



Modular Program Report

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 (MP) #1 (version2.1) to investigate prevalent and new use of dabigatran, rivaroxaban, and warfarin among all members. The query was run against the Mini-Sentinel Distributed Database for the time period 10/19/2010 to 12/31/2011 (query period). The package was distributed to Data Partners on June 5, 2012.

Results provide counts of prevalent and new dabigatran, rivaroxaban, and warfarin users, dispensings, total days supplied, eligible members (denominator), and member days. Prevalent users are members with at least one day of enrollment and one or more dispensings of the drug during the query period. A new user was defined in two ways (both with two washout periods): 1) as a member with use of the drug of interest during the query period and **no prior use of the same drug** during the previous 183 or 365 days and 2) as a member with use of the drug of interest during the query period and **no prior use of any of the three drugs** during the previous 183 or 365 days. The query period was October 19, 2010 to December 31, 2011.

Request MSY3_MPR31

Request ID msy3_mpr31 - Dabigatran/Rivaroxaban/Warfarin

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<u>Notes:</u>	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 Query ID MPR31 Part 1

Modular Program (MP) #1 (version2.1) was used to investigate prevalent and new use of dabigatran, rivaroxaban, and warfarin among all members. The query period was from October 19, 2010 to December 31, 2011, and was run against the Mini-Sentinel Distributed Database. Results of MP #1 provide counts of prevalent and new dabigatran, rivaroxaban, and warfarin users, dispensings, total days supplied, eligible members (denominator), and member days. Prevalent users are members with at least one day of enrollment and one or more dispensings of the drug during the query period. A new user was defined in two ways (both with two washout periods): 1) as a member with use of the drug of interest during the query period and no prior use of the same drug during the previous 183 or 365 days and 2) as a member with use of the drug of interest during the query period and no prior use of any of the three drugs during the previous 183 or 365 days. Age groups were split as follows: 0-40, 41-54, 55-64, 65-74, 75-84, and 85+ years. In total, 12 different scenarios were examined in this report with differing exposures of interest, incidence criteria, and washout period. See below for a description of each of these scenarios.

Drug/Exposure Criteria

Scenario	Prevalent/Incident exposure	Incident w/ respect to (incidence criteria):	Washout (days)	Washout type*
1	Dabigatran	Dabigatran	183	MULT
2	Dabigatran	Dabigatran, Rivaroxaban, Warfarin	183	MULT
3	Rivaroxaban	Rivaroxaban	183	MULT
4	Rivaroxaban	Dabigatran, Rivaroxaban, Warfarin	183	MULT
5	Warfarin	Warfarin	183	MULT
6	Warfarin	Dabigatran, Rivaroxaban, Warfarin	183	MULT
7	Dabigatran	Dabigatran	365	MULT
8	Dabigatran	Dabigatran, Rivaroxaban, Warfarin	365	MULT
9	Rivaroxaban	Rivaroxaban	365	MULT
10	Rivaroxaban	Dabigatran, Rivaroxaban, Warfarin	365	MULT
11	Warfarin	Warfarin	365	MULT
12	Warfarin	Dabigatran, Rivaroxaban, Warfarin	365	MULT

*A Multiple washout type for the exposure will consider all dispensings for each member that meet the 183 washout period. There can be more than one incident dispensing per member. The enrollment requirement is based on the number of days in the washout.

**Modular Program 1 will consider those members with at least drug coverage.

Glossary of Terms in Modular Program 1*

Eligible Members (incidence-based cohort) - Number of members eligible for incident exposure (defined by the washout period) with drug and medical coverage during the query period.

Eligible Members (prevalence-based cohort) - Number of members with at least one day of drug and medical

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

Member-Days (incidence-based cohort) - Sum of all days of enrollment with medical and drug coverage** in the query period preceded by an exposure washout period.

Member-Days (prevalence-based cohort) - Sum of all days members are enrolled with drug and medical

New Starts- Number of incident exposures during the query period. User must have no prior exposures in the washout period. For a minimum washout type, an individual may have no more than one new start. For a multiple washout type, an individual may have more than one new start.

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

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

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.

*all terms may not be used in this report

**in cases where only NDCs are used to identify exposure, only drug coverage is required

Table 1. Summary of Prevalent Users in MSDD between October 19, 2010 and December 31, 2011, by Drug Product

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Dabigatran	46,965	169,764	6,190,497	44,583,126	13,503,424,710	1.05	131.81	3.61	36.47
Rivaroxaban	1,327	1,377	23,289	44,583,126	13,503,424,710	0.03	17.55	1.04	16.91
Warfarin	687,709	3,709,999	154,013,262	44,583,126	13,503,424,710	15.43	223.95	5.39	41.51

Table 2. Summary of Prevalent Users in MSDD between October 19, 2010 and December 31, 2011, by Drug Product and Age Group

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Dabigatran									
0 to 40 years	442	1,278	41,245	23,017,901	6,547,737,317	0.02	93.31	2.89	32.27
41 to 54 years	2,871	9,141	308,822	9,574,824	2,820,973,128	0.30	107.57	3.18	33.78
55 to 64 years	7,211	25,322	904,059	5,915,924	1,707,633,880	1.22	125.37	3.51	35.70
65 to 74 years	15,340	53,600	2,009,051	4,598,759	1,357,414,054	3.34	130.97	3.49	37.48
75 to 84 years	16,002	57,648	2,127,446	2,454,829	762,567,819	6.52	132.95	3.60	36.90
85+ years	6,223	22,775	799,874	1,011,614	307,098,512	6.15	128.54	3.66	35.12
Rivaroxaban									
0 to 40 years	34	36	730	23,017,901	6,547,737,317	0.00	21.47	1.06	20.28
41 to 54 years	200	211	3,653	9,574,824	2,820,973,128	0.02	18.27	1.06	17.31
55 to 64 years	331	345	5,886	5,915,924	1,707,633,880	0.06	17.78	1.04	17.06
65 to 74 years	509	520	8,597	4,598,759	1,357,414,054	0.11	16.89	1.02	16.53
75 to 84 years	218	226	3,709	2,454,829	762,567,819	0.09	17.01	1.04	16.41
85+ years	35	39	714	1,011,614	307,098,512	0.03	20.40	1.11	18.31
Warfarin									
0 to 40 years	20,193	95,662	3,357,213	23,017,901	6,547,737,317	0.88	166.26	4.74	35.09
41 to 54 years	63,068	302,583	11,229,468	9,574,824	2,820,973,128	6.59	178.05	4.80	37.11
55 to 64 years	104,760	485,185	19,473,678	5,915,924	1,707,633,880	17.71	185.89	4.63	40.14
65 to 74 years	204,178	974,970	44,222,392	4,598,759	1,357,414,054	44.40	216.59	4.78	45.36
75 to 84 years	222,076	1,188,823	51,358,615	2,454,829	762,567,819	90.46	231.27	5.35	43.20
85+ years	102,954	662,776	24,371,896	1,011,614	307,098,512	101.77	236.73	6.44	36.77

Table 3. Summary of Prevalent Users in MSDD between October 19, 2010 and December 31, 2011, by Drug Product and Sex

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Dabigatran									
Female	20,611	75,596	2,690,791	23,113,910	7,008,352,900	0.89	130.55	3.67	35.59
Male	26,347	94,142	3,498,926	21,406,683	6,474,461,316	1.23	132.80	3.57	37.17
Unknown	7	26	780	62,533	20,610,494	0.11	111.43	3.71	30.00
Rivaroxaban									
Female	812	839	13,415	23,113,910	7,008,352,900	0.04	16.52	1.03	15.99
Male	515	538	9,874	21,406,683	6,474,461,316	0.02	19.17	1.04	18.35
Unknown	0	0	0	62,533	20,610,494	0.00	---	---	---
Warfarin									
Female	335,147	1,891,010	74,859,734	23,113,910	7,008,352,900	14.50	223.36	5.64	39.59
Male	352,354	1,818,031	79,116,372	21,406,683	6,474,461,316	16.46	224.54	5.16	43.52
Unknown	208	958	37,156	62,533	20,610,494	3.33	178.63	4.61	38.78

Table 4. Summary of Prevalent Users in MSDD between October 19, 2010 and December 31, 2011, by Drug Product and Year

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Dabigatran									
2010	4,728	5,918	215,334	35,660,008	2,552,322,867	0.13	45.54	1.25	36.39
2011	45,768	163,846	5,975,163	38,869,062	10,951,101,843	1.18	130.55	3.58	36.47
Rivaroxaban									
2010	0	0	0	35,660,008	2,552,322,867	---	---	---	---
2011	1,327	1,377	23,289	38,869,062	10,951,101,843	0.03	17.55	1.04	16.91
Warfarin									
2010	399,955	742,678	29,645,867	35,660,008	2,552,322,867	11.22	74.12	1.86	39.92
2011	609,347	2,967,321	124,367,395	38,869,062	10,951,101,843	15.68	204.10	4.87	41.91

Table 5. Summary of Incident Users in MSDD between October 19, 2010 and December 31, 2011, by Drug Product

	Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Dabigatran										
<i>With Respect to Dabigatran</i>										
183-Day Washout	39,955	40,120	143,428	5,242,599	39,398,724	11,655,338,038	1.01	131.21	3.59	36.55
365-Day Washout	36,448	36,451	133,993	4,902,353	32,468,319	10,168,693,349	1.12	134.50	3.68	36.59
<i>With Respect to Dabigatran, Rivaroxaban, and Warfarin</i>										
183-Day Washout	19,865	19,929	63,737	2,272,784	38,973,382	11,475,627,810	0.51	114.41	3.21	35.66
365-Day Washout	16,484	16,485	54,329	1,928,596	32,018,543	9,979,289,472	0.51	117.00	3.30	35.50
Rivaroxaban										
<i>With Respect to Dabigatran</i>										
183-Day Washout	1,238	1,238	1,285	21,865	39,403,258	11,662,677,780	0.03	17.66	1.04	17.02
365-Day Washout	985	985	1,024	17,755	32,469,663	10,175,606,938	0.03	18.03	1.04	17.34
<i>With Respect to Dabigatran, Rivaroxaban, and Warfarin</i>										
183-Day Washout	1,151	1,151	1,190	19,598	38,973,382	11,475,627,810	0.03	17.03	1.03	16.47
365-Day Washout	905	905	935	15,597	32,018,543	9,979,289,472	0.03	17.23	1.03	16.68
Warfarin										
<i>With Respect to Dabigatran</i>										
183-Day Washout	198,252	202,661	673,887	26,556,362	38,986,528	11,480,352,077	5.09	133.95	3.40	39.41
365-Day Washout	138,780	138,798	498,682	17,559,789	32,022,380	9,982,245,996	4.33	126.53	3.59	35.21
<i>With Respect to Dabigatran, Rivaroxaban, and Warfarin</i>										
183-Day Washout	196,371	200,713	668,464	26,341,607	38,973,382	11,475,627,810	5.04	134.14	3.40	39.41
365-Day Washout	137,588	137,606	494,814	17,418,382	32,018,543	9,979,289,472	4.30	126.60	3.60	35.20

Table 6. Summary of Incident Users in MSDD between October 19, 2010 and December 31, 2011, by Drug Product and Age Group

	Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Dabigatran										
<i>With Respect to Dabigatran</i>										
183-Day Washout										
0 to 40 years	350	351	1,040	33,985	19,755,213	5,495,322,399	0.02	97.10	2.97	32.68
41 to 54 years	2,315	2,322	7,280	244,993	8,580,093	2,485,804,951	0.27	105.83	3.14	33.65
55 to 64 years	5,972	5,997	21,219	758,308	5,249,169	1,535,293,095	1.14	126.98	3.55	35.74
65 to 74 years	12,402	12,449	42,930	1,617,385	4,118,252	1,157,906,819	3.01	130.41	3.46	37.67
75 to 84 years	13,652	13,702	48,818	1,809,167	2,337,883	696,862,455	5.84	132.52	3.58	37.06
85+ years	5,279	5,299	19,564	684,249	951,293	284,148,319	5.55	129.62	3.71	34.97
365-Day Washout										
0 to 40 years	292	293	867	28,400	15,968,508	4,646,997,151	0.02	97.26	2.97	32.76
41 to 54 years	2,015	2,015	6,400	215,956	7,279,999	2,201,516,635	0.28	107.17	3.18	33.74
55 to 64 years	5,359	5,359	19,342	692,353	4,565,104	1,388,330,020	1.17	129.19	3.61	35.80
65 to 74 years	11,008	11,008	39,321	1,485,129	3,229,279	1,014,698,317	3.41	134.91	3.57	37.77
75 to 84 years	12,768	12,769	46,712	1,730,079	2,012,131	648,230,432	6.35	135.50	3.66	37.04
85+ years	5,007	5,007	18,881	660,124	845,914	268,920,794	5.92	131.84	3.77	34.96
<i>With Respect to Dabigatran, Rivaroxaban, and Warfarin</i>										
183-Day Washout										
0 to 40 years	229	229	594	18,800	19,744,842	5,491,098,834	0.01	82.10	2.59	31.65
41 to 54 years	1,390	1,396	3,823	126,040	8,544,778	2,471,534,474	0.16	90.68	2.75	32.97
55 to 64 years	3,164	3,173	9,968	346,708	5,187,630	1,510,524,554	0.61	109.58	3.15	34.78
65 to 74 years	6,285	6,302	19,607	718,167	3,988,385	1,108,600,319	1.58	114.27	3.12	36.63
75 to 84 years	6,407	6,426	20,845	755,929	2,184,033	637,623,805	2.93	117.98	3.25	36.26
85+ years	2,396	2,403	7,924	271,350	875,764	256,245,824	2.74	113.25	3.31	34.24
365-Day Washout										
0 to 40 years	181	181	461	14,780	15,956,933	4,642,438,005	0.01	81.66	2.55	32.06
41 to 54 years	1,133	1,133	3,074	101,218	7,241,470	2,185,971,841	0.16	89.34	2.71	32.93
55 to 64 years	2,574	2,574	8,298	287,363	4,496,859	1,361,244,686	0.57	111.64	3.22	34.63
65 to 74 years	5,033	5,033	16,358	597,659	3,098,580	963,821,174	1.62	118.75	3.25	36.54
75 to 84 years	5,468	5,468	18,263	658,188	1,848,624	586,388,788	2.96	120.37	3.34	36.04
85+ years	2,096	2,096	7,030	238,998	763,420	239,424,978	2.75	114.03	3.35	34.00

Table 6. Summary of Incident Users in MSDD between October 19, 2010 and December 31, 2011, by Drug Product and Age Group

	Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Rivaroxaban										
<i>With Respect to Dabigatran</i>										
183-Day Washout										
0 to 40 years	30	30	32	626	19,755,254	5,495,386,787	0.00	20.87	1.07	19.56
41 to 54 years	178	178	189	3,288	8,580,411	2,486,233,225	0.02	18.47	1.06	17.40
55 to 64 years	305	305	318	5,454	5,249,972	1,536,446,443	0.06	17.88	1.04	17.15
65 to 74 years	478	478	488	8,145	4,120,367	1,160,141,080	0.12	17.04	1.02	16.69
75 to 84 years	214	214	222	3,672	2,339,796	699,347,129	0.09	17.16	1.04	16.54
85+ years	33	33	36	680	952,134	285,123,116	0.03	20.61	1.09	18.89
365-Day Washout										
0 to 40 years	26	26	28	534	15,968,552	4,647,056,836	0.00	20.54	1.08	19.07
41 to 54 years	140	140	147	2,645	7,280,248	2,201,916,070	0.02	18.89	1.05	17.99
55 to 64 years	246	246	257	4,448	4,565,650	1,389,421,969	0.05	18.08	1.04	17.31
65 to 74 years	362	362	371	6,372	3,230,054	1,016,712,111	0.11	17.60	1.02	17.18
75 to 84 years	182	182	189	3,155	2,012,978	650,617,003	0.09	17.34	1.04	16.69
85+ years	29	29	32	601	846,428	269,882,949	0.03	20.72	1.10	18.78
<i>With Respect to Dabigatran, Rivaroxaban, and Warfarin</i>										
183-Day Washout										
0 to 40 years	28	28	30	590	19,744,842	5,491,098,834	0.00	21.07	1.07	19.67
41 to 54 years	165	165	175	2,922	8,544,778	2,471,534,474	0.02	17.71	1.06	16.70
55 to 64 years	288	288	301	5,058	5,187,630	1,510,524,554	0.06	17.56	1.05	16.80
65 to 74 years	449	449	457	7,425	3,988,385	1,108,600,319	0.11	16.54	1.02	16.25
75 to 84 years	194	194	198	3,101	2,184,033	637,623,805	0.09	15.98	1.02	15.66
85+ years	27	27	29	502	875,764	256,245,824	0.03	18.59	1.07	17.31
365-Day Washout										
0 to 40 years	24	24	26	498	15,956,933	4,642,438,005	0.00	20.75	1.08	19.15
41 to 54 years	129	129	134	2,309	7,241,470	2,185,971,841	0.02	17.90	1.04	17.23
55 to 64 years	230	230	241	4,085	4,496,859	1,361,244,686	0.05	17.76	1.05	16.95
65 to 74 years	340	340	347	5,766	3,098,580	963,821,174	0.11	16.96	1.02	16.62
75 to 84 years	158	158	161	2,486	1,848,624	586,388,788	0.09	15.73	1.02	15.44
85+ years	24	24	26	453	763,420	239,424,978	0.03	18.88	1.08	17.42

Table 6. Summary of Incident Users in MSDD between October 19, 2010 and December 31, 2011, by Drug Product and Age Group

	Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Warfarin										
With Respect to Dabigatran										
183-Day Washout										
0 to 40 years	6,847	6,919	24,658	823,414	19,744,925	5,491,149,245	0.35	120.26	3.60	33.39
41 to 54 years	20,316	20,540	66,323	2,296,516	8,545,456	2,471,849,711	2.38	113.04	3.26	34.63
55 to 64 years	33,330	33,900	100,912	3,713,972	5,189,662	1,511,317,529	6.42	111.43	3.03	36.80
65 to 74 years	58,163	59,394	181,066	7,590,271	3,992,961	1,110,061,115	14.57	130.50	3.11	41.92
75 to 84 years	57,659	59,151	197,840	8,274,678	2,188,873	639,147,379	26.34	143.51	3.43	41.83
85+ years	22,200	22,757	91,829	3,376,962	877,812	256,827,098	25.29	152.12	4.14	36.77
365-Day Washout										
0 to 40 years	4,987	4,987	18,383	600,080	15,956,982	4,642,475,432	0.31	120.33	3.69	32.64
41 to 54 years	15,339	15,341	50,844	1,679,708	7,241,799	2,186,197,612	2.12	109.51	3.31	33.04
55 to 64 years	24,717	24,720	75,733	2,568,220	4,497,734	1,361,766,968	5.50	103.91	3.06	33.91
65 to 74 years	39,652	39,658	130,375	4,841,179	3,099,857	964,694,250	12.79	122.09	3.29	37.13
75 to 84 years	39,101	39,105	145,890	5,327,265	1,850,030	587,320,361	21.14	136.24	3.73	36.52
85+ years	14,985	14,987	68,972	2,212,273	764,020	239,791,373	19.61	147.63	4.60	32.07
With Respect to Dabigatran, Rivaroxaban, and Warfarin										
183-Day Washout										
0 to 40 years	6,836	6,908	24,624	822,061	19,744,842	5,491,098,834	0.35	120.25	3.60	33.38
41 to 54 years	20,241	20,464	66,096	2,289,524	8,544,778	2,471,534,474	2.37	113.11	3.27	34.64
55 to 64 years	33,122	33,688	100,369	3,694,143	5,187,630	1,510,524,554	6.38	111.53	3.03	36.81
65 to 74 years	57,598	58,807	179,406	7,522,241	3,988,385	1,108,600,319	14.44	130.60	3.11	41.93
75 to 84 years	56,900	58,368	195,686	8,188,475	2,184,033	637,623,805	26.05	143.91	3.44	41.84
85+ years	21,931	22,478	91,088	3,346,998	875,764	256,245,824	25.04	152.61	4.15	36.74
365-Day Washout										
0 to 40 years	4,981	4,981	18,361	599,304	15,956,933	4,642,438,005	0.31	120.32	3.69	32.64
41 to 54 years	15,277	15,279	50,653	1,673,781	7,241,470	2,185,971,841	2.11	109.56	3.32	33.04
55 to 64 years	24,585	24,588	75,359	2,555,586	4,496,859	1,361,244,686	5.47	103.95	3.07	33.91
65 to 74 years	39,297	39,303	129,226	4,796,760	3,098,580	963,821,174	12.68	122.06	3.29	37.12
75 to 84 years	38,620	38,624	144,340	5,270,711	1,848,624	586,388,788	20.89	136.48	3.74	36.52
85+ years	14,829	14,831	68,464	2,193,940	763,420	239,424,978	19.42	147.95	4.62	32.05

Table 7. Summary of Incident Users in MSDD between October 19, 2010 and December 31, 2011, by Drug Product and Sex

	Users	New Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Dabigatran										
<i>With Respect to Dabigatran</i>										
183-Day Washout										
Female	17,630	17,695	64,317	2,295,075	20,494,163	6,064,942,455	0.86	130.18	3.65	35.68
Male	22,318	22,418	79,085	2,946,744	18,848,123	5,572,411,143	1.18	132.03	3.54	37.26
Unknown	7	7	26	780	56,438	17,984,440	0.12	0.03	3.71	30.00
365-Day Washout										
Female	16,199	16,200	60,543	2,161,542	16,934,394	5,305,710,410	0.96	133.44	3.74	35.70
Male	20,242	20,244	73,424	2,740,031	15,485,580	4,847,358,475	1.31	135.36	3.63	37.32
Unknown	7	7	26	780	48,345	15,624,464	0.14	111.43	3.71	30.00
<i>With Respect to Dabigatran, Rivaroxaban, and Warfarin</i>										
183-Day Washout										
Female	8,328	8,352	27,185	949,729	20,290,592	5,977,840,721	0.41	114.04	3.26	34.94
Male	11,533	11,573	36,539	1,322,665	18,626,455	5,479,863,652	0.62	114.69	3.17	36.20
Unknown	4	4	13	390	56,335	17,923,437	0.07	97.50	3.25	30.00
365-Day Washout										
Female	6,994	6,994	23,466	814,377	16,718,385	5,212,868,437	0.42	116.44	3.36	34.70
Male	9,486	9,487	30,850	1,113,829	15,251,970	4,750,866,895	0.62	117.42	3.25	36.10
Unknown	4	4	13	390	48,188	15,554,140	0.08	97.50	3.25	30.00
Rivaroxaban										
<i>With Respect to Dabigatran</i>										
183-Day Washout										
Female	765	765	792	12,687	20,496,081	6,068,083,264	0.04	16.58	1.04	16.02
Male	473	473	493	9,178	18,850,739	5,576,608,529	0.03	19.40	1.04	18.62
Unknown	0	0	0	0	56,438	17,985,987	0.00	---	---	---
365-Day Washout										
Female	608	608	628	10,174	16,934,842	5,308,682,645	0.04	16.73	1.03	16.20
Male	377	377	396	7,581	15,486,476	4,851,298,164	0.02	20.11	1.05	19.14
Unknown	0	0	0	0	48,345	15,626,129	0.00	---	---	---

Table 7. Summary of Incident Users in MSDD between October 19, 2010 and December 31, 2011, by Drug Product and Sex

	Users	New Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Rivaroxaban										
<i>With Respect to Dabigatran, Rivaroxaban, and Warfarin</i>										
183-Day Washout										
Female	723	723	747	11,762	20,290,592	5,977,840,721	0.04	16.27	1.03	15.75
Male	428	428	443	7,836	18,626,455	5,479,863,652	0.02	18.31	1.04	17.69
Unknown	0	0	0	0	56,335	17,923,437	0.00	---	---	---
365-Day Washout										
Female	568	568	584	9,226	16,718,385	5,212,868,437	0.03	16.24	1.03	15.80
Male	337	337	351	6,371	15,251,970	4,750,866,895	0.02	18.91	1.04	18.15
Unknown	0	0	0	0	48,188	15,554,140	0.00	---	---	---
Warfarin										
<i>With Respect to Dabigatran</i>										
183-Day Washout										
Female	100,386	102,438	347,299	13,046,048	20,296,307	5,979,781,294	4.95	129.96	3.46	37.56
Male	97,804	100,161	326,421	13,503,392	18,633,884	5,482,646,317	5.25	138.07	3.34	41.37
Unknown	62	62	167	6,922	56,337	17,924,466	1.10	111.65	2.69	41.45
365-Day Washout										
Female	72,612	72,625	263,051	8,910,909	16,719,798	5,214,060,661	4.34	122.72	3.62	33.88
Male	66,125	66,130	235,504	8,644,913	15,254,394	4,752,630,189	4.33	130.74	3.56	36.71
Unknown	43	43	127	3,967	48,188	15,555,146	0.89	92.26	2.95	31.24
<i>With Respect to Dabigatran, Rivaroxaban, and Warfarin</i>										
183-Day Washout										
Female	99,492	101,504	344,645	12,944,718	20,290,592	5,977,840,721	4.90	130.11	3.46	37.56
Male	96,817	99,147	323,652	13,389,967	18,626,455	5,479,863,652	5.20	138.30	3.34	41.37
Unknown	62	62	167	6,922	56,335	17,923,437	1.10	111.65	2.69	41.45
365-Day Washout										
Female	72,042	72,055	261,127	8,844,262	16,718,385	5,212,868,437	4.31	122.77	3.62	33.87
Male	65,503	65,508	233,560	8,570,153	15,251,970	4,750,866,895	4.29	130.84	3.57	36.69
Unknown	43	43	127	3,967	48,188	15,554,140	0.89	92.26	2.95	31.24

Table 8. Summary of Incident Users in MSDD between October 19, 2010 and December 31, 2011, by Drug Product and Year

	Users	New Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Dabigatran										
<i>With Respect to Dabigatran</i>										
183-Day Washout										
2010	4,548	4,548	5,689	207,248	32,193,549	2,240,019,674	0.14	45.57	1.25	36.43
2011	35,480	35,572	117,945	4,315,249	34,369,550	9,415,318,364	1.03	121.62	3.32	36.59
365-Day Washout										
2010	4,145	4,145	5,185	189,092	26,969,011	1,921,060,102	0.15	45.62	1.25	36.47
2011	32,306	32,306	110,440	4,045,551	28,377,390	8,247,633,247	1.14	125.23	3.42	36.63
<i>With Respect to Dabigatran, Rivaroxaban, and Warfarin</i>										
183-Day Washout										
2010	1,555	1,555	1,919	66,773	31,738,582	2,204,681,363	0.049	42.941	1.234	34.796
2011	18,333	18,374	55,793	1,987,228	33,973,696	9,270,946,447	0.540	108.396	3.043	35.618
365-Day Washout										
2010	1,267	1,267	1,565	53,961	26,482,077	1,884,112,057	0.048	42.590	1.235	34.480
2011	15,218	15,218	47,810	1,695,119	27,958,094	8,095,177,415	0.544	111.389	3.142	35.455
Rivaroxaban										
<i>With Respect to Dabigatran</i>										
183-Day Washout										
2010	0	0	0	0	32,193,577	2,240,128,637	0.00	---	---	---
2011	1,238	1,238	1,285	21,865	34,376,974	9,422,549,143	0.04	17.66	1.04	17.02
365-Day Washout										
2010	0	0	0	0	26,969,016	1,921,159,283	0.00	---	---	---
2011	985	985	1,024	17,755	28,382,412	8,254,447,655	0.03	18.03	1.04	17.34
<i>With Respect to Dabigatran, Rivaroxaban, and Warfarin</i>										
183-Day Washout										
2010	0	0	0	0	31,738,582	2,204,681,363	0.000	---	---	---
2011	1,151	1,151	1,190	19,598	33,973,696	9,270,946,447	0.034	17.027	1.034	16.469
365-Day Washout										
2010	0	0	0	0	26,482,077	1,884,112,057	0.000	---	---	---
2011	905	905	935	15,597	27,958,094	8,095,177,415	0.032	17.234	1.033	16.681

Table 8. Summary of Incident Users in MSDD between October 19, 2010 and December 31, 2011, by Drug Product and Year

	Users	New Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Warfarin										
<i>With Respect to Dabigatran</i>										
183-Day Washout										
2010	44,848	44,848	73,627	2,692,841	31,738,632	2,204,716,781	1.41	60.04	1.64	36.57
2011	155,744	157,813	475,818	18,753,971	33,988,645	9,275,635,296	4.58	120.42	3.06	39.41
365-Day Washout										
2010	30,788	30,788	53,628	1,705,383	26,482,092	1,884,140,515	1.16	55.39	1.74	31.80
2011	108,010	108,010	353,625	12,403,914	27,963,153	8,098,105,481	3.86	114.84	3.27	35.08
<i>With Respect to Dabigatran, Rivaroxaban, and Warfarin</i>										
183-Day Washout										
2010	44,816	44,816	73,583	2,691,020	31,738,582	2,204,681,363	1.412	60.046	1.642	36.571
2011	153,853	155,897	470,472	18,541,700	33,973,696	9,270,946,447	4.529	120.516	3.058	39.411
365-Day Washout										
2010	30,761	30,761	53,589	1,703,892	26,482,077	1,884,112,057	1.162	55.391	1.742	31.796
2011	106,845	106,845	349,929	12,269,613	27,958,094	8,095,177,415	3.822	114.836	3.275	35.063