.67	1.70
2011	17,305	17,305	84,514	3,071,432	6,132,895	8,974.0	27	34,495,117	28,912,309.5	0.50	177.49	4.88	36.34	0.82
2012	12,442	12,442	47,861	1,671,533	3,337,160	4,936.3	18	36,521,961	28,433,159.6	0.34	134.35	3.85	34.92	1.00
2013	3,950	3,950	10,232	336,587	670,279	1,004.0	1	29,946,319	13,709,735.4	0.13	85.21	2.59	32.90	0.27
<i>GIH or ICH</i>														
183-Day Washout Period														
2010	1,385	1,385	7,855	280,507	560,018	810.1	7	36,977,997	7,084,676.6	0.04	202.53	5.67	35.71	2.37
2011	20,320	20,320	98,150	3,546,759	7,081,921	10,369.0	56	42,184,425	33,427,237.9	0.48	174.55	4.83	36.14	1.48
2012	14,406	14,406	53,903	1,879,682	3,751,255	5,560.0	43	41,179,496	32,767,407.2	0.35	130.48	3.74	34.87	2.12
2013	4,492	4,492	11,430	377,693	751,284	1,128.4	2	33,960,458	15,399,513.4	0.13	84.08	2.54	33.04	0.49
365-Day Washout Period														
2010	1,119	1,119	6,215	221,701	442,491	642.0	5	30,215,924	5,952,047.1	0.04	198.12	5.55	35.67	2.13
2011	17,292	17,292	84,447	3,069,067	6,128,375	8,965.4	48	34,494,115	28,906,007.0	0.50	177.48	4.88	36.34	1.47
2012	12,426	12,426	47,800	1,669,597	3,333,378	4,927.8	39	36,520,225	28,426,739.0	0.34	134.36	3.85	34.93	2.17
2013	3,945	3,945	10,226	336,494	670,093	1,003.1	2	29,945,208	13,706,480.2	0.13	85.30	2.59	32.91	0.55

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Warfarin (Incident with respect to Warfarin)														
<i>GIH</i>														
183-Day Washout Period														
2010	34,771	34,771	128,942	4,817,715	6,638,438	14,111.0	84	36,981,765	7,085,829.3	0.94	138.56	3.71	37.36	1.63
2011	150,465	150,465	566,432	21,364,320	29,267,728	62,598.6	402	42,182,397	33,435,801.1	3.57	141.99	3.76	37.72	1.76
2012	140,190	140,190	480,378	17,526,145	23,941,526	51,563.6	332	41,129,784	32,749,043.2	3.41	125.02	3.43	36.48	1.76
2013	59,298	59,298	147,031	4,796,491	6,548,765	14,293.7	120	33,883,448	15,375,265.5	1.75	80.89	2.48	32.62	2.30
365-Day Washout Period														
2010	27,029	27,029	103,246	3,786,776	5,255,276	11,083.6	64	30,218,959	5,953,008.6	0.89	140.10	3.82	36.68	1.58
2011	123,100	123,100	474,560	17,625,883	24,267,541	51,620.2	345	34,495,554	28,919,320.0	3.57	143.18	3.86	37.14	1.83
2012	119,023	119,023	414,478	14,929,728	20,442,829	43,927.2	295	36,504,416	28,437,133.0	3.26	125.44	3.48	36.02	1.84
2013	52,980	52,980	133,035	4,274,768	5,824,157	12,742.4	108	29,914,387	13,700,583.7	1.77	80.69	2.51	32.13	2.32
<i>ICH</i>														
183-Day Washout Period														
2010	34,696	34,696	128,512	4,801,063	6,614,670	14,080.9	98	36,983,059	7,086,243.0	0.94	138.38	3.70	37.36	1.91
2011	150,223	150,223	564,585	21,301,356	29,180,190	62,453.4	469	42,182,660	33,438,014.6	3.56	141.80	3.76	37.73	2.06
2012	139,970	139,970	478,798	17,474,958	23,876,246	51,434.6	378	41,130,121	32,751,284.9	3.40	124.85	3.42	36.50	2.01
2013	59,158	59,158	146,560	4,782,544	6,530,391	14,255.6	113	33,883,808	15,376,394.7	1.75	80.84	2.48	32.63	2.17
365-Day Washout Period														
2010	26,976	26,976	102,940	3,774,730	5,237,449	11,064.2	78	30,219,907	5,953,334.9	0.89	139.93	3.82	36.67	1.93
2011	122,887	122,887	473,023	17,574,205	24,196,042	51,504.8	394	34,495,693	28,921,144.7	3.56	143.01	3.85	37.15	2.09
2012	118,830	118,830	413,071	14,884,047	20,384,075	43,815.5	328	36,504,891	28,438,936.6	3.26	125.25	3.48	36.03	2.05
2013	52,854	52,854	132,599	4,261,356	5,806,367	12,708.0	104	29,914,578	13,701,537.1	1.77	80.63	2.51	32.14	2.24
<i>GIH or ICH</i>														
183-Day Washout Period														
2010	34,615	34,615	128,149	4,789,759	6,600,569	14,018.3	180	36,978,034	7,084,763.3	0.94	138.37	3.70	37.38	3.52
2011	149,812	149,812	562,693	21,236,572	29,098,842	62,156.0	854	42,181,261	33,430,748.5	3.55	141.75	3.76	37.74	3.76
2012	139,578	139,578	477,126	17,420,117	23,805,383	51,206.6	702	41,128,919	32,743,967.6	3.39	124.81	3.42	36.51	3.75
2013	58,975	58,975	146,002	4,766,030	6,508,238	14,193.5	230	33,882,672	15,372,890.9	1.74	80.81	2.48	32.64	4.44
365-Day Washout Period														
2010	26,905	26,905	102,622	3,764,762	5,224,685	11,009.9	141	30,215,934	5,952,116.4	0.89	139.93	3.81	36.69	3.51
2011	122,536	122,536	471,339	17,516,507	24,123,498	51,242.6	727	34,494,699	28,914,833.9	3.55	142.95	3.85	37.16	3.88
2012	118,479	118,479	411,574	14,835,112	20,320,739	43,611.0	615	36,503,251	28,432,544.0	3.25	125.21	3.47	36.04	3.86
2013	52,686	52,686	132,091	4,246,417	5,786,532	12,650.5	209	29,913,608	13,698,329.7	1.76	80.60	2.51	32.15	4.52

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Warfarin (Incident with respect to Dabigatran and Warfarin)														
<i>GIH</i>														
183-Day Washout Period														
2010	34,744	34,744	128,356	4,781,077	6,593,017	13,993.5	84	36,981,727	7,085,742.1	0.94	137.61	3.69	37.25	1.64
2011	148,758	148,758	557,342	20,954,044	28,760,686	61,373.7	396	42,171,678	33,423,411.0	3.53	140.86	3.75	37.60	1.77
2012	137,259	137,259	467,615	17,017,600	23,314,047	50,078.9	325	41,104,144	32,719,814.0	3.34	123.98	3.41	36.39	1.78
2013	58,419	58,419	144,457	4,703,222	6,431,957	14,017.7	119	33,859,648	15,362,002.9	1.73	80.51	2.47	32.56	2.32
365-Day Washout Period														
2010	27,004	27,004	102,749	3,756,538	5,217,626	10,986.5	64	30,218,949	5,952,938.9	0.89	139.11	3.80	36.56	1.59
2011	121,857	121,857	467,551	17,310,003	23,874,455	50,675.3	341	34,491,268	28,910,227.3	3.53	142.05	3.84	37.02	1.84
2012	116,480	116,480	403,187	14,485,029	19,891,119	42,630.6	288	36,475,913	28,410,032.9	3.19	124.36	3.46	35.93	1.85
2013	51,982	51,982	130,230	4,173,811	5,698,011	12,443.2	107	29,886,170	13,685,719.3	1.74	80.29	2.51	32.05	2.35
<i>ICH</i>														
183-Day Washout Period														
2010	34,669	34,669	127,941	4,765,136	6,569,992	13,965.8	96	36,983,022	7,086,156.4	0.94	137.45	3.69	37.24	1.88
2011	148,515	148,515	555,478	20,891,057	28,674,789	61,228.9	459	42,171,938	33,425,632.7	3.52	140.67	3.74	37.61	2.05
2012	137,039	137,039	466,059	16,967,470	23,249,907	49,956.0	366	41,104,468	32,722,056.3	3.33	123.81	3.40	36.41	2.01
2013	58,278	58,278	143,982	4,689,255	6,413,428	13,979.8	110	33,860,005	15,363,125.9	1.72	80.46	2.47	32.57	2.15
365-Day Washout Period														
2010	26,951	26,951	102,458	3,745,203	5,200,542	10,969.5	76	30,219,897	5,953,265.6	0.89	138.96	3.80	36.55	1.90
2011	121,647	121,647	465,976	17,257,956	23,803,382	50,558.8	389	34,491,402	28,912,061.4	3.53	141.87	3.83	37.04	2.11
2012	116,289	116,289	401,815	14,440,551	19,833,636	42,524.0	319	36,476,383	28,411,837.3	3.19	124.18	3.46	35.94	2.05
2013	51,854	51,854	129,789	4,160,294	5,679,876	12,409.3	100	29,886,357	13,686,667.5	1.74	80.23	2.50	32.05	2.21
<i>GIH or ICH</i>														
183-Day Washout Period														
2010	34,588	34,588	127,581	4,753,975	6,556,112	13,903.7	178	36,977,997	7,084,676.6	0.94	137.45	3.69	37.26	3.51
2011	148,116	148,116	553,684	20,829,155	28,595,902	60,940.9	838	42,170,539	33,418,379.1	3.51	140.63	3.74	37.62	3.76
2012	136,654	136,654	464,438	16,914,088	23,180,516	49,734.7	683	41,103,260	32,714,765.7	3.32	123.77	3.40	36.42	3.76
2013	58,100	58,100	143,438	4,673,173	6,391,836	13,919.0	226	33,858,859	15,359,634.7	1.72	80.43	2.47	32.58	4.45
365-Day Washout Period														
2010	26,880	26,880	102,143	3,735,378	5,188,000	10,915.8	139	30,215,924	5,952,047.1	0.89	138.96	3.80	36.57	3.49
2011	121,301	121,301	464,371	17,202,113	23,732,272	50,302.5	718	34,490,407	28,905,759.4	3.52	141.81	3.83	37.04	3.91
2012	115,942	115,942	400,350	14,392,567	19,771,386	42,325.0	599	36,474,748	28,405,471.2	3.18	124.14	3.45	35.95	3.87
2013	51,693	51,693	129,300	4,145,970	5,660,891	12,353.6	204	29,885,380	13,683,475.1	1.73	80.20	2.50	32.06	4.52

Appendix A: Codes Used to Define Exposures in this Report

Event	Description	Code
ICH	Intracerebral hemorrhage	431*
GIH	Acute gastric ulcer with hemorrhage	531.0
GIH	Acute gastric ulcer with hemorrhage and perforation	531.2
GIH	Chronic or unspecified gastric ulcer with hemorrhage	531.4
GIH	Chronic or unspecified gastric ulcer with hemorrhage and perforation	531.6
GIH	Acute duodenal ulcer with hemorrhage	532.0
GIH	Acute duodenal ulcer with hemorrhage and perforation	532.2
GIH	Chronic or unspecified duodenal ulcer with hemorrhage	532.4
GIH	Chronic or unspecified duodenal ulcer with hemorrhage and perforation	532.6
GIH	Acute peptic ulcer of unspecified site with hemorrhage	533.0
GIH	Acute peptic ulcer of unspecified site with hemorrhage and perforation	533.2
GIH	Chronic or unspecified peptic ulcer of unspecified site with hemorrhage	533.4
GIH	Chronic or unspecified peptic ulcer of unspecified site with hemorrhage and perforation	533.6
GIH	Acute gastrojejunal ulcer with hemorrhage	534.0
GIH	Acute gastrojejunal ulcer with hemorrhage and perforation	534.2
GIH	Chronic or unspecified gastrojejunal ulcer with hemorrhage	534.4
GIH	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation	534.6
GIH	Hematemesis	578.0
Afib	Atrial Fibrillation	427.31