



## 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	
<b><u>Request Description</u></b>	Mini-Sentinel's National Death Index (NDI) Workgroup requested execution of Modular Program #3 (MP3) to produce sample size estimates of anti-arrhythmic drug product use among members with different pre-existing condition inclusions/exclusions in the Mini-Sentinel Distributed Database (MSDD). These drug products of interest included amiodarone, dronedarone, dofetilide, flecainide, propafenone, and sotalol. This involved one run of MP3. No event was queried. The time window for the request was January 1, 2000 to December 31, 2012. The package was distributed to 18 Data Partners on February 7, 2014.
<b><u>Request ID</u></b>	to09y05_mpr_wp17_v01
<b><u>Specifications</u></b>	Program parameter inputs and scenarios
<b><u>Glossary</u></b>	List of Terms found in this Report and their Definitions
<b><u>Table 1a</u></b>	Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, Years at Risk, Eligible Members, Member-Years, New Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, and Days Supplied per Dispensing by Drug Product, Pre-Existing Condition Criteria, and Exposure Washout Period/Pre-Existing Condition Lookback Period (All Drug Products are Incident with Respect to Itself)
<b><u>Table 1b</u></b>	Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, Years at Risk, Eligible Members, Member-Years, New Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, and Days Supplied per Dispensing by Drug Product (All Drug Products are Incident with Respect to All Anti-Arrhythmic Drug Products)
<b><u>Table 2a</u></b>	Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, Years at Risk, Eligible Members, Member-Years, New Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, and Days Supplied per Dispensing by Drug Product, Pre-Existing Condition Criteria, Exposure Washout Period/Pre-Existing Condition Lookback Period and Age Group (All Drug Products are Incident with Respect to Itself)
<b><u>Table 2b</u></b>	Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, Years at Risk, Eligible Members, Member-Years, New Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, and Days Supplied per Dispensing by Drug Product and Age Group (All Drug Products are Incident with Respect to All Anti-Arrhythmic Drug Products)
<b><u>Table 3a</u></b>	Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, Years at Risk, Eligible Members, Member-Years, New Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, and Days Supplied per Dispensing by Drug Product, Pre-Existing Condition Criteria, Exposure Washout Period/Pre-Existing Condition Lookback Period and Sex (All Drug Products are Incident with Respect to Itself)
<b><u>Table 3b</u></b>	Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, Years at Risk, Eligible Members, Member-Years, New Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, and Days Supplied per Dispensing by Drug Product and Sex (All Drug Products are Incident with Respect to All Anti-Arrhythmic Drug Products)
<b><u>Table 4a</u></b>	Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, Years at Risk, Eligible Members, Member-Years, New Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, and Days Supplied per Dispensing by Drug Product, Pre-Existing Condition Criteria, Exposure Washout Period/Pre-Existing Condition Lookback Period and Year (All Drug Products are Incident with Respect to Itself)
<b><u>Table 4b</u></b>	Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, Years at Risk, Eligible Members, Member-Years, New Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, and Days Supplied per Dispensing by Drug Product and Year (All Drug Products are Incident with Respect to All Anti-Arrhythmic Drug Products)
<b><u>Appendix A</u></b>	International Classification of Disease, Ninth Edition, Clinical Modification Diagnosis Codes Used to Define Pre-Existing Condition Inclusions/Exclusions in this Report
<b><u>Appendix B</u></b>	Modular Program Specifications for Query ID to09y05_mpr_wp17_v01 - Anti-arrhythmic Use
<b><u>Notes:</u></b>	Please contact the Mini-Sentinel Operations Center ( <a href="mailto:qf@sentinelssystem.org">qf@sentinelssystem.org</a> ) for questions and to provide comments/suggestions for future enhancements to this document.

### 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" value in the MSCDM.

**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).

**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.

**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" sequence.

**Episode Gap** - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.

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

**Incidence Type (event/outcome)**- *Minimum incidence type* considers the first event in a valid episode as long as it is the first event in the user's entire available history. *Multiple incidence type* uses the washout period to establish incidence and considers all qualifying incident treatment episodes. The program will only consider one event per episode, but the *Multiple incidence type* will consider more than one event per user if a user has more than one incident 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 period all divided by 365.23.

**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 bridged by the episode gap).

**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.

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

**Query Period** - period in which the modular program 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.

**Years at Risk** - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.23.

\*all terms may not be used in this report

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

**Table 1a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, and Exposure Washout Period/Pre-Existing Condition Lookback Period (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<b>Amiodarone</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>	124,876	124,876	391,088	15,493,244	21,389,159	43,022.9	1,658,400	2,079,608.9	75.30	124.07	3.13	39.62
<i>365-Day Exposure Washout Period/Lookback Period</i>	123,111	123,111	386,069	15,199,196	21,122,890	42,209.2	1,737,545	2,626,264.9	70.85	123.46	3.14	39.37
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>	58,652	58,652	174,564	7,043,622	9,743,855	19,547.9	1,490,291	2,269,752.0	39.36	120.09	2.98	40.35
<i>365-Day Exposure Washout Period/Lookback Period</i>	54,587	54,587	161,300	6,461,313	9,011,097	17,931.8	1,432,407	2,237,189.5	38.11	118.37	2.95	40.06
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>	27,300	27,300	87,753	3,641,024	5,073,856	10,103.6	1,402,258	2,409,057.3	19.47	133.37	3.21	41.49
<i>365-Day Exposure Washout Period/Lookback Period</i>	23,844	23,844	76,372	3,151,356	4,460,886	8,744.7	1,204,613	2,003,933.3	19.79	132.17	3.20	41.26
<b>Dofetilide</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>	7,091	7,091	59,612	2,204,686	4,919,555	6,120.7	1,701,599	2,337,091.6	4.17	310.91	8.41	36.98
<i>365-Day Exposure Washout Period/Lookback Period</i>	7,004	7,004	59,205	2,190,801	4,894,690	6,081.7	1,793,290	2,948,427.9	3.91	312.79	8.45	37.00
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>	3,840	3,840	32,528	1,221,844	2,648,450	3,390.2	1,525,611	2,509,088.8	2.52	318.19	8.47	37.56
<i>365-Day Exposure Washout Period/Lookback Period</i>	3,533	3,533	30,013	1,129,115	2,448,537	3,132.4	1,469,043	2,447,031.7	2.40	319.59	8.50	37.62
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>	2,302	2,302	18,778	715,306	1,584,778	1,984.0	1,431,213	2,632,787.7	1.61	310.73	8.16	38.09
<i>365-Day Exposure Washout Period/Lookback Period</i>	2,000	2,000	16,550	630,757	1,402,503	1,749.4	1,228,669	2,164,215.5	1.63	315.38	8.28	38.11
<b>Dronedarone</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>	26,513	26,513	121,943	4,557,331	9,022,953	12,717.0	1,700,990	2,315,633.6	15.59	171.89	4.60	37.37

**Table 1a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, and Exposure Washout Period/Pre-Existing Condition Lookback Period (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<b>365-Day Exposure Washout Period/Lookback Period</b>												
	26,807	26,807	123,581	4,618,297	9,144,525	12,887.2	1,791,966	2,924,448.4	14.96	172.28	4.61	37.37
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
	18,692	18,692	87,208	3,289,133	6,521,851	9,177.4	1,524,676	2,491,340.0	12.26	175.96	4.67	37.72
<i>365-Day Exposure Washout Period/Lookback Period</i>												
	17,813	17,813	83,264	3,138,571	6,226,006	8,757.3	1,467,420	2,428,897.8	12.14	176.20	4.67	37.69
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
	12,042	12,042	55,714	2,071,257	4,109,633	5,780.9	1,430,409	2,616,241.3	8.42	172.00	4.63	37.18
<i>365-Day Exposure Washout Period/Lookback Period</i>												
	10,862	10,862	50,460	1,869,618	3,709,501	5,219.1	1,227,449	2,150,860.2	8.85	172.12	4.65	37.05
<b>Flecainide</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
	30,151	30,151	186,699	8,152,389	17,076,019	22,593.0	1,687,276	2,268,616.3	17.87	270.39	6.19	43.67
<i>365-Day Exposure Washout Period/Lookback Period</i>												
	30,175	30,175	188,469	8,224,205	17,221,672	22,792.5	1,776,268	2,861,540.7	16.99	272.55	6.25	43.64
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
	26,343	26,343	164,900	7,237,338	15,127,883	20,054.6	1,510,886	2,438,767.2	17.44	274.73	6.26	43.89
<i>365-Day Exposure Washout Period/Lookback Period</i>												
	25,718	25,718	162,983	7,163,413	14,962,940	19,849.6	1,451,478	2,364,256.4	17.72	278.54	6.34	43.95
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
	22,589	22,589	141,386	6,271,715	13,066,388	17,375.7	1,416,444	2,559,334.8	15.95	277.64	6.26	44.36
<i>365-Day Exposure Washout Period/Lookback Period</i>												
	21,308	21,308	135,097	6,016,171	12,530,006	16,667.5	1,211,535	2,086,130.3	17.59	282.34	6.34	44.53
<b>Propafenone</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
	22,420	22,420	113,205	4,392,536	11,598,402	12,217.5	1,691,172	2,285,173.0	13.26	195.92	5.05	38.80
<i>365-Day Exposure Washout Period/Lookback Period</i>												
	22,252	22,252	113,071	4,388,643	11,612,925	12,206.6	1,780,609	2,881,786.3	12.50	197.22	5.08	38.81
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												

**Table 1a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, and Exposure Washout Period/Pre-Existing Condition Lookback Period (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
	18,246	18,246	94,020	3,664,959	9,630,459	10,190.4	1,514,908	2,455,668.6	12.04	200.86	5.15	38.98
<i>365-Day Exposure Washout Period/Lookback Period</i>	17,510	17,510	90,999	3,550,607	9,309,102	9,872.0	1,456,104	2,385,651.9	12.03	202.78	5.20	39.02
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>	14,373	14,373	73,627	2,873,356	7,463,958	7,986.7	1,420,741	2,577,273.9	10.12	199.91	5.12	39.03
<i>365-Day Exposure Washout Period/Lookback Period</i>	13,259	13,259	68,781	2,686,421	6,956,196	7,467.0	1,216,841	2,109,247.2	10.90	202.61	5.19	39.06
<b>Sotalol</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>	38,605	38,605	263,378	10,979,203	21,542,617	30,431.9	1,676,714	2,229,616.1	23.02	284.40	6.82	41.69
<i>365-Day Exposure Washout Period/Lookback Period</i>	38,203	38,203	264,438	11,006,773	21,595,088	30,507.3	1,763,631	2,815,985.5	21.66	288.11	6.92	41.62
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>	25,517	25,517	175,591	7,442,234	14,510,026	20,620.6	1,501,723	2,399,559.8	16.99	291.66	6.88	42.38
<i>365-Day Exposure Washout Period/Lookback Period</i>	23,964	23,964	167,965	7,115,927	13,871,675	19,715.4	1,442,744	2,338,043.3	16.61	296.94	7.01	42.37
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>	15,463	15,463	105,328	4,469,186	8,736,528	12,381.3	1,409,979	2,521,227.1	10.97	289.02	6.81	42.43
<i>365-Day Exposure Washout Period/Lookback Period</i>	13,784	13,784	95,543	4,065,153	7,968,589	11,260.8	1,208,958	2,075,654.6	11.40	294.92	6.93	42.55

**Table 1b: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product (Pre-Existing Inclusion of Atrial Fibrillation, 183-Day Exposure Washout Period/Pre-Existing Condition Lookback Period, and Incidence is Defined with Respect to All Anti-Arrhythmic Drug Products)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<b>Amiodarone</b>	110,349	110,349	337,897	13,303,201	17,991,821	36,942.1	1,585,432	1,845,208.0	69.60	120.56	3.06	39.37
<b>Dofetilide</b>	3,642	3,642	31,062	1,144,040	2,627,168	3,178.5	1,585,432	1,897,575.0	2.30	314.12	8.53	36.83
<b>Dronedarone</b>	17,677	17,677	78,573	2,848,435	5,644,106	7,953.1	1,585,432	1,894,617.1	11.15	161.14	4.44	36.25
<b>Flecainide</b>	24,003	24,003	142,331	6,168,052	12,841,765	17,099.2	1,585,432	1,890,200.6	15.14	256.97	5.93	43.34
<b>Propafenone</b>	17,501	17,501	86,120	3,232,121	8,466,012	8,999.1	1,585,432	1,890,220.5	11.04	184.68	4.92	37.53
<b>Sotalol</b>	31,180	31,180	212,074	8,718,678	16,992,372	24,180.2	1,585,432	1,887,583.1	19.67	279.62	6.80	41.11

**Table 2a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Age Group (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<b>Amiodarone</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	1,176	1,176	3,331	108,816	179,683	304.3	69,836	42,823.9	16.84	92.53	2.83	32.67
41 to 54 Years	9,957	9,957	29,660	1,021,844	1,844,636	2,850.6	198,171	162,720.9	50.24	102.63	2.98	34.45
55 to 64 Years	26,178	26,178	80,020	2,930,619	4,361,342	8,150.4	347,480	339,829.1	75.34	111.95	3.06	36.62
65 to 74 Years	37,703	37,703	114,737	4,747,113	6,535,429	13,170.5	450,270	505,316.0	83.73	125.91	3.04	41.37
75 to 84 Years	36,911	36,911	117,389	4,885,991	6,340,961	13,556.3	512,565	659,754.6	72.01	132.37	3.18	41.62
85+ Years	12,951	12,951	45,951	1,798,861	2,127,108	4,990.9	307,141	369,164.4	42.17	138.90	3.55	39.15
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	1,180	1,180	3,299	107,739	177,883	301.3	79,609	69,319.8	14.82	91.30	2.80	32.66
41 to 54 Years	9,853	9,853	29,353	1,006,832	1,825,168	2,809.2	216,086	231,649.7	45.60	102.19	2.98	34.30
55 to 64 Years	25,846	25,846	79,128	2,889,768	4,310,018	8,036.8	369,780	444,832.1	69.90	111.81	3.06	36.52
65 to 74 Years	37,152	37,152	113,229	4,656,154	6,438,400	12,918.4	472,437	628,975.2	78.64	125.33	3.05	41.12
75 to 84 Years	36,336	36,336	115,611	4,770,215	6,239,181	13,236.8	532,035	800,461.4	68.30	131.28	3.18	41.26
85+ Years	12,744	12,744	45,449	1,768,488	2,132,241	4,906.7	319,272	451,026.7	39.92	138.77	3.57	38.91
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	543	543	1,391	44,212	77,753	123.9	66,647	42,627.8	8.15	81.42	2.56	31.78
41 to 54 Years	4,942	4,942	13,276	455,561	915,170	1,269.8	186,119	168,603.3	26.55	92.18	2.69	34.31
55 to 64 Years	13,328	13,328	37,868	1,384,504	2,115,810	3,848.2	321,183	357,172.0	41.50	103.88	2.84	36.56
65 to 74 Years	18,623	18,623	53,960	2,271,339	3,069,060	6,296.6	408,854	549,190.2	45.55	121.96	2.90	42.09
75 to 84 Years	16,435	16,435	51,301	2,197,448	2,759,048	6,092.8	457,401	738,755.4	35.93	133.71	3.12	42.83
85+ Years	4,781	4,781	16,768	690,558	807,014	1,916.5	262,012	413,403.3	18.25	144.44	3.51	41.18
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	518	518	1,332	42,429	74,982	118.8	74,001	63,360.9	7.00	81.91	2.57	31.85
41 to 54 Years	4,712	4,712	12,476	424,629	843,695	1,183.8	193,755	209,702.8	24.32	90.12	2.65	34.04
55 to 64 Years	12,573	12,573	35,415	1,294,143	1,989,446	3,596.6	320,204	395,130.2	39.27	102.93	2.82	36.54
65 to 74 Years	17,422	17,422	50,062	2,093,102	2,847,609	5,802.5	393,611	544,808.8	44.26	120.14	2.87	41.81
75 to 84 Years	15,044	15,044	46,762	1,981,498	2,521,233	5,494.9	425,521	672,385.7	35.35	131.71	3.11	42.37
85+ Years	4,318	4,318	15,253	625,512	734,131	1,735.2	234,700	351,801.1	18.40	144.86	3.53	41.01
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	449	449	1,100	35,250	64,467	99.0	65,155	42,297.5	6.89	78.51	2.45	32.05



**Table 2a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Age Group (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
41 to 54 Years	2,946	2,946	8,567	300,697	640,165	838.3	178,330	170,815.8	16.52	102.07	2.91	35.10
55 to 64 Years	6,514	6,514	20,104	750,015	1,136,380	2,084.4	303,334	372,522.4	21.47	115.14	3.09	37.31
65 to 74 Years	7,854	7,854	25,480	1,129,998	1,500,678	3,131.6	382,202	586,525.0	20.55	143.88	3.24	44.35
75 to 84 Years	7,126	7,126	24,074	1,073,277	1,328,732	2,974.7	430,473	794,117.4	16.55	150.61	3.38	44.58
85+ Years	2,411	2,411	8,428	351,787	403,434	975.6	250,273	442,779.1	9.63	145.91	3.50	41.74
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	415	415	1,012	32,526	60,297	91.3	71,361	60,885.1	5.82	78.38	2.44	32.14
41 to 54 Years	2,689	2,689	7,596	264,808	590,785	738.4	176,676	194,279.9	15.22	98.48	2.82	34.86
55 to 64 Years	5,832	5,832	17,827	669,178	1,019,855	1,859.9	275,318	355,457.5	21.18	114.74	3.06	37.54
65 to 74 Years	6,821	6,821	22,105	980,952	1,307,152	2,717.8	320,477	478,777.6	21.28	143.81	3.24	44.38
75 to 84 Years	6,045	6,045	20,602	903,775	1,137,096	2,505.1	345,029	593,468.0	17.52	149.51	3.41	43.87
85+ Years	2,042	2,042	7,230	300,117	345,702	832.1	197,703	321,065.2	10.33	146.97	3.54	41.51
<b>Dofetilide</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	171	171	1,329	45,080	96,843	125.9	70,254	44,273.0	2.43	263.63	7.77	33.92
41 to 54 Years	1,105	1,105	8,314	296,690	696,458	825.7	201,778	176,606.5	5.48	268.50	7.52	35.69
55 to 64 Years	2,462	2,462	20,710	769,163	1,647,864	2,133.8	359,746	382,724.9	6.84	312.41	8.41	37.14
65 to 74 Years	2,024	2,024	17,928	670,511	1,595,424	1,860.2	470,204	579,459.9	4.30	331.28	8.86	37.40
75 to 84 Years	1,157	1,157	9,948	372,994	778,421	1,035.6	536,055	748,970.0	2.16	322.38	8.60	37.49
85+ Years	172	172	1,383	50,248	104,546	139.6	320,137	405,057.3	0.54	292.14	8.04	36.33
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	166	166	1,327	44,922	96,407	125.5	80,210	71,344.8	2.07	270.61	7.99	33.85
41 to 54 Years	1,093	1,093	8,263	294,955	692,988	820.9	221,131	250,087.7	4.94	269.86	7.56	35.70
55 to 64 Years	2,433	2,433	20,609	764,478	1,640,415	2,120.7	385,536	500,367.6	6.31	314.21	8.47	37.09
65 to 74 Years	2,004	2,004	17,795	666,403	1,588,585	1,848.6	497,209	722,288.2	4.03	332.54	8.88	37.45
75 to 84 Years	1,136	1,136	9,820	368,584	769,148	1,023.2	559,761	909,726.2	2.03	324.46	8.64	37.53
85+ Years	172	172	1,391	51,459	107,148	142.9	333,992	494,613.4	0.51	299.18	8.09	36.99
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	77	77	643	22,137	47,775	61.4	66,954	43,880.4	1.15	287.49	8.35	34.43
41 to 54 Years	594	594	4,353	159,336	397,112	443.9	188,948	180,652.9	3.14	268.24	7.33	36.60
55 to 64 Years	1,460	1,460	12,217	458,388	984,763	1,270.1	330,742	395,476.8	4.41	313.96	8.37	37.52

**Table 2a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Age Group (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
65 to 74 Years	1,085	1,085	9,940	373,006	785,982	1,034.7	424,219	618,416.0	2.56	343.78	9.16	37.53
75 to 84 Years	548	548	4,768	186,165	386,188	516.6	475,175	823,066.5	1.15	339.72	8.70	39.04
85+ Years	76	76	607	22,812	46,629	63.4	271,162	447,596.2	0.28	300.16	7.99	37.58
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	72	72	611	21,175	44,171	58.6	74,342	64,620.5	0.97	294.10	8.49	34.66
41 to 54 Years	553	553	4,098	149,353	376,662	416.1	196,893	221,520.5	2.81	270.08	7.41	36.45
55 to 64 Years	1,362	1,362	11,473	428,719	919,453	1,187.8	330,231	431,332.5	4.12	314.77	8.42	37.37
65 to 74 Years	995	995	9,058	342,411	720,498	949.8	409,582	607,559.5	2.43	344.13	9.10	37.80
75 to 84 Years	483	483	4,216	167,091	346,015	463.3	442,984	743,672.1	1.09	345.94	8.73	39.63
85+ Years	68	68	557	20,366	41,737	56.7	243,253	378,326.7	0.28	299.50	8.19	36.56
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	74	74	625	21,517	46,535	59.7	65,450	43,522.5	1.13	290.77	8.45	34.43
41 to 54 Years	441	441	3,219	119,412	315,941	332.2	180,785	182,293.9	2.44	270.78	7.30	37.10
55 to 64 Years	929	929	7,688	296,235	634,763	820.2	311,174	408,341.0	2.99	318.88	8.28	38.53
65 to 74 Years	552	552	4,746	182,071	387,618	504.9	394,568	651,166.6	1.40	329.84	8.60	38.36
75 to 84 Years	260	260	2,129	82,062	170,890	228.1	444,384	872,209.4	0.59	315.62	8.19	38.54
85+ Years	46	46	371	14,009	29,030	38.9	257,580	475,254.3	0.18	304.54	8.07	37.76
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	65	65	520	18,336	38,373	50.8	71,650	62,064.9	0.91	282.09	8.00	35.26
41 to 54 Years	396	396	2,891	107,393	290,013	298.9	179,093	204,258.0	2.21	271.19	7.30	37.15
55 to 64 Years	812	812	6,870	263,865	563,807	730.6	282,016	383,561.4	2.88	324.96	8.46	38.41
65 to 74 Years	478	478	4,198	161,319	344,807	447.4	330,818	525,823.6	1.44	337.49	8.78	38.43
75 to 84 Years	215	215	1,773	68,866	143,126	191.2	356,201	646,463.1	0.60	320.31	8.25	38.84
85+ Years	34	34	298	10,978	22,376	30.5	203,548	342,044.6	0.17	322.88	8.76	36.84
<b>Dronedaron</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	451	451	1,361	44,660	88,180	125.7	70,256	44,100.0	6.42	99.02	3.02	32.81
41 to 54 Years	3,509	3,509	15,237	523,739	1,043,351	1,471.8	201,662	174,245.2	17.40	149.26	4.34	34.37
55 to 64 Years	7,877	7,877	37,798	1,357,520	2,700,515	3,792.8	359,211	376,892.2	21.93	172.34	4.80	35.92
65 to 74 Years	7,561	7,561	35,029	1,373,323	2,717,756	3,822.2	469,480	573,527.2	16.11	181.63	4.63	39.21
75 to 84 Years	5,610	5,610	25,722	1,006,747	1,983,485	2,804.4	535,341	743,694.7	10.48	179.46	4.59	39.14

**Table 2a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Age Group (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
85+ Years	1,505	1,505	6,796	251,342	489,665	700.1	319,589	403,174.4	4.71	167.00	4.52	36.98
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	455	455	1,420	45,977	90,844	129.3	80,191	71,117.5	5.67	101.05	3.12	32.38
41 to 54 Years	3,551	3,551	15,459	531,494	1,058,827	1,493.2	220,872	247,333.0	16.08	149.67	4.35	34.38
55 to 64 Years	7,960	7,960	38,213	1,371,996	2,728,966	3,833.1	384,736	493,785.9	20.69	172.36	4.80	35.90
65 to 74 Years	7,638	7,638	35,480	1,393,871	2,758,912	3,879.7	496,206	715,691.9	15.39	182.49	4.65	39.29
75 to 84 Years	5,670	5,670	26,077	1,019,132	2,008,276	2,839.2	558,896	903,986.7	10.15	179.74	4.60	39.08
85+ Years	1,533	1,533	6,932	255,827	498,699	712.7	333,380	492,533.3	4.60	166.88	4.52	36.91
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	349	349	1,019	31,431	62,509	88.5	66,948	43,724.3	5.21	90.06	2.92	30.84
41 to 54 Years	2,665	2,665	11,660	400,251	797,389	1,125.4	188,788	178,604.0	14.12	150.19	4.38	34.33
55 to 64 Years	5,899	5,899	28,680	1,032,880	2,057,302	2,884.2	330,179	390,584.4	17.87	175.09	4.86	36.01
65 to 74 Years	5,332	5,332	25,061	1,000,059	1,980,435	2,782.9	423,492	613,402.9	12.59	187.56	4.70	39.90
75 to 84 Years	3,591	3,591	16,725	668,722	1,320,958	1,862.5	474,564	818,875.3	7.57	186.22	4.66	39.98
85+ Years	856	856	4,063	155,790	303,258	433.8	270,766	446,149.1	3.16	182.00	4.75	38.34
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	337	337	993	30,530	60,737	86.0	74,298	64,380.4	4.54	90.59	2.95	30.75
41 to 54 Years	2,584	2,584	11,219	385,773	768,535	1,084.7	196,573	219,189.9	13.15	149.29	4.34	34.39
55 to 64 Years	5,711	5,711	27,756	998,569	1,989,186	2,788.7	329,408	426,023.2	17.34	174.85	4.86	35.98
65 to 74 Years	5,048	5,048	23,824	953,851	1,889,472	2,653.7	408,608	602,519.3	12.35	188.96	4.72	40.04
75 to 84 Years	3,341	3,341	15,692	625,665	1,237,237	1,743.0	442,283	739,685.8	7.55	187.27	4.70	39.87
85+ Years	792	792	3,780	144,183	280,839	401.2	242,843	377,099.1	3.26	182.05	4.77	38.14
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	317	317	961	29,564	58,775	83.2	65,443	43,388.4	4.84	93.26	3.03	30.76
41 to 54 Years	2,103	2,103	8,921	303,650	605,406	854.4	180,638	180,503.3	11.64	144.39	4.24	34.04
55 to 64 Years	4,074	4,074	19,754	703,046	1,400,565	1,963.1	310,698	403,717.8	13.11	172.57	4.85	35.59
65 to 74 Years	3,149	3,149	14,698	583,265	1,155,226	1,622.7	393,975	646,431.5	7.99	185.22	4.67	39.68
75 to 84 Years	1,935	1,935	9,174	365,718	722,166	1,018.0	443,974	868,340.1	4.36	189.00	4.74	39.86
85+ Years	464	464	2,206	86,014	167,495	239.4	257,283	473,860.0	1.80	185.38	4.75	38.99
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	300	300	882	27,056	53,789	76.3	71,608	61,845.4	4.19	90.19	2.94	30.68

**Table 2a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Age Group (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
41 to 54 Years	1,977	1,977	8,405	285,993	570,127	804.7	178,817	202,463.9	11.06	144.66	4.25	34.03
55 to 64 Years	3,745	3,745	18,116	643,765	1,281,846	1,797.6	281,393	379,557.8	13.31	171.90	4.84	35.54
65 to 74 Years	2,781	2,781	13,126	522,192	1,034,577	1,452.7	330,136	522,171.0	8.42	187.77	4.72	39.78
75 to 84 Years	1,654	1,654	8,007	315,878	623,180	879.8	355,780	643,704.7	4.65	190.98	4.84	39.45
85+ Years	405	405	1,924	74,734	145,982	208.0	203,304	341,117.4	1.99	184.53	4.75	38.84
<b>Flecainide</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	1,805	1,805	7,914	277,631	594,470	774.3	69,365	41,686.8	26.02	153.81	4.38	35.08
41 to 54 Years	6,630	6,630	40,086	1,572,483	3,349,392	4,373.4	197,654	163,989.3	33.54	237.18	6.05	39.23
55 to 64 Years	10,086	10,086	66,882	2,829,646	5,942,001	7,841.9	352,833	361,273.5	28.59	280.55	6.63	42.31
65 to 74 Years	7,220	7,220	46,424	2,288,393	4,806,368	6,326.0	464,747	561,580.5	15.54	316.95	6.43	49.29
75 to 84 Years	3,744	3,744	22,098	1,043,003	2,101,254	2,885.6	532,845	737,921.1	7.03	278.58	5.90	47.20
85+ Years	666	666	3,295	141,233	282,535	391.7	319,060	402,165.1	2.09	212.06	4.95	42.86
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	1,833	1,833	8,143	285,624	610,281	796.9	78,993	67,624.6	23.20	155.82	4.44	35.08
41 to 54 Years	6,671	6,671	40,569	1,592,123	3,388,530	4,427.8	216,182	233,261.5	30.86	238.66	6.08	39.24
55 to 64 Years	10,080	10,080	67,408	2,849,916	5,995,273	7,898.5	377,603	472,995.1	26.69	282.73	6.69	42.28
65 to 74 Years	7,189	7,189	46,746	2,303,567	4,831,020	6,367.7	491,004	700,300.2	14.64	320.43	6.50	49.28
75 to 84 Years	3,735	3,735	22,271	1,050,463	2,111,986	2,906.5	556,187	896,320.5	6.72	281.25	5.96	47.17
85+ Years	667	667	3,332	142,512	284,581	395.2	332,777	491,038.7	2.00	213.66	5.00	42.77
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	1,680	1,680	7,312	257,789	554,700	718.8	66,038	41,280.8	25.44	153.45	4.35	35.26
41 to 54 Years	6,047	6,047	36,368	1,426,913	2,982,744	3,968.3	184,771	167,978.6	32.73	235.97	6.01	39.24
55 to 64 Years	9,016	9,016	60,009	2,564,005	5,384,718	7,104.1	323,756	373,694.9	27.85	284.38	6.66	42.73
65 to 74 Years	6,177	6,177	40,487	2,012,448	4,233,671	5,562.3	418,695	599,811.4	14.75	325.80	6.55	49.71
75 to 84 Years	2,971	2,971	18,394	876,462	1,772,749	2,424.1	471,985	811,462.3	6.29	295.01	6.19	47.65
85+ Years	452	452	2,330	99,721	199,301	276.9	270,172	444,539.3	1.67	220.62	5.15	42.80
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	1,689	1,689	7,357	259,911	558,799	725.0	73,098	61,010.7	23.11	153.88	4.36	35.33
41 to 54 Years	5,979	5,979	36,235	1,424,433	2,972,589	3,961.1	191,832	205,111.7	31.17	238.24	6.06	39.31
55 to 64 Years	8,829	8,829	59,560	2,546,492	5,361,396	7,055.9	322,169	404,787.2	27.40	288.42	6.75	42.76

**Table 2a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Age Group (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
65 to 74 Years	5,969	5,969	39,830	1,985,740	4,164,401	5,488.4	403,341	586,395.8	14.80	332.68	6.67	49.86
75 to 84 Years	2,831	2,831	17,779	851,895	1,716,146	2,355.6	439,492	731,519.1	6.44	300.92	6.28	47.92
85+ Years	421	421	2,222	94,942	189,609	263.6	242,209	375,431.9	1.74	225.52	5.28	42.73
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	1,593	1,593	6,839	241,992	521,382	674.3	64,546	40,966.8	24.68	151.91	4.29	35.38
41 to 54 Years	5,463	5,463	32,960	1,302,583	2,724,651	3,621.9	176,598	169,558.6	30.93	238.44	6.03	39.52
55 to 64 Years	7,833	7,833	51,906	2,252,904	4,720,642	6,240.7	304,236	386,062.4	25.75	287.62	6.63	43.40
65 to 74 Years	5,060	5,060	33,476	1,693,041	3,521,207	4,678.5	389,101	631,143.9	13.00	334.59	6.62	50.57
75 to 84 Years	2,307	2,307	14,533	707,065	1,430,183	1,954.6	441,318	859,620.2	5.23	306.49	6.30	48.65
85+ Years	333	333	1,672	74,130	148,324	205.7	256,670	471,983.1	1.30	222.61	5.02	44.34
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	1,586	1,586	6,849	242,714	522,591	676.6	70,441	58,615.1	22.52	153.04	4.32	35.44
41 to 54 Years	5,268	5,268	32,037	1,270,646	2,651,273	3,532.7	174,122	188,833.1	30.25	241.20	6.08	39.66
55 to 64 Years	7,441	7,441	49,942	2,173,784	4,571,345	6,021.9	274,189	358,601.7	27.14	292.14	6.71	43.53
65 to 74 Years	4,672	4,672	31,569	1,608,560	3,333,337	4,445.0	324,854	505,739.7	14.38	344.30	6.76	50.95
75 to 84 Years	2,050	2,050	13,192	653,266	1,317,386	1,805.0	353,032	635,076.7	5.81	318.67	6.44	49.52
85+ Years	291	291	1,508	67,201	134,074	186.4	202,642	339,263.9	1.44	230.93	5.18	44.56
<b>Propafenone</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	987	987	3,462	107,964	260,134	302.4	69,822	42,987.6	14.14	109.39	3.51	31.19
41 to 54 Years	4,365	4,365	19,965	706,798	1,868,458	1,973.0	199,582	169,278.9	21.87	161.92	4.57	35.40
55 to 64 Years	6,805	6,805	38,017	1,417,001	3,726,771	3,938.7	355,314	368,815.7	19.15	208.23	5.59	37.27
65 to 74 Years	5,767	5,767	30,285	1,288,474	3,544,282	3,577.1	465,880	565,226.9	12.38	223.42	5.25	42.54
75 to 84 Years	3,670	3,670	18,017	741,448	1,893,112	2,061.8	532,709	737,496.8	6.89	202.03	4.91	41.15
85+ Years	826	826	3,459	130,851	305,647	364.5	318,693	401,367.2	2.59	158.42	4.19	37.83
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	989	989	3,417	105,449	252,663	295.4	79,627	69,451.6	12.42	106.62	3.46	30.86
41 to 54 Years	4,330	4,330	19,826	701,079	1,856,029	1,957.2	218,340	240,207.4	19.83	161.91	4.58	35.36
55 to 64 Years	6,755	6,755	37,793	1,410,098	3,714,643	3,919.7	380,284	482,384.0	17.76	208.75	5.59	37.31
65 to 74 Years	5,720	5,720	30,492	1,295,403	3,573,725	3,596.4	492,123	704,310.2	11.62	226.47	5.33	42.48
75 to 84 Years	3,638	3,638	18,072	743,561	1,903,745	2,067.5	555,957	895,449.1	6.54	204.39	4.97	41.14

**Table 2a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Age Group (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
85+ Years	820	820	3,471	133,053	312,120	370.3	332,355	489,984.1	2.47	162.26	4.23	38.33
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	892	892	3,149	98,162	234,587	274.9	66,503	42,571.2	13.41	110.05	3.53	31.17
41 to 54 Years	3,864	3,864	17,859	633,425	1,678,882	1,767.7	186,716	173,243.4	20.69	163.93	4.62	35.47
55 to 64 Years	5,813	5,813	32,815	1,234,400	3,167,441	3,429.9	326,258	381,458.5	17.82	212.35	5.65	37.62
65 to 74 Years	4,552	4,552	24,541	1,058,186	2,936,431	2,935.9	419,878	603,753.7	10.84	232.47	5.39	43.12
75 to 84 Years	2,614	2,614	13,561	558,133	1,425,030	1,551.6	471,935	810,812.3	5.54	213.52	5.19	41.16
85+ Years	511	511	2,095	82,653	188,087	230.4	269,898	443,829.4	1.89	161.75	4.10	39.45
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	883	883	3,120	96,049	229,652	269.1	73,730	62,749.6	11.98	108.78	3.53	30.78
41 to 54 Years	3,746	3,746	17,315	613,275	1,631,903	1,711.4	194,034	211,938.5	19.31	163.71	4.62	35.42
55 to 64 Years	5,598	5,598	31,618	1,193,619	3,072,536	3,316.4	324,931	414,183.4	17.23	213.22	5.65	37.75
65 to 74 Years	4,342	4,342	23,968	1,035,043	2,831,325	2,871.5	404,565	590,751.5	10.73	238.38	5.52	43.18
75 to 84 Years	2,466	2,466	12,970	532,699	1,360,733	1,480.8	439,432	731,195.5	5.61	216.02	5.26	41.07
85+ Years	475	475	2,008	79,922	182,953	222.8	241,919	374,833.4	1.96	168.26	4.23	39.80
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	833	833	2,872	89,471	216,141	250.6	64,999	42,240.4	12.82	107.41	3.45	31.15
41 to 54 Years	3,401	3,401	15,764	559,199	1,497,837	1,560.2	178,564	174,938.5	19.05	164.42	4.64	35.47
55 to 64 Years	4,683	4,683	26,062	989,532	2,477,890	2,747.9	306,822	393,931.5	15.26	211.30	5.57	37.97
65 to 74 Years	3,367	3,367	18,221	796,111	2,164,924	2,208.2	390,414	635,598.1	8.62	236.45	5.41	43.69
75 to 84 Years	1,752	1,752	9,262	383,099	977,062	1,063.7	441,411	859,321.4	3.97	218.66	5.29	41.36
85+ Years	337	337	1,446	55,944	130,104	156.1	256,463	471,244.0	1.31	166.01	4.29	38.69
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	816	816	2,830	86,942	210,198	243.6	71,049	60,303.1	11.49	106.55	3.47	30.72
41 to 54 Years	3,216	3,216	14,927	526,509	1,418,209	1,469.0	176,328	195,386.6	18.24	163.72	4.64	35.27
55 to 64 Years	4,352	4,352	24,303	932,090	2,343,773	2,588.2	277,117	367,984.9	15.70	214.18	5.58	38.35
65 to 74 Years	3,043	3,043	17,085	742,712	1,976,826	2,060.3	326,412	510,817.0	9.32	244.07	5.61	43.47
75 to 84 Years	1,543	1,543	8,401	348,719	890,651	968.0	353,271	635,761.9	4.37	226.00	5.44	41.51
85+ Years	289	289	1,235	49,449	116,538	137.8	202,509	338,993.7	1.43	171.10	4.27	40.04

**Sotalol**

**Pre-Existing Inclusion of Atrial Fibrillation**

**Table 2a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Age Group (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	920	920	5,559	202,574	545,402	564.2	69,575	42,617.7	13.22	220.19	6.04	36.44
41 to 54 Years	4,954	4,954	34,052	1,269,823	2,633,874	3,535.6	198,356	166,797.1	24.98	256.32	6.87	37.29
55 to 64 Years	10,529	10,529	73,805	2,844,790	5,737,385	7,892.4	351,861	359,257.4	29.92	270.19	7.01	38.54
65 to 74 Years	11,348	11,348	79,113	3,575,143	6,975,580	9,890.6	459,693	548,080.1	24.69	315.05	6.97	45.19
75 to 84 Years	8,572	8,572	57,038	2,519,186	4,692,412	6,975.1	526,310	718,663.4	16.29	293.89	6.65	44.17
85+ Years	2,282	2,282	13,811	567,687	957,964	1,574.0	315,627	394,200.4	7.23	248.77	6.05	41.10
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	928	928	5,760	213,120	567,743	593.4	79,336	69,032.4	11.70	229.66	6.21	37.00
41 to 54 Years	4,928	4,928	34,303	1,279,546	2,653,329	3,562.3	216,938	237,325.3	22.72	259.65	6.96	37.30
55 to 64 Years	10,430	10,430	73,744	2,838,865	5,726,913	7,875.1	376,125	471,010.4	27.73	272.18	7.07	38.50
65 to 74 Years	11,265	11,265	79,612	3,593,059	7,006,581	9,939.5	485,113	683,952.4	23.22	318.96	7.07	45.13
75 to 84 Years	8,436	8,436	57,267	2,523,172	4,695,832	6,986.8	548,591	873,255.8	15.38	299.10	6.79	44.06
85+ Years	2,216	2,216	13,752	559,011	944,691	1,550.2	328,916	481,409.2	6.74	252.26	6.21	40.65
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	643	643	3,719	135,078	281,081	375.9	66,310	42,159.5	9.70	210.07	5.78	36.32
41 to 54 Years	3,536	3,536	24,360	922,071	1,865,977	2,566.9	185,703	170,878.7	19.04	260.77	6.89	37.85
55 to 64 Years	7,320	7,320	51,080	1,983,206	3,995,964	5,500.3	323,291	372,138.3	22.64	270.93	6.98	38.83
65 to 74 Years	7,664	7,664	54,363	2,508,027	4,887,666	6,934.5	414,435	586,294.7	18.49	327.25	7.09	46.13
75 to 84 Years	5,144	5,144	34,602	1,577,173	2,950,652	4,366.0	466,246	791,621.3	11.03	306.60	6.73	45.58
85+ Years	1,210	1,210	7,467	316,679	528,686	877.1	267,319	436,467.4	4.53	261.72	6.17	42.41
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	636	636	3,655	133,577	278,334	371.7	73,585	62,617.8	8.64	210.03	5.75	36.55
41 to 54 Years	3,392	3,392	23,851	905,257	1,832,114	2,519.5	193,175	210,533.9	17.56	266.88	7.03	37.95
55 to 64 Years	6,941	6,941	49,011	1,897,403	3,818,109	5,261.6	321,894	406,584.5	21.56	273.36	7.06	38.71
65 to 74 Years	7,219	7,219	52,180	2,408,817	4,693,934	6,659.7	399,155	575,460.9	18.09	333.68	7.23	46.16
75 to 84 Years	4,705	4,705	32,542	1,484,447	2,773,892	4,109.4	433,570	714,141.7	10.85	315.50	6.92	45.62
85+ Years	1,071	1,071	6,726	286,426	475,292	793.3	239,403	368,704.6	4.47	267.44	6.28	42.58
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	579	579	3,162	111,771	227,840	311.2	64,817	41,812.1	8.93	193.04	5.46	35.35
41 to 54 Years	2,681	2,681	17,979	679,496	1,368,234	1,892.2	177,738	172,382.7	15.08	253.45	6.71	37.79

**Table 2a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Age Group (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
55 to 64 Years	4,662	4,662	32,267	1,263,858	2,564,508	3,503.4	304,461	384,735.0	15.31	271.10	6.92	39.17
65 to 74 Years	4,206	4,206	29,599	1,406,692	2,732,461	3,886.2	386,044	618,371.8	10.90	334.45	7.04	47.52
75 to 84 Years	2,678	2,678	18,270	836,800	1,561,356	2,316.0	436,725	840,161.4	6.13	312.47	6.82	45.80
85+ Years	657	657	4,051	170,569	282,129	472.2	254,264	463,764.1	2.58	259.62	6.17	42.11
<i>365-Day Exposure Washout Period/Lookback Period</i>												
00 to 40 Years	561	561	2,993	106,786	217,200	297.5	70,923	60,157.8	7.91	190.35	5.34	35.68
41 to 54 Years	2,460	2,460	16,920	644,399	1,296,339	1,794.3	175,798	194,484.0	13.99	261.95	6.88	38.09
55 to 64 Years	4,239	4,239	29,565	1,156,732	2,352,261	3,206.3	275,433	363,036.6	15.39	272.88	6.97	39.13
65 to 74 Years	3,722	3,722	26,912	1,286,674	2,503,097	3,554.1	323,310	500,345.5	11.51	345.69	7.23	47.81
75 to 84 Years	2,250	2,250	15,643	722,854	1,353,529	1,999.7	349,616	623,329.4	6.44	321.27	6.95	46.21
85+ Years	552	552	3,510	147,708	246,164	409.0	200,826	334,301.3	2.75	267.59	6.36	42.08



**Table 2b: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product and Age Group (Pre-Existing Inclusion of Atrial Fibrillation, 183-Day Exposure Washout Period/Pre-Existing Condition Lookback Period, and Incidence is Defined with Respect to All Anti-Arrhythmic Drug Products)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<b>Pre-Existing Inclusion of AF, Amiodarone Incident with Respect to All Anti-Arrhythmics, 183-Day Exposure Washout Period/Lookback Period</b>												
00 to 40 Years	977	977	2,625	84,880	141,051	237.2	67,245	37,346.5	14.53	86.88	2.69	32.34
41 to 54 Years	8,373	8,373	24,262	831,169	1,347,351	2,318.7	185,123	131,779.9	45.23	99.27	2.90	34.26
55 to 64 Years	22,380	22,380	66,128	2,399,763	3,516,014	6,673.2	321,719	275,844.2	69.56	107.23	2.95	36.29
65 to 74 Years	33,357	33,357	98,965	4,054,490	5,529,719	11,250.6	423,866	438,880.9	78.70	121.55	2.97	40.97
75 to 84 Years	33,322	33,322	104,238	4,308,095	5,547,906	11,953.4	493,380	608,340.2	67.54	129.29	3.13	41.33
85+ Years	11,940	11,940	41,679	1,624,804	1,909,780	4,508.9	299,963	353,016.2	39.80	136.08	3.49	38.98
<b>Pre-Existing Inclusion of AF, Dofetilide Incident with Respect to All Anti-Arrhythmics, 183-Day Exposure Washout Period/Lookback Period</b>												
00 to 40 Years	83	83	530	18,250	40,772	51.5	67,245	37,556.3	1.23	219.88	6.39	34.43
41 to 54 Years	519	519	3,946	139,762	351,318	389.0	185,245	133,926.0	2.80	269.29	7.60	35.42
55 to 64 Years	1,198	1,198	10,135	376,783	787,316	1,045.7	322,909	283,192.4	3.71	314.51	8.46	37.18
65 to 74 Years	1,079	1,079	10,034	369,498	953,264	1,025.9	426,332	453,249.4	2.53	342.44	9.30	36.82
75 to 84 Years	649	649	5,529	208,938	432,948	580.6	498,048	628,426.6	1.30	321.94	8.52	37.79
85+ Years	114	114	888	30,809	61,549	85.8	303,368	361,224.4	0.38	270.25	7.79	34.69
<b>Pre-Existing Inclusion of AF, Dronedaron Incident with Respect to All Anti-Arrhythmics, 183-Day Exposure Washout Period/Lookback Period</b>												
00 to 40 Years	302	302	799	25,280	50,024	71.0	67,245	37,524.4	4.49	83.71	2.65	31.64
41 to 54 Years	2,344	2,344	9,930	332,871	662,747	936.7	185,225	133,614.5	12.65	142.01	4.24	33.52
55 to 64 Years	5,097	5,097	23,666	822,310	1,635,063	2,299.6	322,790	282,452.7	15.79	161.33	4.64	34.75
65 to 74 Years	5,054	5,054	22,596	863,226	1,710,349	2,402.4	426,176	452,496.5	11.86	170.80	4.47	38.20
75 to 84 Years	3,819	3,819	16,757	631,243	1,247,098	1,760.3	497,831	627,614.8	7.67	165.29	4.39	37.67
85+ Years	1,061	1,061	4,825	173,505	338,825	483.2	303,221	360,914.3	3.50	163.53	4.55	35.96
<b>Pre-Existing Inclusion of AF, Flecainide Incident with Respect to All Anti-Arrhythmics, 183-Day Exposure Washout Period/Lookback Period</b>												
00 to 40 Years	1,587	1,587	6,653	230,990	494,115	644.1	67,245	37,271.4	23.60	145.55	4.19	34.72
41 to 54 Years	5,452	5,452	30,909	1,198,990	2,482,026	3,336.4	185,104	132,699.8	29.45	219.92	5.67	38.79
55 to 64 Years	7,946	7,946	50,613	2,134,536	4,455,030	5,916.7	322,443	281,146.2	24.64	268.63	6.37	42.17
65 to 74 Years	5,631	5,631	34,930	1,726,011	3,647,480	4,772.1	425,893	451,408.1	13.22	306.52	6.20	49.41
75 to 84 Years	2,851	2,851	16,714	771,998	1,552,679	2,137.2	497,625	626,918.0	5.73	270.78	5.86	46.19
85+ Years	536	536	2,512	105,527	210,436	292.8	303,193	360,757.1	1.77	196.88	4.69	42.01
<b>Pre-Existing Inclusion of AF, Propafenone Incident with Respect to All Anti-Arrhythmics, 183-Day Exposure Washout Period/Lookback Period</b>												
00 to 40 Years	840	840	2,798	84,236	202,382	235.8	67,245	37,379.6	12.49	100.28	3.33	30.11
41 to 54 Years	3,481	3,481	15,509	529,428	1,300,633	1,479.9	185,150	133,011.9	18.80	152.09	4.46	34.14
55 to 64 Years	5,173	5,173	28,017	1,004,103	2,646,177	2,794.6	322,554	281,474.8	16.04	194.10	5.42	35.84

**Table 2b: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product and Age Group (Pre-Existing Inclusion of Atrial Fibrillation, 183-Day Exposure Washout Period/Pre-Existing Condition Lookback Period, and Incidence is Defined with Respect to All Anti-Arrhythmic Drug Products)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
65 to 74 Years	4,470	4,470	22,955	949,298	2,639,372	2,637.5	425,956	451,326.2	10.49	212.37	5.14	41.35
75 to 84 Years	2,881	2,881	14,171	568,102	1,452,806	1,580.6	497,555	626,461.4	5.79	197.19	4.92	40.09
85+ Years	656	656	2,670	96,954	224,642	270.7	303,107	360,566.7	2.16	147.80	4.07	36.31
<b>Pre-Existing Inclusion of AF, Sotalol Incident with Respect to All Anti-Arrhythmics, 183-Day Exposure Washout Period/Lookback Period</b>												
00 to 40 Years	733	733	4,249	153,696	442,280	428.5	67,245	37,410.1	10.90	209.68	5.80	36.17
41 to 54 Years	3,874	3,874	26,205	964,319	1,993,689	2,687.5	185,195	133,165.6	20.92	248.92	6.76	36.80
55 to 64 Years	8,306	8,306	58,449	2,212,488	4,425,043	6,143.3	322,537	281,155.4	25.75	266.37	7.04	37.85
65 to 74 Years	9,194	9,194	64,416	2,869,346	5,563,312	7,941.6	425,754	450,538.3	21.59	312.09	7.01	44.54
75 to 84 Years	7,084	7,084	46,745	2,028,060	3,749,093	5,618.3	497,195	625,238.2	14.25	286.29	6.60	43.39
85+ Years	1,989	1,989	12,010	490,769	818,955	1,361.1	302,852	360,075.5	6.57	246.74	6.04	40.86

**Table 3a: Summary of Incident Anti-Arhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Sex (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<b>Amiodarone</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	47,669	47,669	157,383	6,220,177	8,063,864	17,268.8	747,862	932,975.0	63.74	130.49	3.30	39.52
Male	77,194	77,194	233,683	9,272,106	13,323,501	25,751.5	910,215	1,146,418.9	84.81	120.11	3.03	39.68
Unknown	13	13	22	961	1,794	2.7	323	215.0	40.25	73.92	1.69	43.68
<i>365-Day Exposure Washout Period/Lookback Period</i>												
Female	47,017	47,017	155,395	6,109,104	7,984,608	16,961.5	786,096	1,183,434.2	59.81	129.93	3.31	39.31
Male	76,081	76,081	230,652	9,089,131	13,136,489	25,245.1	951,093	1,442,562.9	79.99	119.47	3.03	39.41
Unknown	13	13	22	961	1,794	2.7	356	267.8	36.52	73.92	1.69	43.68
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	22,164	22,164	71,376	2,905,954	3,774,216	8,064.2	672,181	1,021,678.9	32.97	131.11	3.22	40.71
Male	36,479	36,479	103,174	4,137,019	5,968,409	11,481.9	817,845	1,247,820.6	44.60	113.41	2.83	40.10
Unknown	9	9	14	649	1,230	1.8	265	252.5	33.96	72.11	1.56	46.36
<i>365-Day Exposure Washout Period/Lookback Period</i>												
Female	20,472	20,472	65,492	2,655,205	3,480,734	7,368.7	649,339	1,007,470.0	31.53	129.70	3.20	40.54
Male	34,106	34,106	95,794	3,805,459	5,529,132	10,561.3	782,801	1,229,483.3	43.57	111.58	2.81	39.73
Unknown	9	9	14	649	1,230	1.8	267	236.3	33.71	72.11	1.56	46.36
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	12,716	12,716	42,016	1,750,272	2,293,419	4,856.1	642,171	1,076,094.3	19.80	137.64	3.30	41.66
Male	14,580	14,580	45,728	1,890,248	2,779,487	5,246.0	759,839	1,332,682.7	19.19	129.65	3.14	41.34
Unknown	4	4	9	504	950	1.4	248	280.3	16.13	126.00	2.25	56.00
<i>365-Day Exposure Washout Period/Lookback Period</i>												
Female	11,078	11,078	36,447	1,515,114	2,005,047	4,203.2	570,753	928,830.3	19.41	136.77	3.29	41.57
Male	12,762	12,762	39,916	1,635,738	2,454,890	4,540.0	633,633	1,074,865.0	20.14	128.17	3.13	40.98
Unknown	4	4	9	504	950	1.4	227	238.0	17.62	126.00	2.25	56.00
<b>Dofetilide</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	2,250	2,250	18,650	676,275	1,440,223	1,876.5	763,051	1,035,828.3	2.95	300.57	8.29	36.26
Male	4,841	4,841	40,962	1,528,411	3,479,332	4,244.2	938,223	1,301,006.9	5.16	315.72	8.46	37.31
Unknown	0	0	0	0	0	0.0	325	256.4	0.00	---	---	---
<i>365-Day Exposure Washout Period/Lookback Period</i>												

**Table 3a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Sex (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
Female	2,224	2,224	18,453	671,351	1,435,070	1,862.7	805,486	1,309,626.0	2.76	301.87	8.30	36.38
Male	4,780	4,780	40,752	1,519,450	3,459,620	4,219.1	987,444	1,638,484.9	4.84	317.88	8.53	37.29
Unknown	0	0	0	0	0	0.0	360	317.0	0.00	---	---	---
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	1,303	1,303	10,655	396,980	853,508	1,100.7	684,986	1,118,194.4	1.90	304.67	8.18	37.26
Male	2,537	2,537	21,873	824,864	1,794,942	2,289.5	840,358	1,390,595.9	3.02	325.13	8.62	37.71
Unknown	0	0	0	0	0	0.0	267	298.6	0.00	---	---	---
<i>365-Day Exposure Washout Period/Lookback Period</i>												
Female	1,187	1,187	9,820	369,461	793,473	1,023.9	662,856	1,090,840.3	1.79	311.26	8.27	37.62
Male	2,346	2,346	20,193	759,654	1,655,064	2,108.5	805,916	1,355,914.3	2.91	323.81	8.61	37.62
Unknown	0	0	0	0	0	0.0	271	277.0	0.00	---	---	---
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	849	849	6,777	255,918	555,282	709.2	653,265	1,168,771.2	1.30	301.43	7.98	37.76
Male	1,453	1,453	12,001	459,388	1,029,496	1,274.9	777,699	1,463,703.3	1.87	316.17	8.26	38.28
Unknown	0	0	0	0	0	0.0	249	313.2	0.00	---	---	---
<i>365-Day Exposure Washout Period/Lookback Period</i>												
Female	723	723	5,997	228,314	493,777	632.3	580,796	997,511.0	1.24	315.79	8.29	38.07
Male	1,277	1,277	10,553	402,443	908,726	1,117.1	647,643	1,166,432.1	1.97	315.15	8.26	38.14
Unknown	0	0	0	0	0	0.0	230	272.5	0.00	---	---	---
<b>Dronedaron</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	10,396	10,396	48,009	1,790,173	3,532,216	4,990.0	762,621	1,026,476.2	13.63	172.20	4.62	37.29
Male	16,114	16,114	73,885	2,765,707	5,487,835	7,722.9	938,044	1,288,905.7	17.18	171.63	4.59	37.43
Unknown	3	3	49	1,451	2,902	4.1	325	251.7	9.23	483.67	16.33	29.61
<i>365-Day Exposure Washout Period/Lookback Period</i>												
Female	10,495	10,495	48,555	1,810,180	3,572,568	5,046.0	804,765	1,299,307.5	13.04	172.48	4.63	37.28
Male	16,309	16,309	74,977	2,806,666	5,569,055	7,837.1	986,841	1,624,828.6	16.53	172.09	4.60	37.43
Unknown	3	3	49	1,451	2,902	4.1	360	312.3	8.33	483.67	16.33	29.61
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	7,266	7,266	34,033	1,290,678	2,553,364	3,597.8	684,486	1,110,590.9	10.62	177.63	4.68	37.92

**Table 3a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Sex (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
Male	11,423	11,423	53,126	1,997,004	3,965,586	5,575.6	839,923	1,380,455.1	13.60	174.82	4.65	37.59
Unknown	3	3	49	1,451	2,902	4.1	267	294.0	11.24	483.67	16.33	29.61
<i>365-Day Exposure Washout Period/Lookback Period</i>												
Female	6,914	6,914	32,341	1,225,580	2,425,969	3,416.2	662,148	1,083,469.0	10.44	177.26	4.68	37.90
Male	10,896	10,896	50,874	1,911,540	3,797,135	5,337.0	805,001	1,345,154.7	13.54	175.44	4.67	37.57
Unknown	3	3	49	1,451	2,902	4.1	271	274.1	11.07	483.67	16.33	29.61
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	5,026	5,026	23,424	888,747	1,759,512	2,476.4	652,771	1,161,585.6	7.70	176.83	4.66	37.94
Male	7,013	7,013	32,241	1,181,059	2,347,219	3,300.5	777,389	1,454,347.1	9.02	168.41	4.60	36.63
Unknown	3	3	49	1,451	2,902	4.1	249	308.6	12.05	483.67	16.33	29.61
<i>365-Day Exposure Washout Period/Lookback Period</i>												
Female	4,553	4,553	21,263	802,912	1,590,382	2,237.4	580,234	991,709.8	7.85	176.35	4.67	37.76
Male	6,306	6,306	29,148	1,065,255	2,116,217	2,977.6	646,985	1,158,880.9	9.75	168.93	4.62	36.55
Unknown	3	3	49	1,451	2,902	4.1	230	269.5	13.04	483.67	16.33	29.61
<b>Flecainide</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	13,285	13,285	83,425	3,715,803	7,727,906	10,291.2	756,360	1,002,832.7	17.56	279.70	6.28	44.54
Male	16,864	16,864	103,245	4,434,511	9,343,963	12,296.1	930,591	1,265,533.4	18.12	262.96	6.12	42.95
Unknown	2	2	29	2,075	4,150	5.8	325	250.2	6.15	1037.50	14.50	71.55
<i>365-Day Exposure Washout Period/Lookback Period</i>												
Female	13,302	13,302	84,210	3,746,563	7,784,947	10,376.7	797,498	1,268,765.5	16.68	281.65	6.33	44.49
Male	16,871	16,871	104,230	4,475,567	9,432,576	12,410.1	978,410	1,592,464.4	17.24	265.28	6.18	42.94
Unknown	2	2	29	2,075	4,150	5.8	360	310.8	5.56	1037.50	14.50	71.55
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	11,351	11,351	72,417	3,247,526	6,708,176	8,992.5	678,197	1,084,622.3	16.74	286.10	6.38	44.84
Male	14,990	14,990	92,454	3,987,737	8,415,557	11,056.4	832,422	1,353,851.2	18.01	266.03	6.17	43.13
Unknown	2	2	29	2,075	4,150	5.8	267	293.7	7.49	1037.50	14.50	71.55
<i>365-Day Exposure Washout Period/Lookback Period</i>												
Female	11,031	11,031	71,186	3,197,245	6,594,730	8,853.1	654,875	1,053,598.7	16.84	289.84	6.45	44.91
Male	14,685	14,685	91,768	3,964,093	8,364,060	10,990.8	796,332	1,310,385.6	18.44	269.94	6.25	43.20
Unknown	2	2	29	2,075	4,150	5.8	271	272.1	7.38	1037.50	14.50	71.55

**Table 3a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Sex (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	9,682	9,682	61,995	2,816,221	5,841,043	7,797.7	646,512	1,134,079.3	14.98	290.87	6.40	45.43
Male	12,906	12,906	79,389	3,455,434	7,225,226	9,577.9	769,683	1,424,953.8	16.77	267.74	6.15	43.53
Unknown	1	1	2	60	120	0.2	249	301.8	4.02	60.00	2.00	30.00
<i>365-Day Exposure Washout Period/Lookback Period</i>												
Female	9,103	9,103	58,983	2,693,417	5,576,672	7,457.3	573,147	962,598.6	15.88	295.88	6.48	45.66
Male	12,204	12,204	76,112	3,322,694	6,953,214	9,210.1	638,158	1,123,265.5	19.12	272.26	6.24	43.66
Unknown	1	1	2	60	120	0.2	230	266.1	4.35	60.00	2.00	30.00
<b>Propafenone</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	9,767	9,767	51,385	2,025,964	5,471,804	5,631.9	757,930	1,009,792.4	12.89	207.43	5.26	39.43
Male	12,652	12,652	61,819	2,366,542	6,126,538	6,585.5	932,917	1,275,130.2	13.56	187.05	4.89	38.28
Unknown	1	1	1	30	60	0.1	325	250.4	3.08	30.00	1.00	30.00
<i>365-Day Exposure Washout Period/Lookback Period</i>												
Female	9,748	9,748	51,848	2,041,511	5,518,834	5,675.8	799,367	1,276,914.0	12.19	209.43	5.32	39.37
Male	12,503	12,503	61,222	2,347,102	6,094,030	6,530.8	980,883	1,604,563.0	12.75	187.72	4.90	38.34
Unknown	1	1	1	30	60	0.1	359	309.4	2.79	30.00	1.00	30.00
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	7,664	7,664	41,678	1,650,386	4,413,343	4,586.5	679,823	1,091,415.2	11.27	215.34	5.44	39.60
Male	10,582	10,582	52,342	2,014,573	5,217,116	5,603.9	834,818	1,363,956.5	12.68	190.38	4.95	38.49
Unknown	0	0	0	0	0	0.0	267	296.9	0.00	---	---	---
<i>365-Day Exposure Washout Period/Lookback Period</i>												
Female	7,353	7,353	40,580	1,610,018	4,261,340	4,474.3	656,856	1,062,083.0	11.19	218.96	5.52	39.68
Male	10,157	10,157	50,419	1,940,589	5,047,762	5,397.7	798,978	1,323,294.9	12.71	191.06	4.96	38.49
Unknown	0	0	0	0	0	0.0	270	274.0	0.00	---	---	---
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	6,110	6,110	33,071	1,321,462	3,564,852	3,670.1	648,241	1,140,935.5	9.43	216.28	5.41	39.96
Male	8,263	8,263	40,556	1,551,894	3,899,106	4,316.6	772,251	1,436,026.9	10.70	187.81	4.91	38.27
Unknown	0	0	0	0	0	0.0	249	311.5	0.00	---	---	---
<i>365-Day Exposure Washout Period/Lookback Period</i>												

**Table 3a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Sex (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
Female	5,623	5,623	30,904	1,235,701	3,295,534	3,432.3	575,331	971,493.8	9.77	219.76	5.50	39.99
Male	7,636	7,636	37,877	1,450,720	3,660,661	4,034.7	641,281	1,137,484.0	11.91	189.98	4.96	38.30
Unknown	0	0	0	0	0	0.0	229	269.4	0.00	---	---	---
<b>Sotalol</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	15,972	15,972	111,773	4,649,888	8,837,157	12,878.3	752,590	988,187.8	21.22	291.13	7.00	41.60
Male	22,630	22,630	151,595	6,328,995	12,704,699	17,552.8	923,799	1,241,180.8	24.50	279.67	6.70	41.75
Unknown	3	3	10	320	760	0.9	325	247.4	9.23	106.67	3.33	32.00
<i>365-Day Exposure Washout Period/Lookback Period</i>												
Female	15,798	15,798	112,373	4,655,003	8,849,398	12,892.8	793,086	1,251,680.7	19.92	294.66	7.11	41.42
Male	22,402	22,402	152,055	6,351,450	12,744,930	17,613.7	970,185	1,563,998.7	23.09	283.52	6.79	41.77
Unknown	3	3	10	320	760	0.9	360	306.2	8.33	106.67	3.33	32.00
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	10,666	10,666	76,534	3,248,909	6,231,816	8,991.4	674,888	1,069,372.2	15.80	304.60	7.18	42.45
Male	14,849	14,849	99,052	4,193,155	8,277,750	11,628.8	826,568	1,329,905.8	17.96	282.39	6.67	42.33
Unknown	2	2	5	170	460	0.5	267	281.8	7.49	85.00	2.50	34.00
<i>365-Day Exposure Washout Period/Lookback Period</i>												
Female	10,012	10,012	73,474	3,110,441	5,970,207	8,608.0	651,676	1,043,091.7	15.36	310.67	7.34	42.33
Male	13,950	13,950	94,486	4,005,316	7,901,008	11,106.9	790,797	1,294,688.6	17.64	287.12	6.77	42.39
Unknown	2	2	5	170	460	0.5	271	263.0	7.38	85.00	2.50	34.00
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
Female	7,067	7,067	51,257	2,192,441	4,229,267	6,066.0	643,984	1,118,836.2	10.97	310.24	7.25	42.77
Male	8,395	8,395	54,067	2,276,625	4,506,901	6,315.0	765,746	1,402,079.5	10.96	271.19	6.44	42.11
Unknown	1	1	4	120	360	0.3	249	311.4	4.02	120.00	4.00	30.00
<i>365-Day Exposure Washout Period/Lookback Period</i>												
Female	6,319	6,319	46,594	1,994,296	3,857,243	5,517.2	571,814	956,795.4	11.05	315.60	7.37	42.80
Male	7,464	7,464	48,945	2,070,737	4,110,986	5,743.3	636,914	1,118,588.6	11.72	277.43	6.56	42.31
Unknown	1	1	4	120	360	0.3	230	270.6	4.35	120.00	4.00	30.00

**Table 3b: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product and Sex (Pre-Existing Inclusion of Atrial Fibrillation, 183-Day Exposure Washout Period/Pre-Existing Condition Lookback Period, and Incidence is Defined with Respect to All Anti-Arrhythmic Drug Products)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<b>Amiodarone</b>												
Female	41,376	41,376	134,342	5,273,855	6,736,483	14,642.1	717,426	833,084.2	57.67	127.46	3.25	39.26
Male	68,961	68,961	203,534	8,028,410	11,253,644	22,297.5	867,683	1,011,915.1	79.48	116.42	2.95	39.45
Unknown	12	12	21	936	1,694	2.6	323	208.7	37.15	78.00	1.75	44.57
<b>Dofetilide</b>												
Female	1,084	1,084	8,870	318,188	661,632	883.6	717,426	854,053.7	1.51	293.53	8.18	35.87
Male	2,558	2,558	22,192	825,852	1,965,536	2,294.8	867,683	1,043,303.5	2.95	322.85	8.68	37.21
Unknown	0	0	0	0	0	0.0	323	217.8	0.00	---	---	---
<b>Dronedaron</b>												
Female	6,963	6,963	31,449	1,144,558	2,262,576	3,191.4	717,426	852,922.4	9.71	164.38	4.52	36.39
Male	10,713	10,713	47,098	1,703,106	3,379,988	4,759.5	867,683	1,041,476.9	12.35	158.98	4.40	36.16
Unknown	1	1	26	771	1,542	2.2	323	217.8	3.10	771.00	26.00	29.65
<b>Flecainide</b>												
Female	10,554	10,554	63,565	2,813,341	5,773,572	7,794.9	717,426	850,653.9	14.71	266.57	6.02	44.26
Male	13,447	13,447	78,737	3,352,651	7,064,074	9,298.6	867,683	1,039,328.9	15.50	249.32	5.86	42.58
Unknown	2	2	29	2,060	4,120	5.7	323	217.8	6.19	1030.00	14.50	71.03
<b>Propafenone</b>												
Female	7,490	7,490	38,614	1,471,823	3,905,013	4,095.7	717,426	850,588.8	10.44	196.51	5.16	38.12
Male	10,011	10,011	47,506	1,760,298	4,560,999	4,903.4	867,683	1,039,413.8	11.54	175.84	4.75	37.05
Unknown	0	0	0	0	0	0.0	323	217.8	0.00	---	---	---
<b>Sotalol</b>												
Female	13,015	13,015	90,960	3,741,820	7,043,964	10,368.5	717,426	849,716.4	18.14	287.50	6.99	41.14
Male	18,162	18,162	121,104	4,976,572	9,947,716	13,810.9	867,683	1,037,653.1	20.93	274.01	6.67	41.09
Unknown	3	3	10	286	692	0.8	323	213.6	9.29	95.33	3.33	28.60



**Table 4a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Year (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<b>Amiodarone</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
2000	8	8	55	2,668	3,359	7.5	39,417	107.9	0.20	333.50	6.88	48.51
2001	4,057	4,057	15,076	653,917	912,547	1,813.6	80,735	38,659.6	50.25	161.18	3.72	43.37
2002	4,248	4,248	14,566	630,423	883,544	1,749.5	84,397	40,718.6	50.33	148.40	3.43	43.28
2003	4,175	4,175	14,340	600,949	861,356	1,669.0	93,540	46,917.1	44.63	143.94	3.43	41.91
2004	3,952	3,952	12,684	530,542	1,288,093	1,472.3	102,791	50,491.0	38.45	134.25	3.21	41.83
2005	3,903	3,903	10,968	494,738	677,667	1,369.2	113,383	60,296.2	34.42	126.76	2.81	45.11
2006	3,271	3,271	9,293	441,927	612,044	1,222.7	106,318	58,440.5	30.77	135.10	2.84	47.55
2007	8,340	8,340	27,838	1,127,454	1,492,259	3,131.1	262,223	147,874.2	31.80	135.19	3.34	40.50
2008	10,929	10,929	36,696	1,437,431	1,882,169	3,992.4	491,618	199,289.4	22.23	131.52	3.36	39.17
2009	19,605	19,605	63,931	2,453,276	3,216,381	6,818.9	586,273	338,317.5	33.44	125.14	3.26	38.37
2010	19,643	19,643	61,364	2,378,590	3,159,088	6,607.1	595,033	349,402.6	33.01	121.09	3.12	38.76
2011	20,707	20,707	63,667	2,471,084	3,295,848	6,863.7	616,486	368,041.3	33.59	119.34	3.07	38.81
2012	22,038	22,038	60,610	2,270,245	3,104,806	6,306.0	683,047	381,053.0	32.26	103.02	2.75	37.46
<i>365-Day Exposure Washout Period/Lookback Period</i>												
2000	7	7	37	2,128	2,789	6.0	57,142	156.4	0.12	304.00	5.29	57.51
2001	3,987	3,987	14,783	631,220	889,959	1,751.1	89,920	53,520.8	44.34	158.32	3.71	42.70
2002	4,190	4,190	14,479	621,762	875,315	1,725.3	94,641	56,401.0	44.27	148.39	3.46	42.94
2003	4,156	4,156	14,358	599,438	859,373	1,664.7	103,067	63,156.3	40.32	144.23	3.45	41.75
2004	3,957	3,957	12,760	532,723	1,317,815	1,478.1	114,196	68,209.0	34.65	134.63	3.22	41.75
2005	3,886	3,886	10,961	493,746	675,186	1,366.5	123,956	79,286.1	31.35	127.06	2.82	45.05
2006	3,268	3,268	9,309	442,124	611,330	1,223.1	113,938	75,420.2	28.68	135.29	2.85	47.49
2007	8,145	8,145	27,182	1,091,985	1,457,629	3,033.4	283,024	189,680.5	28.78	134.07	3.34	40.17
2008	10,721	10,721	36,205	1,403,416	1,850,267	3,898.3	558,334	251,472.9	19.20	130.90	3.38	38.76
2009	19,202	19,202	62,606	2,383,888	3,148,073	6,626.6	641,551	425,630.7	29.93	124.15	3.26	38.08
2010	19,351	19,351	60,392	2,322,101	3,099,440	6,450.6	644,960	434,600.7	30.00	120.00	3.12	38.45
2011	20,457	20,457	62,957	2,435,564	3,261,344	6,765.6	664,975	456,280.5	30.76	119.06	3.08	38.69
2012	21,784	21,784	60,040	2,239,101	3,074,371	6,219.9	744,318	472,449.7	29.27	102.79	2.76	37.29
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
2000	4	4	28	776	1,051	2.2	34,860	100.2	0.11	194.00	7.00	27.71

**Table 4a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Year (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2001	1,939	1,939	6,777	312,327	431,605	864.7	72,962	39,950.0	26.58	161.08	3.50	46.09
2002	2,053	2,053	6,675	298,657	415,874	827.6	78,818	48,855.4	26.05	145.47	3.25	44.74
2003	1,942	1,942	6,280	269,139	405,502	746.6	89,485	60,595.9	21.70	138.59	3.23	42.86
2004	1,838	1,838	5,819	257,639	610,338	714.4	99,478	68,118.5	18.48	140.17	3.17	44.28
2005	1,799	1,799	4,761	218,080	303,525	603.2	109,959	80,087.9	16.36	121.22	2.65	45.81
2006	1,581	1,581	4,317	209,604	286,559	579.3	104,331	76,952.7	15.15	132.58	2.73	48.55
2007	3,999	3,999	12,743	523,671	694,667	1,454.4	245,987	164,993.8	16.26	130.95	3.19	41.09
2008	5,065	5,065	16,635	654,472	862,450	1,818.4	448,959	219,782.0	11.28	129.21	3.28	39.34
2009	9,141	9,141	27,840	1,094,105	1,432,725	3,038.4	540,602	355,899.1	16.91	119.69	3.05	39.30
2010	9,100	9,100	26,789	1,046,125	1,400,409	2,904.9	552,534	375,284.6	16.47	114.96	2.94	39.05
2011	9,792	9,792	28,449	1,118,973	1,479,560	3,105.9	571,921	391,576.7	17.12	114.27	2.91	39.33
2012	10,399	10,399	27,451	1,040,054	1,419,588	2,887.8	618,552	387,555.2	16.81	100.01	2.64	37.89
<i>365-Day Exposure Washout Period/Lookback Period</i>												
2000	2	2	3	67	142	0.2	45,724	125.2	0.04	33.50	1.50	22.33
2001	1,831	1,831	6,341	288,257	405,912	798.3	73,963	44,291.8	24.76	157.43	3.46	45.46
2002	1,913	1,913	6,217	278,070	387,355	770.3	79,448	49,731.8	24.08	145.36	3.25	44.73
2003	1,858	1,858	5,941	257,264	387,870	713.6	88,454	58,986.0	21.01	138.46	3.20	43.30
2004	1,733	1,733	5,446	241,986	558,849	670.7	99,256	66,283.9	17.46	139.63	3.14	44.43
2005	1,690	1,690	4,476	205,678	286,453	568.9	108,862	77,983.6	15.52	121.70	2.65	45.95
2006	1,505	1,505	4,011	193,239	267,807	533.9	101,753	74,423.4	14.79	128.40	2.67	48.18
2007	3,725	3,725	11,603	467,801	632,446	1,299.7	242,345	168,630.9	15.37	125.58	3.11	40.32
2008	4,684	4,684	15,354	595,252	794,932	1,654.1	456,537	216,682.7	10.26	127.08	3.28	38.77
2009	8,431	8,431	25,467	991,325	1,309,411	2,753.1	532,430	357,102.8	15.83	117.58	3.02	38.93
2010	8,455	8,455	24,723	958,855	1,293,650	2,662.4	534,815	365,453.7	15.81	113.41	2.92	38.78
2011	9,105	9,105	26,374	1,031,078	1,372,792	2,862.0	547,274	378,214.1	16.64	113.24	2.90	39.09
2012	9,655	9,655	25,344	952,441	1,313,479	2,644.6	597,303	379,279.5	16.16	98.65	2.62	37.58
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
2000	2	2	25	709	909	2.1	33,280	97.0	0.06	354.50	12.50	28.36
2001	952	952	3,593	168,178	237,034	465.6	70,291	40,002.5	13.54	176.66	3.77	46.81
2002	962	962	3,480	165,673	230,455	458.8	77,518	51,221.4	12.41	172.22	3.62	47.61
2003	842	842	2,992	135,685	218,579	376.1	89,251	65,115.6	9.43	161.15	3.55	45.35

**Table 4a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Year (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2004	828	828	2,777	135,172	365,533	374.4	100,008	74,601.0	8.28	163.25	3.35	48.68
2005	822	822	2,465	121,642	165,466	336.5	110,837	88,182.1	7.42	147.98	3.00	49.35
2006	727	727	2,314	122,811	161,306	339.4	105,591	85,781.6	6.89	168.93	3.18	53.07
2007	1,807	1,807	6,534	273,504	359,788	759.3	239,277	173,304.4	7.55	151.36	3.62	41.86
2008	2,267	2,267	8,185	327,938	436,811	911.5	426,158	231,496.4	5.32	144.66	3.61	40.07
2009	4,075	4,075	13,197	537,581	703,173	1,492.9	515,997	367,684.4	7.90	131.92	3.24	40.74
2010	4,219	4,219	13,125	518,196	686,957	1,438.8	533,660	397,646.1	7.91	122.82	3.11	39.48
2011	4,712	4,712	14,840	591,035	769,369	1,640.9	555,135	419,763.9	8.49	125.43	3.15	39.83
2012	5,085	5,085	14,226	542,900	738,477	1,507.2	593,211	414,160.9	8.57	106.76	2.80	38.16
<i>365-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	40,941	112.1	0.00	---	---	---
2001	849	849	3,217	152,839	217,231	423.1	66,295	40,065.9	12.81	180.02	3.79	47.51
2002	855	855	3,124	150,368	208,811	416.1	72,251	46,154.6	11.83	175.87	3.65	48.13
2003	750	750	2,639	122,563	198,022	339.5	81,879	56,464.8	9.16	163.42	3.52	46.44
2004	744	744	2,504	121,194	346,890	335.5	93,101	65,040.3	7.99	162.90	3.37	48.40
2005	729	729	2,206	110,379	149,034	305.0	103,013	77,291.6	7.08	151.41	3.03	50.04
2006	657	657	1,993	105,235	142,337	290.5	97,112	74,884.1	6.77	160.18	3.03	52.80
2007	1,578	1,578	5,634	231,317	308,581	642.5	214,898	154,836.8	7.34	146.59	3.57	41.06
2008	1,975	1,975	7,217	282,413	379,190	785.5	384,852	195,512.2	5.13	142.99	3.65	39.13
2009	3,527	3,527	11,449	462,368	608,029	1,284.1	450,016	309,296.5	7.84	131.09	3.25	40.39
2010	3,668	3,668	11,313	441,260	591,274	1,225.5	454,440	320,122.5	8.07	120.30	3.08	39.00
2011	4,099	4,099	12,808	506,294	670,137	1,406.0	466,796	332,716.6	8.78	123.52	3.12	39.53
2012	4,413	4,413	12,268	465,126	641,350	1,291.4	504,109	331,435.3	8.75	105.40	2.78	37.91
<b>Dofetilide</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	43,919	120.2	0.00	---	---	---
2001	48	48	575	17,451	34,866	48.2	85,776	43,555.6	0.56	363.56	11.98	30.35
2002	74	74	1,265	43,809	273,991	120.5	91,263	46,754.6	0.81	592.01	17.09	34.63
2003	60	60	655	20,366	100,854	56.3	102,291	54,170.5	0.59	339.43	10.92	31.09
2004	67	67	663	24,858	53,630	68.9	113,563	58,733.5	0.59	371.01	9.90	37.49
2005	78	78	644	24,011	48,816	66.2	125,374	69,810.6	0.62	307.83	8.26	37.28

**Table 4a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Year (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2006	87	87	941	38,567	80,781	107.0	117,062	67,211.8	0.74	443.30	10.82	40.99
2007	462	462	4,913	191,605	412,414	531.7	281,086	165,042.2	1.64	414.73	10.63	39.00
2008	657	657	7,358	261,389	546,454	726.1	529,685	221,807.9	1.24	397.85	11.20	35.52
2009	1,291	1,291	12,520	466,974	1,016,945	1,296.0	625,896	375,418.8	2.06	361.71	9.70	37.30
2010	1,238	1,238	10,448	401,935	856,615	1,115.5	639,588	390,095.6	1.94	324.66	8.44	38.47
2011	1,476	1,476	11,211	412,022	869,039	1,145.0	665,803	413,218.6	2.22	279.15	7.60	36.75
2012	1,553	1,553	8,419	301,699	625,150	839.4	742,023	431,151.8	2.09	194.27	5.42	35.84
<i>365-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	63,519	173.9	0.00	---	---	---
2001	46	46	474	14,421	28,806	39.7	96,459	60,435.7	0.48	313.50	10.30	30.42
2002	74	74	1,265	43,809	273,991	120.5	103,068	64,650.9	0.72	592.01	17.09	34.63
2003	60	60	655	20,366	100,854	56.3	113,341	72,856.6	0.53	339.43	10.92	31.09
2004	68	68	677	25,227	54,388	69.9	126,676	79,089.4	0.54	370.99	9.96	37.26
2005	79	79	645	24,041	48,876	66.3	137,679	91,578.0	0.57	304.32	8.16	37.27
2006	88	88	943	38,620	80,887	107.2	125,782	86,491.2	0.70	438.86	10.72	40.95
2007	460	460	4,910	191,492	412,248	531.3	305,246	211,958.1	1.51	416.29	10.67	39.00
2008	652	652	7,414	263,130	552,856	731.0	604,919	280,198.5	1.08	403.57	11.37	35.49
2009	1,266	1,266	12,455	465,020	1,013,666	1,290.5	688,207	472,688.1	1.84	367.31	9.84	37.34
2010	1,229	1,229	10,395	401,555	855,495	1,114.4	695,697	484,669.3	1.77	326.73	8.46	38.63
2011	1,459	1,459	11,132	407,833	860,601	1,133.2	720,302	511,123.9	2.03	279.53	7.63	36.64
2012	1,523	1,523	8,240	295,287	612,022	821.4	810,215	532,514.4	1.88	193.89	5.41	35.84
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	38,609	111.0	0.00	---	---	---
2001	25	25	317	9,647	19,258	26.7	77,319	44,784.3	0.32	385.88	12.68	30.43
2002	37	37	667	24,225	53,854	66.6	84,610	55,674.7	0.44	654.73	18.03	36.32
2003	36	36	368	11,480	83,082	31.6	96,696	69,253.5	0.37	318.89	10.22	31.20
2004	37	37	398	16,435	34,066	45.5	108,073	78,054.3	0.34	444.19	10.76	41.29
2005	45	45	353	13,177	27,094	36.4	119,216	91,267.7	0.38	292.82	7.84	37.33
2006	40	40	396	16,091	32,642	44.7	112,285	86,855.8	0.36	402.28	9.90	40.63
2007	259	259	2,713	104,923	225,415	291.3	260,761	182,329.5	0.99	405.11	10.47	38.67
2008	347	347	4,063	142,313	294,578	395.4	477,796	241,858.0	0.73	410.12	11.71	35.03

**Table 4a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Year (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2009	696	696	6,813	259,993	562,174	721.1	570,288	390,061.6	1.22	373.55	9.79	38.16
2010	670	670	5,747	225,051	483,382	624.1	584,348	412,044.5	1.15	335.90	8.58	39.16
2011	804	804	6,180	231,745	484,356	643.3	605,502	430,217.6	1.33	288.24	7.69	37.50
2012	844	844	4,513	166,764	348,549	463.5	657,133	426,576.5	1.28	197.59	5.35	36.95
<i>365-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	50,240	137.5	0.00	---	---	---
2001	20	20	205	6,336	12,636	17.5	78,718	49,338.9	0.25	316.80	10.25	30.91
2002	36	36	603	22,275	49,924	61.2	85,520	56,120.8	0.42	618.75	16.75	36.94
2003	31	31	286	8,568	77,258	23.6	95,791	66,866.2	0.32	276.39	9.23	29.96
2004	32	32	379	15,840	32,876	43.8	107,977	75,130.1	0.30	495.00	11.84	41.79
2005	39	39	319	11,725	24,160	32.4	118,243	87,907.9	0.33	300.64	8.18	36.76
2006	39	39	394	16,031	32,522	44.5	109,558	83,094.8	0.36	411.05	10.10	40.69
2007	238	238	2,469	95,992	207,299	266.5	257,359	184,821.5	0.92	403.33	10.37	38.88
2008	323	323	3,875	135,209	279,830	375.8	485,762	236,538.5	0.66	418.60	12.00	34.89
2009	629	629	6,241	240,148	510,598	665.7	561,509	387,482.9	1.12	381.79	9.92	38.48
2010	617	617	5,265	204,687	442,043	567.7	564,955	396,841.7	1.09	331.75	8.53	38.88
2011	749	749	5,803	218,068	456,783	605.1	578,703	410,754.0	1.29	291.15	7.75	37.58
2012	780	780	4,174	154,236	322,608	428.6	632,544	411,996.7	1.23	197.74	5.35	36.95
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	36,842	107.4	0.00	---	---	---
2001	12	12	95	3,051	6,112	8.4	74,419	44,761.7	0.16	254.25	7.92	32.12
2002	26	26	454	17,756	40,878	48.8	82,888	58,048.4	0.31	682.92	17.46	39.11
2003	22	22	236	7,447	75,001	20.5	95,750	73,785.4	0.23	338.50	10.73	31.56
2004	23	23	216	10,735	21,706	29.7	107,628	84,507.9	0.21	466.74	9.39	49.70
2005	29	29	252	9,692	20,040	26.8	118,881	99,169.6	0.24	334.21	8.69	38.46
2006	29	29	292	12,071	24,602	33.4	112,265	95,418.3	0.26	416.24	10.07	41.34
2007	157	157	1,593	62,156	134,966	172.5	251,876	189,807.3	0.62	395.90	10.15	39.02
2008	191	191	2,105	72,879	151,614	202.4	450,155	252,248.5	0.42	381.57	11.02	34.62
2009	382	382	3,491	135,944	299,932	377.0	540,185	399,209.9	0.71	355.87	9.14	38.94
2010	429	429	3,544	139,356	296,419	386.5	558,963	431,435.4	0.77	324.84	8.26	39.32
2011	506	506	3,934	148,218	308,773	411.1	581,061	455,006.2	0.87	292.92	7.77	37.68

**Table 4a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Year (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2012	496	496	2,566	96,001	204,735	266.9	622,385	449,281.8	0.80	193.55	5.17	37.41
<i>365-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	44,713	122.4	0.00	---	---	---
2001	10	10	88	2,867	5,744	7.9	70,251	44,338.2	0.14	286.70	8.80	32.58
2002	23	23	427	16,856	39,078	46.3	77,280	51,670.2	0.30	732.87	18.57	39.48
2003	17	17	151	4,437	68,981	12.2	87,935	63,298.6	0.19	261.00	8.88	29.38
2004	18	18	193	10,007	20,250	27.7	100,188	72,798.1	0.18	555.94	10.72	51.85
2005	27	27	249	9,482	19,620	26.2	110,579	85,995.1	0.24	351.19	9.22	38.08
2006	27	27	259	11,122	22,524	30.7	103,317	82,439.6	0.26	411.93	9.59	42.94
2007	137	137	1,398	54,178	118,756	150.5	226,176	167,824.7	0.61	395.46	10.20	38.75
2008	157	157	1,810	62,383	128,830	173.3	405,001	210,855.8	0.39	397.34	11.53	34.47
2009	325	325	3,115	121,775	264,218	337.4	469,764	331,460.6	0.69	374.69	9.58	39.09
2010	384	384	3,137	122,049	259,227	338.6	474,413	342,821.1	0.81	317.84	8.17	38.91
2011	445	445	3,530	133,330	278,854	369.9	487,200	355,972.4	0.91	299.62	7.93	37.77
2012	430	430	2,193	82,271	176,421	228.6	526,604	354,618.6	0.82	191.33	5.10	37.52
<b>Dronedaron</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	43,943	120.3	0.00	---	---	---
2001	0	0	0	0	0	0.0	85,786	43,591.2	0.00	---	---	---
2002	0	0	0	0	0	0.0	91,312	46,830.5	0.00	---	---	---
2003	0	0	0	0	0	0.0	102,405	54,289.7	0.00	---	---	---
2004	0	0	0	0	0	0.0	113,741	58,889.2	0.00	---	---	---
2005	0	0	0	0	0	0.0	125,602	70,022.9	0.00	---	---	---
2006	0	0	0	0	0	0.0	117,271	67,420.1	0.00	---	---	---
2007	0	0	0	0	0	0.0	281,904	165,959.7	0.00	---	---	---
2008	0	0	0	0	0	0.0	532,454	223,240.8	0.00	---	---	---
2009	3,235	3,235	17,196	668,116	1,326,937	1,863.4	628,794	377,977.8	5.14	206.53	5.32	38.85
2010	10,502	10,502	52,462	1,990,085	3,936,620	5,551.7	639,175	385,726.4	16.43	189.50	5.00	37.93
2011	7,974	7,974	35,107	1,296,676	2,568,197	3,620.6	656,682	402,294.2	12.14	162.61	4.40	36.93
2012	4,802	4,802	17,178	602,454	1,191,199	1,681.3	728,818	419,270.9	6.59	125.46	3.58	35.07
<i>365-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	63,543	174.0	0.00	---	---	---

**Table 4a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Year (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2001	0	0	0	0	0	0.0	96,477	60,478.9	0.00	---	---	---
2002	0	0	0	0	0	0.0	103,119	64,733.1	0.00	---	---	---
2003	0	0	0	0	0	0.0	113,461	72,993.5	0.00	---	---	---
2004	0	0	0	0	0	0.0	126,867	79,264.0	0.00	---	---	---
2005	0	0	0	0	0	0.0	137,923	91,823.5	0.00	---	---	---
2006	0	0	0	0	0	0.0	126,004	86,728.2	0.00	---	---	---
2007	0	0	0	0	0	0.0	306,168	213,018.2	0.00	---	---	---
2008	0	0	0	0	0	0.0	608,091	281,815.7	0.00	---	---	---
2009	3,290	3,290	17,423	679,109	1,348,626	1,893.8	691,401	475,665.5	4.76	206.42	5.30	38.98
2010	10,666	10,666	53,482	2,025,131	4,006,303	5,649.8	695,250	480,288.3	15.34	189.87	5.01	37.87
2011	8,044	8,044	35,470	1,311,563	2,598,259	3,662.2	710,494	498,846.9	11.32	163.05	4.41	36.98
2012	4,807	4,807	17,206	602,494	1,191,337	1,681.4	795,638	518,618.7	6.04	125.34	3.58	35.02
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	38,633	111.1	0.00	---	---	---
2001	0	0	0	0	0	0.0	77,331	44,820.8	0.00	---	---	---
2002	0	0	0	0	0	0.0	84,645	55,753.5	0.00	---	---	---
2003	0	0	0	0	0	0.0	96,782	69,376.3	0.00	---	---	---
2004	0	0	0	0	0	0.0	108,210	78,219.4	0.00	---	---	---
2005	0	0	0	0	0	0.0	119,391	91,499.4	0.00	---	---	---
2006	0	0	0	0	0	0.0	112,447	87,072.7	0.00	---	---	---
2007	0	0	0	0	0	0.0	261,481	183,228.7	0.00	---	---	---
2008	0	0	0	0	0	0.0	480,120	243,229.1	0.00	---	---	---
2009	2,211	2,211	11,872	472,667	938,717	1,318.0	572,677	392,407.1	3.86	213.78	5.37	39.81
2010	7,238	7,238	36,965	1,416,898	2,808,312	3,951.6	583,787	408,039.5	12.40	195.76	5.11	38.33
2011	5,643	5,643	25,245	937,783	1,861,476	2,618.8	598,080	420,673.6	9.44	166.19	4.47	37.15
2012	3,600	3,600	13,126	461,785	913,346	1,288.9	646,910	416,908.9	5.56	128.27	3.65	35.18
<i>365-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	50,262	137.6	0.00	---	---	---
2001	0	0	0	0	0	0.0	78,734	49,374.4	0.00	---	---	---
2002	0	0	0	0	0	0.0	85,554	56,184.3	0.00	---	---	---
2003	0	0	0	0	0	0.0	95,868	66,966.5	0.00	---	---	---

**Table 4a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Year (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2004	0	0	0	0	0	0.0	108,112	75,261.0	0.00	---	---	---
2005	0	0	0	0	0	0.0	118,412	88,103.1	0.00	---	---	---
2006	0	0	0	0	0	0.0	109,711	83,274.0	0.00	---	---	---
2007	0	0	0	0	0	0.0	258,070	185,623.1	0.00	---	---	---
2008	0	0	0	0	0	0.0	488,030	237,735.9	0.00	---	---	---
2009	2,089	2,089	11,293	452,721	899,563	1,262.1	563,795	389,561.0	3.71	216.72	5.41	40.09
2010	6,945	6,945	35,499	1,358,237	2,692,949	3,788.3	564,251	393,238.8	12.31	195.57	5.11	38.26
2011	5,378	5,378	24,125	893,779	1,775,223	2,496.1	571,165	401,386.6	9.42	166.19	4.49	37.05
2012	3,401	3,401	12,347	433,834	858,270	1,210.8	621,979	402,051.5	5.47	127.56	3.63	35.14

**Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft**

*183-Day Exposure Washout Period/Lookback Period*

2000	0	0	0	0	0	0.0	36,865	107.5	0.00	---	---	---
2001	0	0	0	0	0	0.0	74,430	44,798.8	0.00	---	---	---
2002	0	0	0	0	0	0.0	82,918	58,125.9	0.00	---	---	---
2003	0	0	0	0	0	0.0	95,823	73,904.8	0.00	---	---	---
2004	0	0	0	0	0	0.0	107,745	84,672.0	0.00	---	---	---
2005	0	0	0	0	0	0.0	119,031	99,399.2	0.00	---	---	---
2006	0	0	0	0	0	0.0	112,404	95,633.1	0.00	---	---	---
2007	0	0	0	0	0	0.0	252,522	190,664.5	0.00	---	---	---
2008	0	0	0	0	0	0.0	452,187	253,556.1	0.00	---	---	---
2009	1,450	1,450	7,732	300,935	597,882	839.0	542,263	401,403.0	2.67	207.54	5.33	38.92
2010	4,604	4,604	23,185	874,196	1,733,086	2,439.7	558,491	427,395.6	8.24	189.88	5.04	37.71
2011	3,627	3,627	16,156	592,934	1,178,835	1,656.2	575,061	445,949.7	6.31	163.48	4.45	36.70
2012	2,361	2,361	8,641	303,192	599,830	846.0	614,478	440,630.9	3.84	128.42	3.66	35.09

*365-Day Exposure Washout Period/Lookback Period*

2000	0	0	0	0	0	0.0	44,734	122.5	0.00	---	---	---
2001	0	0	0	0	0	0.0	70,266	44,370.5	0.00	---	---	---
2002	0	0	0	0	0	0.0	77,309	51,721.7	0.00	---	---	---
2003	0	0	0	0	0	0.0	87,994	63,380.6	0.00	---	---	---
2004	0	0	0	0	0	0.0	100,294	72,913.8	0.00	---	---	---
2005	0	0	0	0	0	0.0	110,720	86,170.9	0.00	---	---	---
2006	0	0	0	0	0	0.0	103,447	82,607.8	0.00	---	---	---



**Table 4a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Year (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2007	0	0	0	0	0	0.0	226,761	168,482.4	0.00	---	---	---
2008	0	0	0	0	0	0.0	406,713	211,806.6	0.00	---	---	---
2009	1,260	1,260	6,728	266,707	529,476	743.5	471,500	333,029.1	2.67	211.67	5.34	39.64
2010	4,192	4,192	21,243	794,640	1,574,953	2,218.7	473,819	339,937.1	8.85	189.56	5.07	37.41
2011	3,277	3,277	14,749	536,570	1,067,039	1,499.0	481,821	348,852.2	6.80	163.74	4.50	36.38
2012	2,133	2,133	7,740	271,701	538,033	757.9	519,371	347,465.0	4.11	127.38	3.63	35.10
<b>Flecainide</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	43,163	118.2	0.00	---	---	---
2001	534	534	4,335	214,922	448,931	593.6	84,937	42,744.7	6.29	402.48	8.12	49.58
2002	468	468	4,509	238,920	506,697	660.0	90,116	45,819.8	5.19	510.51	9.63	52.99
2003	454	454	4,104	231,892	506,287	640.7	100,908	53,034.4	4.50	510.78	9.04	56.50
2004	513	513	4,651	261,627	709,950	720.6	111,857	57,447.0	4.59	509.99	9.07	56.25
2005	660	660	5,223	314,199	677,284	866.5	123,325	68,149.1	5.35	476.06	7.91	60.16
2006	758	758	5,933	349,944	735,898	966.8	114,750	65,258.7	6.61	461.67	7.83	58.98
2007	1,959	1,959	16,501	774,770	1,597,384	2,143.8	275,979	160,734.9	7.10	395.49	8.42	46.95
2008	2,565	2,565	19,497	870,043	1,822,537	2,410.2	519,212	216,157.8	4.94	339.20	7.60	44.62
2009	5,192	5,192	35,619	1,464,251	3,022,793	4,065.5	614,115	365,214.7	8.45	282.02	6.86	41.11
2010	5,229	5,229	32,092	1,325,951	2,727,716	3,679.2	625,538	378,204.1	8.36	253.58	6.14	41.32
2011	5,642	5,642	29,188	1,184,079	2,445,316	3,285.8	649,549	399,513.8	8.69	209.87	5.17	40.57
2012	6,177	6,177	25,047	921,791	1,875,227	2,560.3	722,963	416,219.0	8.54	149.23	4.05	36.80
<i>365-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	62,461	171.0	0.00	---	---	---
2001	535	535	4,376	218,395	455,912	603.1	95,422	59,305.9	5.61	408.21	8.18	49.91
2002	473	473	4,605	244,665	518,893	675.9	101,722	63,363.8	4.65	517.26	9.74	53.13
2003	465	465	4,197	238,503	529,626	659.0	111,750	71,337.8	4.16	512.91	9.03	56.83
2004	511	511	4,704	262,650	710,483	723.7	124,727	77,387.5	4.10	513.99	9.21	55.84
2005	675	675	5,371	324,907	696,154	895.8	135,452	89,456.0	4.98	481.34	7.96	60.49
2006	769	769	6,033	352,901	743,563	975.1	123,299	84,043.6	6.24	458.91	7.85	58.50
2007	1,932	1,932	16,605	776,418	1,600,202	2,148.5	299,522	206,348.2	6.45	401.87	8.59	46.76
2008	2,569	2,569	19,762	878,469	1,840,464	2,433.7	592,586	273,014.0	4.34	341.95	7.69	44.45

**Table 4a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Year (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2009	5,152	5,152	35,841	1,472,735	3,037,383	4,088.8	674,925	459,553.6	7.63	285.86	6.96	41.09
2010	5,235	5,235	32,305	1,335,989	2,746,048	3,706.9	680,204	469,757.0	7.70	255.20	6.17	41.36
2011	5,662	5,662	29,421	1,191,954	2,460,765	3,307.9	702,498	493,950.1	8.06	210.52	5.20	40.51
2012	6,197	6,197	25,249	926,619	1,882,180	2,574.1	789,111	513,852.2	7.85	149.53	4.07	36.70
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	37,889	108.9	0.00	---	---	---
2001	449	449	3,763	192,711	400,951	532.1	76,502	43,915.3	5.87	429.20	8.38	51.21
2002	413	413	3,952	210,262	440,634	580.8	83,507	54,584.0	4.95	509.11	9.57	53.20
2003	377	377	3,561	201,892	439,167	557.9	95,356	67,885.5	3.95	535.52	9.45	56.70
2004	443	443	4,088	231,832	591,631	638.6	106,435	76,526.9	4.16	523.32	9.23	56.71
2005	573	573	4,775	288,176	624,427	794.6	117,242	89,372.1	4.89	502.92	8.33	60.35
2006	658	658	5,196	310,561	651,228	857.8	110,075	84,678.4	5.98	471.98	7.90	59.77
2007	1,709	1,709	14,691	697,310	1,439,128	1,929.3	255,762	177,766.1	6.68	408.02	8.60	47.47
2008	2,221	2,221	17,143	768,825	1,613,107	2,129.4	467,483	235,898.7	4.75	346.16	7.72	44.85
2009	4,523	4,523	31,301	1,292,819	2,676,856	3,589.7	558,612	379,580.9	8.10	285.83	6.92	41.30
2010	4,595	4,595	28,551	1,178,624	2,422,797	3,270.2	570,603	399,957.1	8.05	256.50	6.21	41.28
2011	4,971	4,971	25,858	1,050,901	2,171,168	2,915.0	589,653	416,520.3	8.43	211.41	5.20	40.64
2012	5,411	5,411	22,021	813,425	1,656,789	2,259.2	638,708	411,972.9	8.47	150.33	4.07	36.94
<i>365-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	49,264	134.9	0.00	---	---	---
2001	436	436	3,764	194,035	403,637	535.7	77,735	48,283.9	5.61	445.03	8.63	51.55
2002	404	404	3,894	209,421	439,838	578.4	84,261	54,869.9	4.79	518.37	9.64	53.78
2003	380	380	3,577	204,666	454,431	565.3	94,275	65,357.6	4.03	538.59	9.41	57.22
2004	427	427	4,071	229,866	585,982	633.4	106,145	73,434.5	4.02	538.33	9.53	56.46
2005	573	573	4,834	295,548	635,836	814.8	116,168	85,821.0	4.93	515.79	8.44	61.14
2006	654	654	5,189	309,604	650,812	855.1	107,249	80,702.0	6.10	473.40	7.93	59.67
2007	1,631	1,631	14,382	681,921	1,405,523	1,886.9	251,835	179,349.4	6.48	418.10	8.82	47.41
2008	2,165	2,165	17,088	764,862	1,604,555	2,118.3	473,807	229,575.2	4.57	353.28	7.89	44.76
2009	4,384	4,384	30,877	1,274,730	2,634,196	3,539.2	548,516	374,804.4	7.99	290.77	7.04	41.28
2010	4,486	4,486	28,167	1,165,404	2,388,913	3,233.5	550,048	382,547.1	8.16	259.79	6.28	41.37
2011	4,863	4,863	25,449	1,033,498	2,132,588	2,867.2	561,803	394,578.0	8.66	212.52	5.23	40.61

**Table 4a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Year (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2012	5,315	5,315	21,691	799,858	1,626,629	2,221.9	612,765	394,798.5	8.67	150.49	4.08	36.88
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cadiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	36,145	105.4	0.00	---	---	---
2001	389	389	3,301	174,217	358,332	480.6	73,616	43,878.1	5.28	447.86	8.49	52.78
2002	337	337	3,210	170,490	363,723	470.9	81,812	56,902.0	4.12	505.91	9.53	53.11
2003	331	331	3,240	184,204	401,005	509.2	94,454	72,302.4	3.50	556.51	9.79	56.85
2004	387	387	3,570	207,753	463,826	572.0	106,045	82,831.6	3.65	536.83	9.22	58.19
2005	500	500	4,341	263,074	569,607	725.4	116,959	97,110.5	4.28	526.15	8.68	60.60
2006	595	595	4,640	283,252	595,156	781.9	110,145	93,053.5	5.40	476.05	7.80	61.05
2007	1,461	1,461	12,320	588,794	1,211,226	1,629.0	246,962	184,937.7	5.92	403.01	8.43	47.79
2008	1,891	1,891	14,508	667,222	1,404,233	1,847.4	440,081	245,839.2	4.30	352.84	7.67	45.99
2009	3,818	3,818	26,547	1,102,332	2,293,212	3,059.9	528,737	388,162.7	7.22	288.72	6.95	41.52
2010	3,916	3,916	24,404	1,016,835	2,083,618	2,820.5	545,664	418,798.6	7.18	259.66	6.23	41.67
2011	4,271	4,271	22,089	902,898	1,872,959	2,504.7	565,945	440,895.3	7.55	211.40	5.17	40.88
2012	4,693	4,693	19,216	710,644	1,449,492	1,974.0	604,921	434,517.8	7.76	151.43	4.09	36.98
<i>365-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	43,805	119.9	0.00	---	---	---
2001	364	364	3,123	166,658	343,212	459.8	69,317	43,344.9	5.25	457.85	8.58	53.36
2002	317	317	3,062	166,718	356,350	460.5	76,094	50,465.3	4.17	525.92	9.66	54.45
2003	323	323	3,163	181,619	403,105	501.9	86,522	61,822.0	3.73	562.29	9.79	57.42
2004	368	368	3,510	201,883	450,289	556.1	98,492	71,136.9	3.74	548.60	9.54	57.52
2005	491	491	4,307	260,095	559,643	717.1	108,635	83,936.6	4.52	529.73	8.77	60.39
2006	584	584	4,565	279,725	589,672	772.1	101,160	80,066.0	5.77	478.98	7.82	61.28
2007	1,331	1,331	11,642	559,787	1,153,480	1,548.6	220,852	162,471.7	6.03	420.58	8.75	48.08
2008	1,771	1,771	13,749	635,891	1,336,048	1,760.7	393,717	204,042.7	4.50	359.06	7.76	46.25
2009	3,554	3,554	25,227	1,046,461	2,175,716	2,904.8	457,401	319,355.7	7.77	294.45	7.10	41.48
2010	3,689	3,689	23,379	976,043	1,996,053	2,707.2	460,461	329,331.3	8.01	264.58	6.34	41.75
2011	4,055	4,055	21,057	863,921	1,787,990	2,396.8	471,711	341,021.7	8.60	213.05	5.19	41.03
2012	4,461	4,461	18,313	677,370	1,378,447	1,882.0	508,777	339,015.5	8.77	151.84	4.11	36.99

**Propafenone**

**Pre-Existing Inclusion of Atrial Fibrillation**

*183-Day Exposure Washout Period/Lookback Period*

**Table 4a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Year (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2000	1	1	15	425	860	1.2	42,665	116.8	0.02	425.00	15.00	28.33
2001	764	764	5,294	229,105	666,816	635.9	84,437	42,304.2	9.05	299.88	6.93	43.28
2002	655	655	4,298	195,630	603,319	543.2	89,609	45,399.3	7.31	298.67	6.56	45.52
2003	516	516	2,954	137,293	526,543	380.5	100,436	52,720.5	5.14	266.07	5.72	46.48
2004	516	516	2,882	122,109	631,391	339.0	111,432	57,177.0	4.63	236.65	5.59	42.37
2005	578	578	2,745	131,303	375,077	363.1	123,168	68,091.9	4.69	227.17	4.75	47.83
2006	426	426	2,846	146,343	398,146	406.2	115,181	65,718.4	3.70	343.53	6.68	51.42
2007	1,836	1,836	11,672	460,924	1,136,481	1,281.4	277,248	161,564.7	6.62	251.05	6.36	39.49
2008	2,147	2,147	13,234	508,148	1,247,966	1,413.0	520,695	217,199.4	4.12	236.68	6.16	38.40
2009	4,194	4,194	21,877	826,481	2,035,056	2,300.9	616,623	367,066.1	6.80	197.06	5.22	37.78
2010	3,532	3,532	16,729	619,771	1,543,664	1,724.6	629,427	381,437.0	5.61	175.47	4.74	37.05
2011	3,542	3,542	15,301	555,512	1,341,711	1,547.6	655,124	404,276.4	5.41	156.84	4.32	36.31
2012	3,713	3,713	13,358	459,492	1,091,372	1,280.9	730,615	422,101.2	5.08	123.75	3.60	34.40
<i>365-Day Exposure Washout Period/Lookback Period</i>												
2000	1	1	15	425	860	1.2	61,647	168.8	0.02	425.00	15.00	28.33
2001	767	767	5,360	233,314	683,589	647.4	94,737	58,585.0	8.10	304.19	6.99	43.53
2002	656	656	4,299	196,333	602,841	545.3	101,092	62,768.7	6.49	299.29	6.55	45.67
2003	521	521	2,952	137,520	527,572	381.1	111,207	70,920.9	4.68	263.95	5.67	46.59
2004	527	527	2,922	124,556	638,885	345.8	124,276	77,035.8	4.24	236.35	5.54	42.63
2005	583	583	2,776	132,307	379,027	365.9	135,190	89,332.1	4.31	226.94	4.76	47.66
2006	429	429	2,876	149,341	407,105	414.4	123,724	84,602.5	3.47	348.11	6.70	51.93
2007	1,824	1,824	11,612	460,323	1,136,546	1,279.8	300,824	207,367.4	6.06	252.37	6.37	39.64
2008	2,143	2,143	13,245	510,690	1,256,243	1,420.0	594,003	274,308.5	3.61	238.31	6.18	38.56
2009	4,101	4,101	21,756	820,677	2,021,952	2,284.8	677,478	461,860.9	6.05	200.12	5.31	37.72
2010	3,502	3,502	16,722	618,821	1,548,410	1,722.0	684,332	473,774.6	5.12	176.71	4.77	37.01
2011	3,522	3,522	15,247	550,818	1,332,386	1,534.6	708,513	499,912.3	4.97	156.39	4.33	36.13
2012	3,676	3,676	13,289	453,518	1,077,510	1,264.3	797,512	521,148.7	4.61	123.37	3.62	34.13
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	37,453	107.7	0.00	---	---	---
2001	543	543	4,181	187,978	552,837	521.3	76,041	43,466.5	7.14	346.18	7.70	44.96
2002	477	477	3,349	156,290	487,514	433.3	83,074	54,081.2	5.74	327.65	7.02	46.67

**Table 4a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Year (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2003	389	389	2,309	114,087	373,598	315.8	94,960	67,462.7	4.10	293.28	5.94	49.41
2004	377	377	2,228	97,620	571,632	271.0	106,118	76,134.7	3.55	258.94	5.91	43.82
2005	438	438	2,194	107,813	307,446	298.3	117,221	89,236.0	3.74	246.15	5.01	49.14
2006	351	351	2,527	131,014	354,269	363.5	110,585	85,183.3	3.17	373.26	7.20	51.85
2007	1,498	1,498	9,770	383,358	938,924	1,065.1	257,135	178,679.5	5.83	255.91	6.52	39.24
2008	1,759	1,759	11,033	422,636	1,029,215	1,174.7	469,177	237,074.2	3.75	240.27	6.27	38.31
2009	3,441	3,441	18,423	696,371	1,699,875	1,938.6	561,328	381,610.6	6.13	202.37	5.35	37.80
2010	2,932	2,932	13,909	514,749	1,275,407	1,432.8	574,685	403,356.0	5.10	175.56	4.74	37.01
2011	2,914	2,914	12,677	460,953	1,108,376	1,283.6	595,392	421,372.6	4.89	158.19	4.35	36.36
2012	3,127	3,127	11,420	392,090	931,364	1,092.3	646,346	417,903.6	4.84	125.39	3.65	34.33
<i>365-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	48,651	133.2	0.00	---	---	---
2001	527	527	4,072	186,908	555,563	518.1	77,182	47,721.9	6.83	354.66	7.73	45.90
2002	455	455	3,241	152,525	474,278	422.7	83,785	54,381.9	5.43	335.22	7.12	47.06
2003	377	377	2,207	110,653	305,204	306.0	93,932	65,013.5	4.01	293.51	5.85	50.14
2004	366	366	2,156	95,956	565,893	266.4	105,895	73,135.8	3.46	262.17	5.89	44.51
2005	430	430	2,140	104,499	302,505	289.1	116,098	85,758.5	3.70	243.02	4.98	48.83
2006	348	348	2,516	131,750	358,648	365.5	107,774	81,318.7	3.23	378.59	7.23	52.36
2007	1,451	1,451	9,517	375,174	918,446	1,042.3	253,279	180,535.9	5.73	258.56	6.56	39.42
2008	1,692	1,692	10,641	409,725	999,397	1,138.6	475,636	231,111.5	3.56	242.15	6.29	38.50
2009	3,253	3,253	17,718	666,860	1,630,883	1,856.8	551,399	377,438.2	5.90	205.00	5.45	37.64
2010	2,815	2,815	13,540	499,328	1,244,082	1,390.0	554,369	386,726.3	5.08	177.38	4.81	36.88
2011	2,810	2,810	12,226	442,152	1,063,773	1,231.3	567,872	400,519.6	4.95	157.35	4.35	36.16
2012	2,986	2,986	11,025	375,077	890,429	1,045.2	620,952	401,856.8	4.81	125.61	3.69	34.02
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	35,728	104.2	0.00	---	---	---
2001	409	409	3,114	146,686	438,271	406.5	73,187	43,429.1	5.59	358.65	7.61	47.11
2002	339	339	2,560	122,157	383,652	338.5	81,431	56,398.4	4.16	360.35	7.55	47.72
2003	289	289	1,739	88,947	302,359	245.8	94,114	71,901.8	3.07	307.78	6.02	51.15
2004	286	286	1,657	75,414	328,614	208.9	105,790	82,468.7	2.70	263.69	5.79	45.51
2005	354	354	1,793	88,446	250,617	244.5	117,035	97,010.9	3.02	249.85	5.06	49.33

**Table 4a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Year (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2006	298	298	2,176	114,179	310,314	316.9	110,688	93,616.1	2.69	383.15	7.30	52.47
2007	1,181	1,181	7,915	311,825	762,731	866.5	248,375	185,948.1	4.75	264.03	6.70	39.40
2008	1,345	1,345	8,335	322,322	786,594	895.8	441,972	247,157.3	3.04	239.64	6.20	38.67
2009	2,690	2,690	14,368	534,600	1,309,000	1,488.4	531,650	390,435.4	5.06	198.74	5.34	37.21
2010	2,363	2,363	11,066	405,025	1,002,103	1,126.6	549,933	422,365.1	4.30	171.40	4.68	36.60
2011	2,333	2,333	10,131	365,330	876,430	1,017.3	571,762	445,916.9	4.08	156.59	4.34	36.06
2012	2,486	2,486	8,773	298,425	713,273	831.0	612,574	440,522.1	4.06	120.04	3.53	34.02
<i>365-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	43,294	118.5	0.00	---	---	---
2001	400	400	3,161	150,917	448,625	418.1	68,877	42,883.1	5.81	377.29	7.90	47.74
2002	307	307	2,313	111,220	350,937	308.0	75,730	50,083.3	4.05	362.28	7.53	48.08
2003	271	271	1,615	83,402	229,457	230.4	86,267	61,583.5	3.14	307.76	5.96	51.64
2004	276	276	1,607	74,236	326,804	205.7	98,327	70,925.4	2.81	268.97	5.82	46.20
2005	339	339	1,723	84,600	245,638	233.9	108,668	83,953.2	3.12	249.56	5.08	49.10
2006	276	276	2,009	104,797	286,684	290.8	101,720	80,752.9	2.71	379.70	7.28	52.16
2007	1,089	1,089	7,339	290,740	710,838	807.9	222,429	163,808.7	4.90	266.98	6.74	39.62
2008	1,255	1,255	7,767	301,587	737,292	838.2	396,070	205,832.6	3.17	240.31	6.19	38.83
2009	2,416	2,416	13,171	489,752	1,198,990	1,363.7	460,719	322,478.1	5.24	202.71	5.45	37.18
2010	2,199	2,199	10,505	383,513	955,489	1,066.9	465,176	333,788.5	4.73	174.40	4.78	36.51
2011	2,159	2,159	9,482	339,743	816,330	946.0	477,903	347,075.2	4.52	157.36	4.39	35.83
2012	2,272	2,272	8,089	271,914	649,111	757.5	516,883	345,964.0	4.40	119.68	3.56	33.62
<b>Sotalol</b>												
<b>Pre-Existing Inclusion of Atrial Fibrillation</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
2000	1	1	2	60	120	0.2	42,274	115.7	0.02	60.00	2.00	30.00
2001	1,100	1,100	10,471	476,541	1,042,888	1,316.6	83,863	41,845.4	13.12	433.22	9.52	45.51
2002	1,093	1,093	10,132	489,357	1,010,846	1,352.4	88,835	44,703.6	12.30	447.72	9.27	48.30
2003	911	911	7,715	340,529	680,400	942.2	99,322	51,873.3	9.17	373.80	8.47	44.14
2004	843	843	6,300	283,429	711,347	785.4	110,098	56,213.1	7.66	336.21	7.47	44.99
2005	892	892	5,751	276,780	560,347	765.0	121,668	66,978.0	7.33	310.29	6.45	48.13
2006	789	789	7,059	356,185	754,855	984.1	113,985	64,696.2	6.92	451.44	8.95	50.46
2007	2,629	2,629	23,795	989,050	1,933,386	2,741.0	273,120	158,081.4	9.63	376.21	9.05	41.57

**Table 4a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Year (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2008	3,719	3,719	30,634	1,256,145	2,464,951	3,480.3	510,957	212,251.3	7.28	337.76	8.24	41.00
2009	7,212	7,212	53,375	2,165,399	4,163,236	6,009.0	606,477	357,701.0	11.89	300.25	7.40	40.57
2010	6,076	6,076	40,455	1,662,067	3,173,184	4,610.8	618,292	371,487.1	9.83	273.55	6.66	41.08
2011	6,427	6,427	36,423	1,498,170	2,829,291	4,155.3	643,326	393,482.2	9.99	233.11	5.67	41.13
2012	6,913	6,913	31,266	1,185,491	2,217,765	3,289.7	716,018	410,187.8	9.65	171.49	4.52	37.92
<i>365-Day Exposure Washout Period/Lookback Period</i>												
2000	2	2	20	573	1,146	1.6	61,084	167.2	0.03	286.50	10.00	28.65
2001	1,112	1,112	10,684	488,160	1,066,858	1,348.6	94,028	57,942.7	11.83	438.99	9.61	45.69
2002	1,100	1,100	10,216	495,907	1,024,983	1,370.3	100,181	61,817.8	10.98	450.82	9.29	48.54
2003	931	931	7,882	347,898	693,208	962.9	109,902	69,739.5	8.47	373.68	8.47	44.14
2004	850	850	6,407	287,633	717,480	796.7	122,675	75,727.0	6.93	338.39	7.54	44.89
2005	893	893	5,890	284,413	571,365	786.1	133,488	87,910.9	6.69	318.49	6.60	48.29
2006	790	790	7,231	364,847	771,898	1,008.0	122,462	83,363.1	6.45	461.83	9.15	50.46
2007	2,642	2,642	24,204	1,005,660	1,972,968	2,787.3	296,212	203,120.2	8.92	380.64	9.16	41.55
2008	3,707	3,707	30,837	1,264,148	2,480,652	3,502.3	582,962	268,387.7	6.36	341.02	8.32	40.99
2009	7,057	7,057	53,207	2,148,025	4,133,573	5,960.3	665,930	450,701.2	10.60	304.38	7.54	40.37
2010	5,963	5,963	40,431	1,655,639	3,159,295	4,592.5	671,970	462,142.0	8.87	277.65	6.78	40.95
2011	6,357	6,357	36,436	1,495,481	2,822,275	4,148.4	695,495	487,362.7	9.14	235.25	5.73	41.04
2012	6,799	6,799	30,993	1,168,389	2,179,386	3,242.4	781,656	507,603.4	8.70	171.85	4.56	37.70
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
2000	1	1	2	60	120	0.2	37,099	106.7	0.03	60.00	2.00	30.00
2001	750	750	7,583	367,017	770,740	1,012.4	75,503	42,961.4	9.93	489.36	10.11	48.40
2002	751	751	7,127	365,124	744,275	1,008.4	82,320	53,225.7	9.12	486.18	9.49	51.23
2003	559	559	4,851	226,552	450,383	626.1	93,950	66,386.2	5.95	405.28	8.68	46.70
2004	518	518	4,089	188,522	393,212	521.9	104,933	74,835.9	4.94	363.94	7.89	46.10
2005	537	537	3,534	176,529	358,875	487.6	115,878	87,717.6	4.63	328.73	6.58	49.95
2006	528	528	4,814	250,919	541,445	692.8	109,552	83,782.5	4.82	475.23	9.12	52.12
2007	1,754	1,754	16,215	679,793	1,337,261	1,883.3	253,357	174,852.9	6.92	387.57	9.24	41.92
2008	2,469	2,469	20,415	849,706	1,679,547	2,353.8	460,792	231,743.2	5.36	344.15	8.27	41.62
2009	4,723	4,723	34,937	1,431,879	2,731,172	3,973.9	552,595	372,275.5	8.55	303.17	7.40	40.98
2010	4,016	4,016	26,479	1,093,065	2,085,973	3,032.0	565,447	393,448.4	7.10	272.18	6.59	41.28

**Table 4a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Year (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2011	4,294	4,294	24,687	1,020,032	1,925,300	2,828.3	586,036	410,976.9	7.33	237.55	5.75	41.32
2012	4,617	4,617	20,858	793,036	1,491,724	2,199.9	635,213	407,246.9	7.27	171.76	4.52	38.02
<i>365-Day Exposure Washout Period/Lookback Period</i>												
2000	1	1	2	60	120	0.2	48,169	131.9	0.02	60.00	2.00	30.00
2001	714	714	7,201	353,529	745,777	975.1	76,558	47,164.4	9.33	495.14	10.09	49.09
2002	730	730	6,972	361,104	735,645	997.3	82,997	53,499.5	8.80	494.66	9.55	51.79
2003	551	551	4,755	225,315	438,702	622.8	92,840	63,928.5	5.93	408.92	8.63	47.38
2004	490	490	3,858	181,698	380,021	502.4	104,592	71,898.5	4.68	370.81	7.87	47.10
2005	500	500	3,330	170,246	341,827	470.2	114,693	84,356.4	4.36	340.49	6.66	51.12
2006	510	510	4,741	247,845	530,161	684.4	106,802	80,099.7	4.78	485.97	9.30	52.28
2007	1,685	1,685	15,751	663,402	1,308,540	1,838.0	249,484	176,950.2	6.75	393.71	9.35	42.12
2008	2,343	2,343	19,644	816,745	1,616,071	2,262.0	467,672	226,379.8	5.01	348.59	8.38	41.58
2009	4,374	4,374	33,241	1,353,734	2,584,939	3,756.8	542,851	369,373.5	8.06	309.50	7.60	40.72
2010	3,760	3,760	25,359	1,039,250	1,984,778	2,882.9	545,804	378,617.4	6.89	276.40	6.74	40.98
2011	4,006	4,006	23,419	961,912	1,816,248	2,667.1	559,299	392,182.9	7.16	240.12	5.85	41.07
2012	4,300	4,300	19,692	741,087	1,388,847	2,056.3	611,128	393,460.7	7.04	172.35	4.58	37.63
<b>Pre-Existing Inclusion of Atrial Fibrillation/Exclusion of Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft</b>												
<i>183-Day Exposure Washout Period/Lookback Period</i>												
2000	0	0	0	0	0	0.0	35,423	103.2	0.00	---	---	---
2001	453	453	4,321	227,331	465,802	626.9	72,672	42,892.6	6.23	501.83	9.54	52.61
2002	454	454	4,355	241,085	493,029	664.9	80,727	55,463.4	5.62	531.02	9.59	55.36
2003	319	319	2,815	137,768	270,345	380.0	93,188	70,732.9	3.42	431.87	8.82	48.94
2004	317	317	2,608	132,606	281,109	366.1	104,710	81,110.5	3.03	418.32	8.23	50.85
2005	344	344	2,144	113,052	233,137	312.4	115,817	95,433.7	2.97	328.64	6.23	52.73
2006	323	323	2,740	148,511	319,495	409.5	109,785	92,204.4	2.94	459.79	8.48	54.20
2007	1,074	1,074	9,985	414,513	810,478	1,148.1	245,064	182,201.8	4.38	385.95	9.30	41.51
2008	1,442	1,442	11,975	495,867	994,565	1,373.4	434,892	241,932.8	3.32	343.87	8.30	41.41
2009	2,866	2,866	20,756	830,878	1,584,764	2,307.1	524,269	381,373.9	5.47	289.91	7.24	40.03
2010	2,422	2,422	15,855	639,043	1,228,493	1,773.9	542,123	412,396.8	4.47	263.85	6.55	40.31
2011	2,637	2,637	15,064	613,454	1,157,598	1,700.8	563,893	435,421.4	4.68	232.63	5.71	40.72
2012	2,812	2,812	12,710	475,078	897,714	1,318.1	603,525	429,959.7	4.66	168.95	4.52	37.38
<i>365-Day Exposure Washout Period/Lookback Period</i>												



**Table 4a: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product, Pre-Existing Condition Requirements, Exposure Washout Period/Pre-Existing Condition Lookback Period, and Year (Incidence is Defined with Respect to the Drug Product Itself)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2000	0	0	0	0	0	0.0	42,929	117.5	0.00	---	---	---
2001	426	426	4,032	215,315	443,077	593.7	68,362	42,410.1	6.23	505.43	9.46	53.40
2002	428	428	4,170	235,021	483,663	648.1	75,073	49,301.0	5.70	549.11	9.74	56.36
2003	298	298	2,584	127,539	247,202	351.8	85,394	60,619.2	3.49	427.98	8.67	49.36
2004	280	280	2,444	125,744	266,919	347.1	97,307	69,830.3	2.88	449.09	8.73	51.45
2005	304	304	1,973	105,041	216,445	290.2	107,588	82,749.2	2.83	345.53	6.49	53.24
2006	300	300	2,613	142,419	307,281	392.8	100,989	79,681.0	2.97	474.73	8.71	54.50
2007	980	980	9,293	387,146	760,329	1,072.1	219,681	161,137.1	4.46	395.05	9.48	41.66
2008	1,299	1,299	10,954	455,362	913,841	1,260.5	391,215	202,417.6	3.32	350.55	8.43	41.57
2009	2,471	2,471	18,087	723,929	1,381,942	2,010.0	455,559	317,142.8	5.42	292.97	7.32	40.02
2010	2,164	2,164	14,440	581,604	1,122,947	1,614.5	459,777	328,374.0	4.71	268.76	6.67	40.28
2011	2,330	2,330	13,457	543,162	1,028,618	1,506.4	472,686	341,453.1	4.93	233.12	5.78	40.36
2012	2,504	2,504	11,496	422,871	796,325	1,173.6	510,975	340,421.7	4.90	168.88	4.59	36.78

**Table 4b: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product and Year (Pre-Existing Inclusion of Atrial Fibrillation, 183-Day Exposure Washout Period/Pre-Existing Condition Lookback Period, and Incidence is Defined with Respect to All Anti-Arrhythmic Drug Products)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
<b>Amiodarone</b>												
2000	8	8	55	2,668	3,359	7.5	35,718	97.8	0.22	333.50	6.88	48.51
2001	3,509	3,509	12,798	553,193	753,881	1,534.0	75,816	34,909.9	46.28	157.65	3.65	43.22
2002	3,804	3,804	12,495	544,057	754,947	1,509.5	79,309	36,816.2	47.96	143.02	3.28	43.54
2003	3,827	3,827	12,740	535,745	760,905	1,487.9	88,333	42,882.8	43.32	139.99	3.33	42.05
2004	3,621	3,621	11,381	473,901	1,008,196	1,315.0	97,171	46,460.7	37.26	130.88	3.14	41.64
2005	3,615	3,615	10,075	455,553	613,433	1,260.5	107,762	55,857.9	33.55	126.02	2.79	45.22
2006	3,042	3,042	8,554	402,456	551,401	1,113.6	101,828	54,521.9	29.87	132.30	2.81	47.05
2007	7,545	7,545	24,580	989,203	1,295,097	2,747.7	245,855	133,631.2	30.69	131.11	3.26	40.24
2008	9,849	9,849	32,428	1,255,185	1,623,263	3,486.2	450,143	179,971.0	21.88	127.44	3.29	38.71
2009	17,572	17,572	56,191	2,135,506	2,753,183	5,937.2	543,215	299,325.7	32.35	121.53	3.20	38.00
2010	17,031	17,031	52,139	1,999,270	2,610,945	5,553.8	549,075	306,321.6	31.02	117.39	3.06	38.35
2011	17,706	17,706	52,804	2,036,965	2,676,471	5,657.6	567,219	320,765.3	31.22	115.04	2.98	38.58
2012	19,220	19,220	51,657	1,919,499	2,586,740	5,331.5	627,691	333,646.0	30.62	99.87	2.69	37.16
<b>Dofetilide</b>												
2000	0	0	0	0	0	0.0	35,718	97.8	0.00	---	---	---
2001	25	25	336	9,996	20,006	27.6	75,817	34,935.5	0.33	399.84	13.44	29.75
2002	36	36	652	22,273	229,670	61.4	80,098	37,138.1	0.45	618.69	18.11	34.16
2003	31	31	432	13,275	86,507	36.7	90,151	43,750.5	0.34	428.23	13.94	30.73
2004	33	33	354	13,051	29,320	36.2	100,070	47,923.6	0.33	395.48	10.73	36.87
2005	49	49	448	17,233	34,777	47.6	111,640	57,964.5	0.44	351.69	9.14	38.47
2006	47	47	488	20,318	41,164	56.5	106,163	56,954.2	0.44	432.30	10.38	41.64
2007	247	247	2,911	113,988	247,506	316.8	250,749	136,565.3	0.99	461.49	11.79	39.16
2008	350	350	4,061	141,258	288,907	392.6	457,133	184,033.9	0.77	403.59	11.60	34.78
2009	714	714	6,841	258,124	547,163	716.4	553,036	305,117.3	1.29	361.52	9.58	37.73
2010	560	560	4,788	182,578	372,979	507.5	563,437	314,721.3	0.99	326.03	8.55	38.13
2011	709	709	5,328	191,885	402,379	533.9	585,537	331,688.5	1.21	270.64	7.51	36.01
2012	841	841	4,423	160,061	326,790	445.2	649,605	346,684.8	1.29	190.32	5.26	36.19
<b>Dronedarone</b>												
2000	0	0	0	0	0	0.0	35,718	97.8	0.00	---	---	---
2001	0	0	0	0	0	0.0	75,817	34,935.8	0.00	---	---	---
2002	0	0	0	0	0	0.0	80,106	37,141.2	0.00	---	---	---

**Table 4b: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product and Year (Pre-Existing Inclusion of Atrial Fibrillation, 183-Day Exposure Washout Period/Pre-Existing Condition Lookback Period, and Incidence is Defined with Respect to All Anti-Arrhythmic Drug Products)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2003	0	0	0	0	0	0.0	90,170	43,760.2	0.00	---	---	---
2004	0	0	0	0	0	0.0	100,092	47,938.4	0.00	---	---	---
2005	0	0	0	0	0	0.0	111,675	57,985.3	0.00	---	---	---
2006	0	0	0	0	0	0.0	106,201	56,975.8	0.00	---	---	---
2007	0	0	0	0	0	0.0	250,792	136,591.5	0.00	---	---	---
2008	0	0	0	0	0	0.0	457,237	184,086.7	0.00	---	---	---
2009	1,411	1,411	7,324	272,917	541,800	762.1	553,225	305,225.4	2.55	193.42	5.19	37.26
2010	6,673	6,673	32,941	1,212,867	2,406,262	3,385.2	563,428	314,727.3	11.84	181.76	4.94	36.82
2011	5,892	5,892	25,277	916,324	1,813,774	2,559.5	583,567	330,672.5	10.10	155.52	4.29	36.25
2012	3,701	3,701	13,031	446,327	882,270	1,246.3	645,798	344,479.5	5.73	120.60	3.52	34.25
<b>Flecainide</b>												
2000	0	0	0	0	0	0.0	35,718	97.8	0.00	---	---	---
2001	399	399	3,128	143,469	308,936	396.8	75,817	34,931.2	5.26	359.57	7.84	45.87
2002	336	336	2,651	125,791	260,255	348.7	80,015	37,097.3	4.20	374.38	7.89	47.45
2003	352	352	2,956	165,443	356,274	457.3	89,982	43,668.0	3.91	470.01	8.40	55.97
2004	378	378	3,382	190,485	471,691	524.7	99,813	47,785.2	3.79	503.93	8.95	56.32
2005	507	507	3,917	233,976	510,078	645.2	111,303	57,779.0	4.56	461.49	7.73	59.73
2006	632	632	4,870	279,469	585,514	772.2	105,743	56,710.7	5.98	442.20	7.71	57.39
2007	1,523	1,523	12,191	575,057	1,172,221	1,591.9	250,166	136,230.6	6.09	377.58	8.00	47.17
2008	2,042	2,042	15,052	676,652	1,412,816	1,875.1	456,225	183,523.4	4.48	331.37	7.37	44.95
2009	4,216	4,216	27,750	1,135,712	2,348,290	3,154.0	551,656	304,352.0	7.64	269.38	6.58	40.93
2010	4,163	4,163	24,507	1,023,736	2,097,064	2,839.2	561,187	313,513.1	7.42	245.91	5.89	41.77
2011	4,460	4,460	22,609	913,905	1,885,693	2,536.9	582,422	329,972.4	7.66	204.91	5.07	40.42
2012	4,995	4,995	19,318	704,357	1,432,934	1,957.3	645,591	344,539.9	7.74	141.01	3.87	36.46
<b>Propafenone</b>												
2000	1	1	15	425	860	1.2	35,718	97.8	0.03	425.00	15.00	28.33
2001	606	606	3,975	160,666	460,529	446.8	75,817	34,927.6	7.99	265.13	6.56	40.42
2002	540	540	3,519	155,711	455,470	432.7	79,967	37,076.2	6.75	288.35	6.52	44.25
2003	426	426	2,278	99,806	419,028	277.1	89,903	43,622.8	4.74	234.29	5.35	43.81
2004	424	424	2,282	92,607	430,636	257.4	99,700	47,722.6	4.25	218.41	5.38	40.58
2005	446	446	1,865	84,010	234,643	232.9	111,160	57,699.1	4.01	188.36	4.18	45.05
2006	313	313	2,075	104,785	278,794	291.0	105,625	56,641.7	2.96	334.78	6.63	50.50

**Table 4b: Summary of Incident Anti-Arrhythmic Drug Product Use in the Mini-Sentinel Distributed Database between January 1, 2000 and December 31, 2012, by Drug Product and Year (Pre-Existing Inclusion of Atrial Fibrillation, 183-Day Exposure Washout Period/Pre-Existing Condition Lookback Period, and Incidence is Defined with Respect to All Anti-Arrhythmic Drug Products)**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing
2007	1,435	1,435	9,135	342,931	844,523	954.7	250,158	136,191.7	5.74	238.98	6.37	37.54
2008	1,702	1,702	10,289	389,262	953,758	1,083.1	456,159	183,477.0	3.73	228.71	6.05	37.83
2009	3,411	3,411	17,199	634,957	1,557,549	1,768.7	551,703	304,310.9	6.18	186.15	5.04	36.92
2010	2,709	2,709	12,760	453,698	1,129,378	1,264.2	561,345	313,527.7	4.83	167.48	4.71	35.56
2011	2,655	2,655	11,007	388,461	933,597	1,082.2	582,833	330,100.8	4.56	146.31	4.15	35.29
2012	2,833	2,833	9,721	324,802	767,246	907.0	646,399	344,824.6	4.38	114.65	3.43	33.41
<b>Sotalol</b>												
2000	0	0	0	0	0	0.0	35,718	97.8	0.00	---	---	---
2001	930	930	8,575	382,956	843,464	1,058.6	75,817	34,931.4	12.27	411.78	9.22	44.66
2002	922	922	8,708	413,290	859,746	1,143.0	79,964	37,082.4	11.53	448.25	9.44	47.46
2003	772	772	6,240	263,979	513,668	731.4	89,829	43,598.9	8.59	341.94	8.08	42.30
2004	712	712	5,121	221,614	574,209	615.0	99,561	47,675.3	7.15	311.26	7.19	43.28
2005	720	720	4,558	211,203	427,124	583.9	110,966	57,595.8	6.49	293.34	6.33	46.34
2006	645	645	5,791	280,908	585,802	776.5	105,501	56,568.8	6.11	435.52	8.98	48.51
2007	2,143	2,143	19,842	808,100	1,571,296	2,241.2	250,017	136,119.3	8.57	377.09	9.26	40.73
2008	3,037	3,037	24,827	1,003,972	1,942,909	2,782.7	455,967	183,364.2	6.66	330.58	8.17	40.44
2009	5,984	5,984	43,981	1,773,110	3,387,515	4,923.5	551,252	304,065.6	10.86	296.31	7.35	40.32
2010	4,887	4,887	32,151	1,305,764	2,469,406	3,624.2	560,591	313,096.5	8.72	267.19	6.58	40.61
2011	4,986	4,986	27,882	1,134,134	2,112,358	3,147.1	581,773	329,438.5	8.57	227.46	5.59	40.68
2012	5,442	5,442	24,398	919,648	1,704,877	2,553.0	644,915	343,948.6	8.44	168.99	4.48	37.69

**Appendix A: International Classification of Disease, Ninth Edition,  
Clinical Modification Diagnosis Codes Used to Define Pre-Existing Condition Inclusions/Exclusions in this Report**

**Atrial Fibrillation/Flutter Codes**

427.3      427.31      427.32

**Congestive Heart Failure Codes**

428\*      404.03      425.1\*      425.8      674.53  
 398.91      404.11      425.2      425.9      674.54  
 402.01      404.13      425.3      674.5      996.83  
 402.11      404.93      425.4      674.50      427.3  
 402.91      425      425.5      674.51      427.31  
 404.01      425.0      425.7      674.52      427.32

**Congestive Heart Failure, Coronary Heart Disease/Ischemic Heart Disease, Cardiomyopathy, Coronary Artery Bypass Graft Codes**

428\*      414.3\*      425.2\*      425.9\*      429.71  
 410\*      414.4\*      425.3\*      413      429.79  
 411\*      414.8\*      425.4\*      413.0      996.03  
 412      414.9\*      425.5\*      413.1      427.3  
 414.0\*      425.0\*      425.7\*      413.9      427.31  
 414.2\*      425.1\*      425.8\*      414.1\*      427.32

**Modular Program Specifications for Query ID to09y05\_mpr\_wp17\_v01 - Anti-arrhythmic Use**

Modular Program #3 was used to investigate the use of several anti-arrhythmic drug products among individuals with selected pre-existing condition inclusions/exclusions. For example, Scenario 1 below examines amiodarone use among members with a pre-existing condition inclusion of Atrial Fibrillation/Flutter. Scenario 19 below examines amiodarone use among members who have a pre-existing condition of Atrial/Fibrillation/Flutter and who do NOT have Congestive Heart Failure. No event was queried. The minimum days supplied and minimum episode duration were both set to 0 days. In total, 44 different scenarios were examined in this request with differing drugs of interest, incident criteria, washout periods, and pre-existing inclusions/exclusions. See below for a description of each of these scenarios.

Query Period	January 1, 2000 - December 31, 2012
Requirement	Drug and Medical
Enrollment Requirement	365 days
Age Stratifications	0<41, 41<55, 55<65, 65<75, 75<85, 85+ years
Enrollment Gap	45 Days
Treatment Episode Truncation Indicator	Yes (This parameter only applies to Scenarios 1-6)

Scenario	Drug/Exposure			Condition Criteria				Event/Outcome				
	Incident exposure	Incident w/ respect to:	Washout (days)	Cohort Definition	Episode Gap	Exposure Extension Period	Pre-Existing Condition	Include/Exclude	Lookback Start	Lookback End	Care Setting PDX	Event/Outcome
1	Amiodarone	All listed anti-arrhythmics	183	01 (Sing)	10	0	AF/Flutter	Include	-183	-1	Any	None
2	Dronedarone	All listed anti-arrhythmics	183	01 (Sing)	10	0	AF/Flutter	Include	-183	-1	Any	None
3	Dofetilide	All listed anti-arrhythmics	183	01 (Sing)	10	0	AF/Flutter	Include	-183	-1	Any	None
4	Flecainide	All listed anti-arrhythmics	183	01 (Sing)	10	0	AF/Flutter	Include	-183	-1	Any	None
5	Propafenone	All listed anti-arrhythmics	183	01 (Sing)	10	0	AF/Flutter	Include	-183	-1	Any	None
6	Sotalol	All listed anti-arrhythmics	183	01 (Sing)	10	0	AF/Flutter	Include	-183	-1	Any	None
7	Amiodarone	Amiodarone	183	01 (Sing)	10	0	AF/Flutter	Include	-183	-1	Any	None
8	Dronedarone	Dronedarone	183	01 (Sing)	10	0	AF/Flutter	Include	-183	-1	Any	None
9	Dofetilide	Dofetilide	183	01 (Sing)	10	0	AF/Flutter	Include	-183	-1	Any	None
10	Flecainide	Flecainide	183	01 (Sing)	10	0	AF/Flutter	Include	-183	-1	Any	None
11	Propafenone	Propafenone	183	01 (Sing)	10	0	AF/Flutter	Include	-183	-1	Any	None
12	Sotalol	Sotalol	183	01 (Sing)	10	0	AF/Flutter	Include	-183	-1	Any	None
13	Amiodarone	Amiodarone	365	01 (Sing)	10	0	AF/Flutter	Include	-365	-1	Any	None
14	Dronedarone	Dronedarone	365	01 (Sing)	10	0	AF/Flutter	Include	-365	-1	Any	None
15	Dofetilide	Dofetilide	365	01 (Sing)	10	0	AF/Flutter	Include	-365	-1	Any	None
16	Flecainide	Flecainide	365	01 (Sing)	10	0	AF/Flutter	Include	-365	-1	Any	None
17	Propafenone	Propafenone	365	01 (Sing)	10	0	AF/Flutter	Include	-365	-1	Any	None
18	Sotalol	Sotalol	365	01 (Sing)	10	0	AF/Flutter	Include	-365	-1	Any	None

**Modular Program Specifications for Query ID to09y05\_mpr\_wp17\_v01 - Anti-arrhythmic Use**

Modular Program #3 was used to investigate the use of several anti-arrhythmic drug products among individuals with selected pre-existing condition inclusions/exclusions. For example, Scenario 1 below examines amiodarone use among members with a pre-existing condition inclusion of Atrial Fibrillation/Flutter. Scenario 19 below examines amiodarone use among members who have a pre-existing condition of Atrial/Fibrillation/Flutter and who do NOT have Congestive Heart Failure. No event was queried. The minimum days supplied and minimum episode duration were both set to 0 days. In total, 44 different scenarios were examined in this request with differing drugs of interest, incident criteria, washout periods, and pre-existing inclusions/exclusions. See below for a description of each of these scenarios.

Query Period: January 1, 2000 - December 31, 2012  
 Requirem: Drug and Medical  
 Enrollment Requirement: 365 days  
 Age Stratifications: 0<41, 41<55, 55<65, 65<75, 75<85, 85+ years  
 Enrollment Gap: 45 Days  
 Treatment Episode Truncation Indicator: Yes (This parameter only applies to Scenarios 1-6)

Scenario	Drug/Exposure			Condition Criteria							Event/Outcome	
	Incident exposure	Incident w/ respect to:	Washout (days)	Cohort Definition	Episode Gap	Exposure Extension Period	Pre-Existing Condition	Include/Exclude	Lookback Start	Lookback End	Care Setting PDX	Event/Outcome
19	Amiodarone	Amiodarone	183	01 (Sing)	10	0	AF/Flutter CHF	Include Exclude	-183	-1	Any	None
20	Dronedarone	Dronedarone	183	01 (Sing)	10	0	AF/Flutter CHF	Include Exclude	-183	-1	Any	None
21	Dofetilide	Dofetilide	183	01 (Sing)	10	0	AF/Flutter CHF	Include Exclude	-183	-1	Any	None
22	Flecainide	Flecainide	183	01 (Sing)	10	0	AF/Flutter CHF	Include Exclude	-183	-1	Any	None
23	Propafenone	Propafenone	183	01 (Sing)	10	0	AF/Flutter CHF	Include Exclude	-183	-1	Any	None
24	Sotalol	Sotalol	183	01 (Sing)	10	0	AF/Flutter CHF	Include Exclude	-183	-1	Any	None
25	Amiodarone	Amiodarone	365	01 (Sing)	10	0	AF/Flutter CHF	Include Exclude	-365	-1	Any	None
26	Dronedarone	Dronedarone	365	01 (Sing)	10	0	AF/Flutter CHF	Include Exclude	-365	-1	Any	None
27	Dofetilide	Dofetilide	365	01 (Sing)	10	0	AF/Flutter CHF	Include Exclude	-365	-1	Any	None
28	Flecainide	Flecainide	365	01 (Sing)	10	0	AF/Flutter CHF	Include Exclude	-365	-1	Any	None
29	Propafenone	Propafenone	365	01 (Sing)	10	0	AF/Flutter CHF	Include Exclude	-365	-1	Any	None
30	Sotalol	Sotalol	365	01 (Sing)	10	0	AF/Flutter CHF	Include Exclude	-365	-1	Any	None

**Modular Program Specifications for Query ID to09y05\_mpr\_wp17\_v01 - Anti-arrhythmic Use**

Modular Program #3 was used to investigate the use of several anti-arrhythmic drug products among individuals with selected pre-existing condition inclusions/exclusions. For example, Scenario 1 below examines amiodarone use among members with a pre-existing condition inclusion of Atrial Fibrillation/Flutter. Scenario 19 below examines amiodarone use among members who have a pre-existing condition of Atrial/Fibrillation/Flutter and who do NOT have Congestive Heart Failure. No event was queried. The minimum days supplied and minimum episode duration were both set to 0 days. In total, 44 different scenarios were examined in this request with differing drugs of interest, incident criteria, washout periods, and pre-existing inclusions/exclusions. See below for a description of each of these scenarios.

Query Period	January 1, 2000 - December 31, 2012
Requirement	Drug and Medical
Enrollment Requirement	365 days
Age Stratifications	0<41, 41<55, 55<65, 65<75, 75<85, 85+ years
Enrollment Gap	45 Days
Treatment Episode Truncation Indicator	Yes (This parameter only applies to Scenarios 1-6)

Scenario	Drug/Exposure			Condition Criteria						Event/Outcome		
	Incident exposure	Incident w/ respect to:	Washout (days)	Cohort Definition	Episode Gap	Exposure Extension Period	Pre-Existing Condition	Include/Exclude	Lookback Start	Lookback End	Care Setting PDX	Event/Outcome
31	Amiodarone	Amiodarone	183	01 (Sing)	10	0	AF/Flutter CHF, CAD/IHD, Cadiomy, CABG	Include Exclude	-183	-1	Any	None
32	Dronedarone	Dronedarone	183	01 (Sing)	10	0	AF/Flutter CHF, CAD/IHD, Cadiomy, CABG	Include Exclude	-183	-1	Any	None
33	Dofetilide	Dofetilide	183	01 (Sing)	10	0	AF/Flutter CHF, CAD/IHD, Cadiomy, CABG	Include Exclude	-183	-1	Any	None
34	Flecainide	Flecainide	183	01 (Sing)	10	0	AF/Flutter CHF, CAD/IHD, Cadiomy, CABG	Include Exclude	-183	-1	Any	None
35	Propafenone	Propafenone	183	01 (Sing)	10	0	AF/Flutter CHF, CAD/IHD, Cadiomy, CABG	Include Exclude	-183	-1	Any	None
36	Sotalol	Sotalol	183	01 (Sing)	10	0	AF/Flutter CHF, CAD/IHD, Cadiomy, CABG	Include Exclude	-365	-1	Any	None
37	Amiodarone	Amiodarone	365	01 (Sing)	10	0	AF/Flutter CHF, CAD/IHD, Cadiomy, CABG	Include Exclude	-365	-1	Any	None
38	Dronedarone	Dronedarone	365	01 (Sing)	10	0	AF/Flutter CHF, CAD/IHD, Cadiomy, CABG	Include Exclude	-365	-1	Any	None
39	Dofetilide	Dofetilide	365	01 (Sing)	10	0	AF/Flutter CHF, CAD/IHD, Cadiomy, CABG	Include Exclude	-365	-1	Any	None
40	Flecainide	Flecainide	365	01 (Sing)	10	0	AF/Flutter CHF, CAD/IHD, Cadiomy, CABG	Include Exclude	-365	-1	Any	None
41	Propafenone	Propafenone	365	01 (Sing)	10	0	AF/Flutter CHF, CAD/IHD, Cadiomy, CABG	Include Exclude	-365	-1	Any	None
42	Sotalol	Sotalol	365	01 (Sing)	10	0	AF/Flutter CHF, CAD/IHD, Cadiomy, CABG	Include Exclude	-365	-1	Any	None

National Drug Codes (NDC) checked against First Data Bank's "National Drug Data File (NDDF®) Plus"  
 International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) diagnosis and procedure codes checked against Ingenix 2012 ICD-9-CM Data File provided by OptumInsight  
 Healthcare Common Procedure Coding System (HCPCS) codes checked against "Optum 2012 HCPCS Level II Data File" provided by OptumInsight  
 Common Procedural Terminology Fourth Edition (CPT-4) codes checked against "Optum 2012 Current Procedure Codes & Relative Values Data File" provided by OptumInsight