Modular Program Report

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

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

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

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

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Overview

Request Description	These results were generated using the Mini-Sentinel Modular Program #1 Version 1.0. The query was run against the **Mini-Sentinel Distributed Database** and distributed on **August 2, 2011.** This request generated counts of users for four different vascular endothelial growth factor (VEGF) inhibitors (Bevacizumab, Sorafenib, Sunitinib, Thalidomide). A total of 3 different categories of counts were generated: (1) Incident counts with respect to any of the four VEGF Inhibitors, (2) Incident counts with respect to only the drug itself, and (3) prevalent counts (i.e., counts of users with at least one dispensing during the period of interest [2007-2010]). Please review the Notes below and review the Specifications page for request details.
Request ID	MSY2_MPR06
Specifications	Program parameter inputs and scenarios.
Table 1	Summary of Incidence Use with respect to any VEGF inhibitors (Bevacizumab, Sorafenib, Sunitinib, Thalidomide) in the MSDD between January 1, 2007 through December 31, 2010, by Drug Product, Age Group, Sex and Year
Table 2	Summary of Incidence Use with respect to Drug Product Itself for VEGF inhibitors (Bevacizumab, Sorafenib, Sunitinib, Thalidomide) in the MSDD between January 1, 2007 through December 31, 2010, by Drug Product, Age Group, Sex and Year
Table 3	Summary of Prevalence Use of VEGF inhibitors (Bevacizumab, Sorafenib, Sunitinib, Thalidomide) in the MSDD between January 1, 2007 through December 31, 2010, by Drug Product, Age Group, Sex and Year
Figure 1	Number of Users with respect to any VEGF Inhibitors (Bevacizumab, Sorafenib, Sunitinib, Thalidomide) in the MSDD between January 1, 2007 through December 31, 2010, by Drug Product
Figure 2	Number of Dispensings per User with respect to any VEGF Inhibitors (Bevacizumab, Sorafenib, Sunitinib, Thalidomide) in the MSDD between January 1, 2007 through December 31, 2010, by Drug Product
Figure 3	Number of Days per User with respect to any VEGF Inhibitors (Bevacizumab, Sorafenib, Sunitinib, Thalidomide) in the MSDD between January 1, 2007 through December 31, 2010, by Drug Product
Figure 4	Number of Days per Dispensing with respect to any VEGF Inhibitors (Bevacizumab, Sorafenib, Sunitinib, Thalidomide) in the MSDD between January 1, 2007 through December 31, 2010, by Drug Product
Notes:	The specifications used a 183-day washout period to define new users. FDA's original specification provides treatment episode definitions and incident definitions. Please refer to the original specifications for details. Please contact the Mini-Sentinel Operations Center (MSOC_Requests@harvardpilgrim.org) for questions and to provide comments/suggestions for future enhancements to this document.

Modular Program Specifications

Modular Program #1 was used to generate counts of users for four different vascular endothelial growth factor (VEGF) inhibitors (Bevacizumab, Sorafenib, Sunitinib, Thalidomide). Three different categories of counts were generated: (1) Incident counts with respect to any of the four VEGF Inhibitors, (2) Incident counts with respect to only the drug itself, and (3) prevalent counts (i.e., counts of users with at least one dispensing during the period of interest [2007-2010]). The query period was from January 1, 2007 through December 31, 2010. This request examined 3 age groups, split as follows: 18-44, 45-64, 65+ years. A total 8 scenarios were examined in this report with a washout period of 183 days and differing incidence criteria. See below for a description of these scenarios.

	Drug/Exposure Criteria		
Scenario	**Incident exposure**	**Incident w/ respect to (incidence criteria):**	**Washout (days)**
1	Bevacizumab	Any VEGF Inhibitors	183
2	Sorafenib	Any VEGF Inhibitors	183
3	Sunitinib	Any VEGF Inhibitors	183
4	Thalidomide	Any VEGF Inhibitors	183
5	Bevacizumab	Bevacizumab	183
6	Sorafenib	Sorafenib	183
7	Sunitinib	Sunitinib	183
8	Thalidomide	Thalidomide	183

Table 1. Summary of Incidence Use with respect to any VEGF Inhibitors (Bevacizumab, Sorafenib, Sunitinib, Thalidomide) in the MSDD between January 1, 2007 through December 31, 2010, by Drug Product, Age Group, Sex and Year

			New Users	Dispensings	Days Supplied	Dispensings per User	Days Supplied per Dispensing	Days Supplied per User
VEGF Inhibitors								
Bevacizumab	***Overall***		**1909**	**10,402**	**131,789**	**5.45**	**12.67**	**69.04**
	Age Group	18 to 44 years	70	629	2,920	8.99	4.64	41.71
		45 to 64 years	438	3,633	16,939	8.29	4.66	38.67
		65+ years	1401	6,140	111,930	4.38	18.23	79.89
	Sex	Female	1,098	6,248	78,009	5.69	12.49	71.05
		Male	811	4,154	53,780	5.12	12.95	66.31
		Unknown	0	0	0	0.00	0.00	0.00
	Year	2007	288	1,402	9,235	4.87	6.59	32.07
		2008	721	2,804	37,853	3.89	13.50	52.50
		2009	1,048	4,241	65,484	4.05	15.44	62.48
		2010	539	1,955	19,217	3.63	9.83	35.65
Sorafenib	***Overall***		**2,877**	**11,907**	**304,705**	**4.14**	**25.59**	**105.91**
	Age Group	18 to 44 years	141	468	12,477	3.32	26.66	88.49
		45 to 64 years	1,315	5,678	141,582	4.32	24.94	107.67
		65+ years	1,421	5,743	150,636	4.04	26.23	106.01
	Sex	Female	818	3,370	86,221	4.12	25.58	105.40
		Male	2,058	8,536	218,484	4.15	25.60	106.16
		Unknown	1	1	0	1.00	0.00	0.00
	Year	2007	569	1,810	41,342	3.18	22.84	72.66
		2008	1,004	3,178	87,425	3.17	27.51	87.08
		2009	1,042	3,666	91,647	3.52	25.00	87.95
		2010	912	3,253	84,291	3.57	25.91	92.42
Sunitinib	***Overall***		**2,502**	**12,266**	**314,648**	**4.90**	**25.65**	**125.76**
	Age Group	18 to 44 years	125	599	14,987	4.79	25.02	119.90
		45 to 64 years	1,152	6,330	166,043	5.49	26.23	144.13
		65+ years	1,225	5,337	133,618	4.36	25.04	109.08
	Sex	Female	890	4,006	103,666	4.50	25.88	116.48
		Male	1,612	8,260	210,982	5.12	25.54	130.88
		Unknown	0	0	0	0.00	0.00	0.00
	Year	2007	581	1,793	45,687	3.09	25.48	78.64
		2008	926	3,298	84,613	3.56	25.66	91.37
		2009	946	3,727	91,405	3.94	24.53	96.62
		2010	891	3,448	92,943	3.87	26.96	104.31
Thalidomide	***Overall***		**3,328**	**22,175**	**566,659**	**6.66**	**25.55**	**170.27**
	Age Group	18 to 44 years	119	891	20,742	7.49	23.28	174.30
		45 to 64 years	1,073	7,373	182,256	6.87	24.72	169.86
		65+ years	2,136	13,911	363,661	6.51	26.14	170.25
	Sex	Female	1,493	10,220	263,820	6.85	25.81	176.70
		Male	1,833	11,945	302,643	6.52	25.34	165.11
		Unknown	2	10	196	5.00	19.60	98.00
	Year	2007	1,052	4,118	104,724	3.91	25.43	99.55
		2008	1,463	6,882	181,979	4.70	26.44	124.39
		2009	1,266	6,376	157,186	5.04	24.65	124.16
		2010	926	4,799	122,770	5.18	25.58	132.58

Table 2. Summary of Incidence Use with respect to Drug Product Itself for VEGF Inhibitors (Bevacizumab, Sorafenib, Sunitinib, Thalidomide) in the MSDD between January 1, 2007 through December 31, 2010, by Drug Product, Age Group, Sex and Year

			New Users	Dispensings	Days Supplied	Dispensings per User	Days Supplied per Dispensing	Days Supplied per User
VEGF Inhibitors								
Bevacizumab	***Overall***		**1,916**	**10,433**	**132032**	**5.45**	**12.66**	**68.91**
	Age Group	18 to 44 years	71	635	2926	8.94	4.61	41.21
		45 to 64 years	440	3,647	17040	8.29	4.67	38.73
		65+ years	1,405	6,151	112066	4.38	18.22	79.76
	Sex	Female	1,098	6,248	78,009	5.69	12.49	71.05
		Male	818	4,185	54,023	5.12	12.91	66.04
		Unknown	0	0	0	0.00	0.00	0.00
	Year	2007	291	1,414	9,334	4.86	6.60	32.08
		2008	723	2,812	37,861	3.89	13.46	52.37
		2009	1,050	4,249	65,532	4.05	15.42	62.41
		2010	541	1,958	19,305	3.62	9.86	35.68
Sorafenib	***Overall***		**3,271**	**13,667**	**350,505**	**4.18**	**25.65**	**107.16**
	Age Group	18 to 44 years	153	510	13,107	3.33	25.70	85.67
		45 to 64 years	1,522	6,635	165,416	4.36	24.93	108.68
		65+ years	1,596	6,522	171,982	4.09	26.37	107.76
	Sex	Female	952	3,963	101,855	4.16	25.70	106.99
		Male	2,318	9,703	248,650	4.19	25.63	107.27
		Unknown	1	1	0	1.00	0.00	0.00
	Year	2007	666	2,120	48,705	3.18	22.97	73.13
		2008	1,153	3,662	100,851	3.18	27.54	87.47
		2009	1,184	4,209	105,128	3.55	24.98	88.79
		2010	1,009	3,676	95,821	3.64	26.07	94.97
Sunitinib	***Overall***		**2,707**	**13,230**	**339,831**	**4.89**	**25.69**	**125.54**
	Age Group	18 to 44 years	131	618	15,417	4.72	24.95	117.69
		45 to 64 years	1,250	6,768	177,569	5.41	26.24	142.06
		65+ years	1,326	5,844	146,845	4.41	25.13	110.74
	Sex	Female	951	4,255	110,089	4.47	25.87	115.76
		Male	1,756	8,975	229,742	5.11	25.60	130.83
		Unknown	0	0	0	0.00	0.00	0.00
	Year	2007	664	2,062	52,454	3.11	25.44	79.00
		2008	1,014	3,620	93,311	3.57	25.78	92.02
		2009	1,003	3,952	97,204	3.94	24.60	96.91
		2010	933	3,596	96,862	3.85	26.94	103.82
Thalidomide	***Overall***		**3,343**	**22,239**	**567,921**	**6.65**	**25.54**	**169.88**
	Age Group	18 to 44 years	120	895	20,854	7.46	23.30	173.78
		45 to 64 years	1,084	7,419	183,068	6.84	24.68	168.88
		65+ years	2,139	13,925	363,999	6.51	26.14	170.17
	Sex	Female	1,496	10,224	263,932	6.83	25.81	176.43
		Male	1,845	12,005	303,793	6.51	25.31	164.66
		Unknown	2	10	196	5.00	19.60	98.00
	Year	2007	1,058	4,142	105,256	3.91	25.41	99.49
		2008	1,469	6,893	182,231	4.69	26.44	124.05
		2009	1,271	6,392	157,468	5.03	24.64	123.89
		2010	928	4,812	122,966	5.19	25.55	132.51

Table 3. Summary of Prevalence Use of VEGF Inhibitors (Bevacizumab, Sorafenib, Sunitinib, Thalidomide) in the MSDD between January 1, 2007 through December 31, 2010, by Drug Product, Age Group, Sex and Year

			New Users	Dispensings	Days Supplied	Dispensings per User	Days Supplied per Dispensing	Days Supplied per User
VEGF Inhibitors								
Bevacizumab	***Overall***		**2,421**	**14,165**	**172,790**	**5.85**	**12.20**	**71.37**
	Age Group	18 to 44 years	98	921	4,040	9.40	4.39	41.22
		45 to 64 years	593	5,189	24,468	8.75	4.72	41.26
		65+ years	1,730	8,055	144,282	4.66	17.91	83.40
	Sex	Female	1,382	8,307	101,391	6.01	12.21	73.37
		Male	1,039	5,858	71,399	5.64	12.19	68.72
		Unknown	0	0	0	0.00	0.00	0.00
	Year	2007	633	2,998	23,654	4.74	7.89	37.37
		2008	889	3,697	50,227	4.16	13.59	56.50
		2009	1,190	5,026	76,257	4.22	15.17	64.08
		2010	644	2,444	22,652	3.80	9.27	35.17
Sorafenib	***Overall***		**4,263**	**19,307**	**497,832**	**4.53**	**25.79**	**116.78**
	Age Group	18 to 44 years	186	657	17,091	3.53	26.01	91.89
		45 to 64 years	1,931	8,760	219,085	4.54	25.01	113.46
		65+ years	2,146	9,890	261,656	4.61	26.46	121.93
	Sex	Female	1,236	5,592	144,336	4.52	25.81	116.78
		Male	3,026	13,714	353,496	4.53	25.78	116.82
		Unknown	1	1	0	1.00	0.00	0.00
	Year	2007	1,261	4,515	110,026	3.58	24.37	87.25
		2008	1,474	5,194	142,733	3.52	27.48	96.83
		2009	1,381	5,231	131,390	3.79	25.12	95.14
		2010	1,214	4,367	113,683	3.60	26.03	93.64
Sunitinib	***Overall***		**3,773**	**19,909**	**510,976**	**5.28**	**25.67**	**135.43**
	Age Group	18 to 44 years	182	857	21,222	4.71	24.76	116.60
		45 to 64 years	1,700	10,016	260,814	5.89	26.04	153.42
		65+ years	1,891	9,036	228,940	4.78	25.34	121.07
	Sex	Female	1,327	6,393	166,818	4.82	26.09	125.71
		Male	2,446	13,516	344,158	5.53	25.46	140.70
		Unknown	0	0	0	0.00	0.00	0.00
	Year	2007	1,377	4,973	124,733	3.61	25.08	90.58
		2008	1,396	5,309	137,837	3.80	25.96	98.74
		2009	1,221	5,073	126,234	4.15	24.88	103.39
		2010	1,152	4,554	122,172	3.95	26.83	106.05
Thalidomide	***Overall***		**5,846**	**48,650**	**1,260,049**	**8.32**	**25.90**	**215.54**
	Age Group	18 to 44 years	227	2,154	50,505	9.49	23.45	222.49
		45 to 64 years	1,874	16,437	409,082	8.77	24.89	218.29
		65+ years	3,745	30,059	800,462	8.03	26.63	213.74
	Sex	Female	2,634	21,951	577,243	8.33	26.30	219.15
		Male	3,210	26,689	682,610	8.31	25.58	212.65
		Unknown	2	10	196	5.00	19.60	98.00
	Year	2007	3,088	15,049	397,692	4.87	26.43	128.79
		2008	2,585	14,521	389,437	5.62	26.82	150.65
		2009	1,841	11,235	275,103	6.10	24.49	149.43
		2010	1,355	7,845	197,817	5.79	25.22	145.99

Figure 1. Number of Users with respect to any VEGF Inhibitors (Bevacizumab, Sorafenib, Sunitinib, Thalidomide) in the MSDD between January 1, 2007 through December 31, 2010, by Drug Product

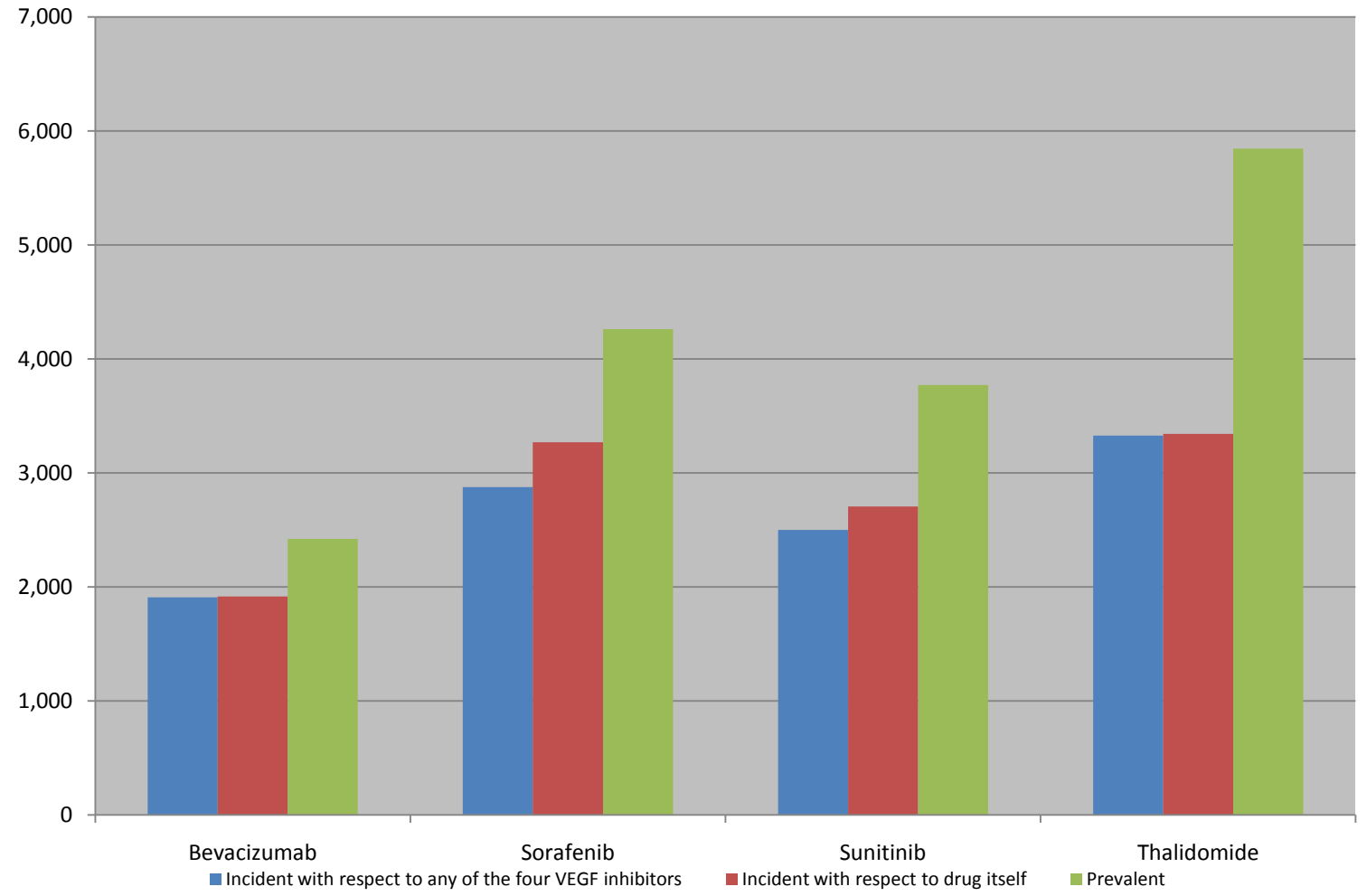

Figure 2. Number of Dispensings per User with respect to any VEGF Inhibitors (Bevacizumab, Sorafenib, Sunitinib, Thalidomide) in the MSDD between January 1, 2007 through December 31, 2010, by Drug Product

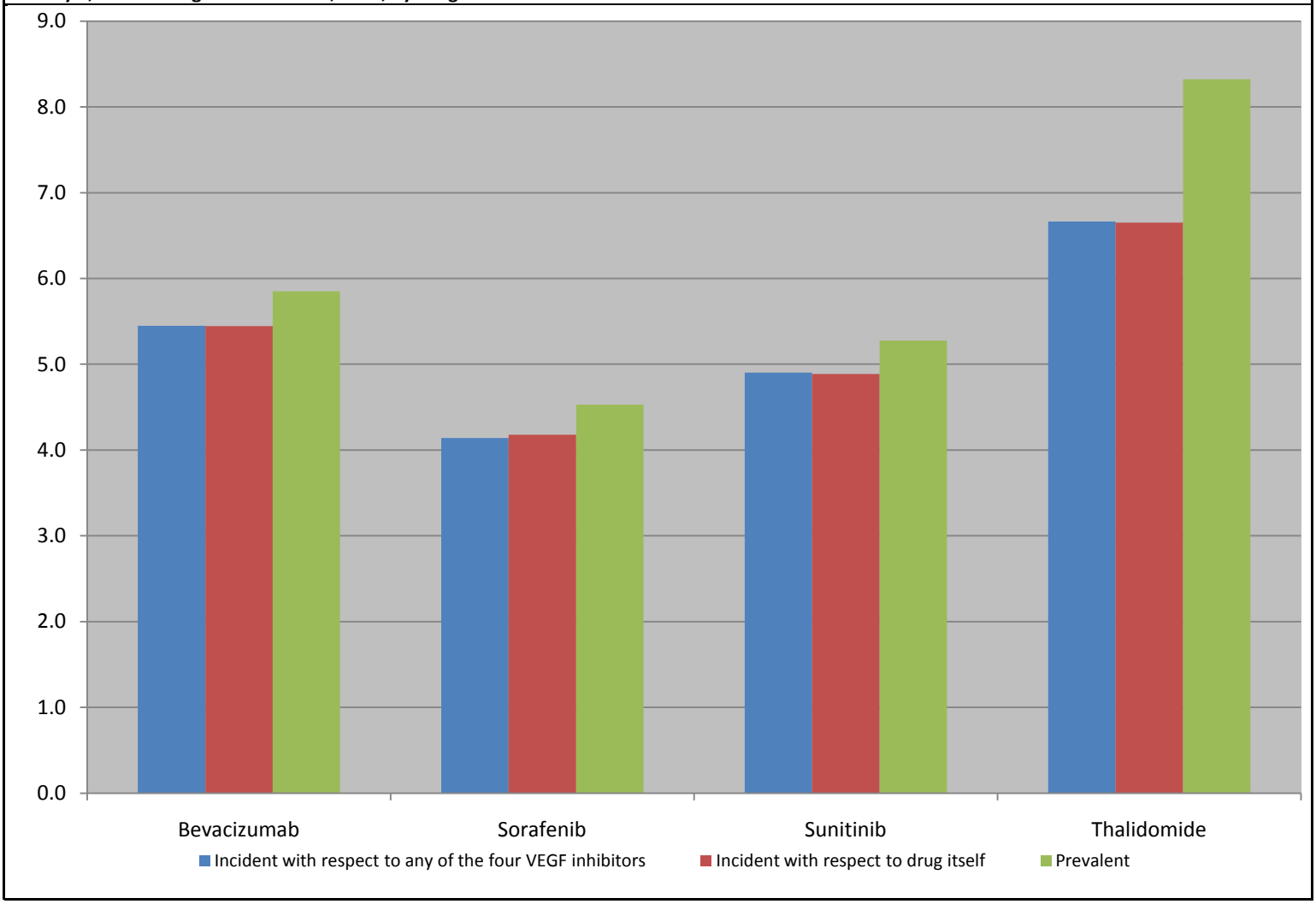

Figure 3. Number of Days per User with respect to any VEGF Inhibitors (Bevacizumab, Sorafenib, Sunitinib, Thalidomide) in the MSDD between January 1, 2007 through December 31, 2010, by Drug Product

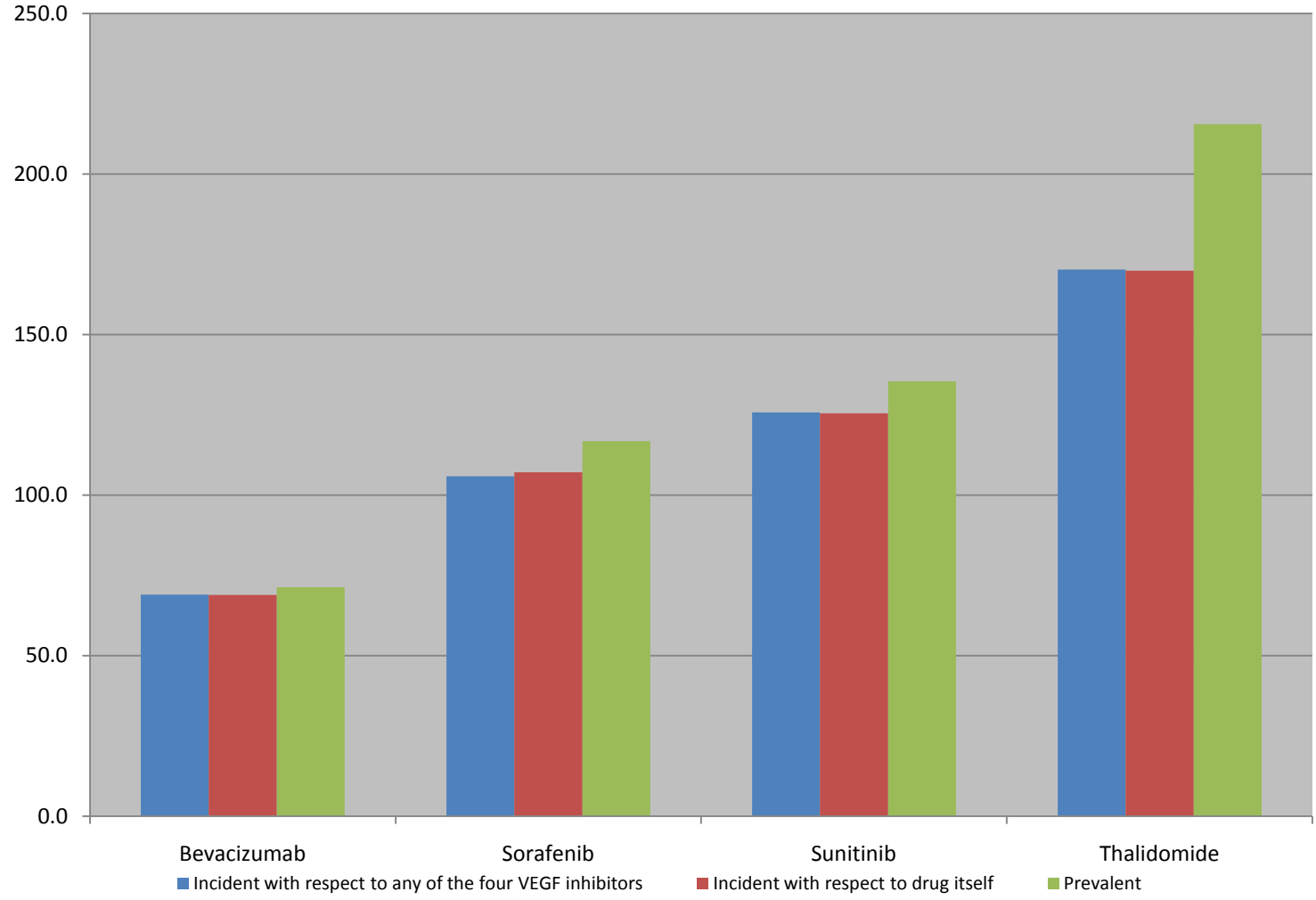

Figure 4. Number of Days per Dispensing with respect to any VEGF Inhibitors (Bevacizumab, Sorafenib, Sunitinib, Thalidomide) in the MSDD between January 1, 2007 through December 31, 2010, by Drug Product