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Data obtained through 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 Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in 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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Table 1.3a. Baseline Characteristics for Inhaled Corticosteroid Users in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015

Characteristic ¹	Number	
Number of episodes	24,381,059	
Number of unique patients	15,855,473	
Demographics	Mean	Standard Deviation
Mean Age (Years)	40.8	20.6
	Number	Percent
Age (Years)		
0-11	3,142,132	12.9%
12-17	1,835,793	7.5%
18-24	1,562,697	6.4%
25-34	2,814,108	11.5%
35-44	3,861,939	15.8%
45-54	4,292,603	17.6%
55-64	3,645,854	15.0%
65-74	1,974,942	8.1%
75+	1,250,991	5.1%
Gender		
Female	8,928,987	56.3%
Male	6,925,643	43.7%
Unknown	843	0.0%
Year		
2000	205,429	0.8%
2001	561,346	2.3%
2002	578,614	2.4%
2003	585,614	2.4%
2004	589,979	2.4%
2005	617,105	2.5%
2006	880,950	3.6%
2007	1,215,612	5.0%
2008	1,822,219	7.5%
2009	2,484,613	10.2%
2010	2,485,244	10.2%
2011	2,481,657	10.2%
2012	2,577,506	10.6%
2013	2,768,811	11.4%
2014	2,865,556	11.8%
2015	1,660,804	6.8%
Recorded History during Baseline Period:	Mean	Standard Deviation
Charlson/Elixhauser combined comorbidity score ²	0.4	1.1
	Number	Percent
Asthma	4,062,594	16.7%
Allergic rhinitis	6,496,334	26.6%

¹All metrics are based on total number of episodes per group, except for sex which is based on total number of unique patients

²The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

Table 1.3b. Baseline Characteristics for Inhaled Corticosteroid Users among Data Partners with Cause-of-Death Data in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015

Characteristic¹	Number	
Number of episodes	8,843,054	
Number of unique patients	4,446,664	
Demographics	Mean	Standard Deviation
Mean Age (Years)	39.9	21.3
	Number	Percent
Age (Years)		
0-11	1,271,026	14.4%
12-17	758,787	8.6%
18-24	563,147	6.4%
25-34	1,014,259	11.5%
35-44	1,347,257	15.2%
45-54	1,446,672	16.4%
55-64	1,243,566	14.1%
65-74	720,150	8.1%
75+	478,190	5.4%
Gender		
Female	2,529,812	56.9%
Male	1,916,649	43.1%
Unknown	203	0.0%
Year		
2000	199,779	2.3%
2001	542,539	6.1%
2002	554,337	6.3%
2003	561,727	6.4%
2004	562,069	6.4%
2005	587,539	6.6%
2006	572,047	6.5%
2007	559,626	6.3%
2008	558,969	6.3%
2009	584,332	6.6%
2010	588,538	6.7%
2011	600,194	6.8%
2012	601,155	6.8%
2013	624,050	7.1%
2014	634,290	7.2%
2015	511,863	5.8%
Recorded History during Baseline Period:	Mean	Standard Deviation
Charlson/Elixhauser combined comorbidity score ²	0.4	1.1
	Number	Percent
Asthma	1,778,330	20.1%
Allergic rhinitis	2,111,522	23.9%

¹All metrics are based on total number of episodes per group, except for sex which is based on total number of unique patients

²The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

Table 1.4a. Baseline Characteristics for Nasal Corticosteroid Users in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015

Characteristic ¹	Number	
Number of episodes	18,280,386	
Number of unique patients	12,647,853	
Demographics	Mean	Standard Deviation
Mean Age (Years)	41.7	19.3
	Number	Percent
Age (Years)		
0-11	1,729,123	9.5%
12-17	1,339,036	7.3%
18-24	1,226,684	6.7%
25-34	2,345,714	12.8%
35-44	3,167,075	17.3%
45-54	3,417,571	18.7%
55-64	2,791,583	15.3%
65-74	1,413,725	7.7%
75+	849,875	4.6%
Gender		
Female	7,222,723	57.1%
Male	5,424,440	42.9%
Unknown	690	0.0%
Year		
2000	147,269	0.8%
2001	420,556	2.3%
2002	425,516	2.3%
2003	414,956	2.3%
2004	413,037	2.3%
2005	418,915	2.3%
2006	621,193	3.4%
2007	890,352	4.9%
2008	1,320,945	7.2%
2009	1,815,722	9.9%
2010	1,873,170	10.2%
2011	1,902,466	10.4%
2012	1,996,518	10.9%
2013	2,166,929	11.9%
2014	2,261,307	12.4%
2015	1,191,535	6.5%
Recorded History during Baseline Period:	Mean	Standard Deviation
Charlson/Elixhauser combined comorbidity score ²	0.2	1
	Number	Percent
Asthma	1,264,472	6.9%
Allergic rhinitis	5,831,972	31.9%

¹All metrics are based on total number of episodes per group, except for sex which is based on total number of unique patients

²The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

Table 1.4b. Baseline Characteristics for Nasal Corticosteroid Users among Data Partners with Cause-of-Death Data in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015

Characteristic ¹	Number	
Number of episodes	6,210,886	
Number of unique patients	3,470,990	
Demographics	Mean	Standard Deviation
Mean Age (Years)	41.2	19.7
	Number	Percent
Age (Years)		
0-11	635,785	10.2%
12-17	521,372	8.4%
18-24	413,452	6.7%
25-34	800,411	12.9%
35-44	1,040,827	16.8%
45-54	1,078,435	17.4%
55-64	896,115	14.4%
65-74	502,488	8.1%
75+	322,001	5.2%
Gender		
Female	2,007,371	57.8%
Male	1,463,462	42.2%
Unknown	157	0.0%
Year		
2000	143,522	2.3%
2001	407,718	6.6%
2002	409,025	6.6%
2003	399,232	6.4%
2004	395,318	6.4%
2005	399,878	6.4%
2006	397,525	6.4%
2007	393,771	6.3%
2008	384,033	6.2%
2009	394,413	6.4%
2010	406,188	6.5%
2011	416,878	6.7%
2012	421,782	6.8%
2013	437,721	7.0%
2014	446,111	7.2%
2015	357,771	5.8%
Recorded History during Baseline Period:	Mean	Standard Deviation
Charlson/Elixhauser combined comorbidity score ²	0.2	0.9
	Number	Percent
Asthma	510,251	8.2%
Allergic rhinitis	1,921,415	30.9%

¹All metrics are based on total number of episodes per group, except for sex which is based on total number of unique patients

²The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

Table 2a. Summary of Incident Drug Exposure in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015

Drug	New Users	Eligible Members¹	New Users per 10,000 Eligible Members	New Episodes	Dispensings	Days Supplied	Amount Supplied	Eligible Member- Years¹
Montelukast	2,966,182	119,778,726	247.64	3,769,064	3,773,519	130,174,488	135,298,250	328,987,147.1
Zafirlukast	22,877	119,778,726	1.91	25,463	25,495	875,468	1,698,711	328,987,147.1
Inhaled Corticosteroids	15,855,473	117,968,359	1,344.04	24,381,059	24,470,600	838,763,030	530,861,874	305,015,697.7
Nasal Corticosteroids	12,647,853	117,968,358	1,072.14	18,280,386	18,286,107	617,149,994	330,384,512	305,015,697.7

¹Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on a least one day during the query period.

Table 2b. Summary of Incident Drug Exposure among Data Partners with Cause-of-Death Data in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015

	New Users	Eligible Members¹	New Users per 10,000 Eligible Members	New Episodes	Dispensings	Days Supplied	Amount Supplied	Eligible Member- Years¹
Montelukast	628,615	19,539,716	321.71	920,698	923,571	34,842,659	39,848,369	95,403,024.4
Zafirlukast	6,231	19,539,716	3.19	7,059	7,082	222,505	469,264	95,403,024.4
Inhaled Corticosteroids	4,446,664	19,307,612	2,303.06	8,843,054	8,888,587	347,478,908	190,919,217	86,479,073.3
Nasal Corticosteroids	3,470,990	19,307,612	1,797.73	6,210,886	6,214,982	239,370,521	127,502,977	86,479,073.3

¹Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on a least one day during the query period.

Table 3a. Summary of Incident Drug Exposure in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015, by Age Group

Age Group (Years)	New Users	Eligible Members ¹	New Users per 10,000 Eligible Members	New Episodes	Dispensings	Days Supplied	Amount Supplied	Eligible Member- Years ¹
Montelukast								
0-11	853,794	20,708,292	412.30	1,126,116	1,128,500	36,617,561	39,343,188	46,177,240.3
12-17	328,463	14,012,914	234.40	407,860	408,241	13,928,737	14,288,940	27,279,720.1
18-24	189,526	18,105,497	104.68	218,229	218,495	7,432,287	7,666,037	29,921,316.8
25-34	289,265	25,041,409	115.51	331,387	331,570	10,955,090	11,274,848	42,286,467.4
35-44	396,042	23,774,846	166.58	466,166	466,497	15,935,145	16,503,831	48,586,565.5
45-54	430,291	23,677,854	181.73	506,105	506,454	17,928,121	18,152,126	53,568,934.2
55-64	355,282	17,822,726	199.34	414,005	414,405	15,317,657	15,600,961	43,044,901.4
65-74	172,357	8,554,651	201.48	197,653	197,772	8,023,911	8,307,495	22,066,689.3
75+	88,752	4,703,994	188.67	101,543	101,585	4,035,979	4,160,824	16,055,312.1
Zafirlukast								
0-11	470	20,708,292	0.23	504	506	15,745	28,627	46,177,240.3
12-17	810	14,012,914	0.58	871	875	26,770	48,699	27,279,720.1
18-24	1,169	18,105,497	0.65	1,234	1,237	38,301	72,075	29,921,316.8
25-34	2,743	25,041,409	1.10	2,948	2,951	90,153	171,158	42,286,467.4
35-44	4,278	23,774,846	1.80	4,619	4,625	146,374	336,390	48,586,565.5
45-54	4,902	23,677,854	2.07	5,418	5,423	184,837	349,074	53,568,934.2
55-64	4,430	17,822,726	2.49	4,939	4,946	184,449	346,096	43,044,901.4
65-74	2,938	8,554,651	3.43	3,244	3,245	125,311	232,457	22,066,689.3
75+	1,538	4,703,994	3.27	1,686	1,687	63,528	114,136	16,055,312.1
Inhaled Corticosteroids								
0-11	2,196,499	20,497,340	1,071.60	3,142,132	3,164,880	107,606,590	87,840,159	43,715,653.7
12-17	1,393,319	13,862,871	1,005.07	1,835,793	1,847,717	63,119,457	35,362,872	25,825,673.5
18-24	1,269,354	17,952,025	707.08	1,562,697	1,569,646	50,948,106	30,994,863	28,711,401.5
25-34	2,178,738	24,721,131	881.33	2,814,108	2,823,669	91,701,668	53,048,090	39,977,031.1
35-44	2,794,957	23,339,307	1,197.53	3,861,939	3,874,117	128,312,626	75,673,846	45,005,698.6
45-54	3,026,630	23,123,437	1,308.90	4,292,603	4,304,422	146,052,974	88,129,501	49,055,513.8
55-64	2,535,765	17,285,474	1,466.99	3,645,854	3,654,690	128,287,161	80,034,375	38,781,681.0
65-74	1,346,968	8,213,764	1,639.89	1,974,942	1,978,628	75,095,003	48,322,468	19,558,074.6
75+	814,961	4,536,137	1,796.60	1,250,991	1,252,831	47,639,445	31,455,701	14,384,970.0

Table 3a. Summary of Incident Drug Exposure in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015, by Age Group

Age Group (Years)	New Users	Eligible Members ¹	New Users per 10,000 Eligible Members	New Episodes	Dispensings	Days Supplied	Amount Supplied	Eligible Member- Years ¹
Nasal Corticosteroids								
0-11	1,351,126	20,497,340	659.17	1,729,123	1,730,052	58,657,101	29,548,498	43,715,653.7
12-17	1,076,164	13,862,871	776.29	1,339,036	1,339,763	44,198,005	23,578,385	25,825,673.5
18-24	1,037,166	17,952,025	577.74	1,226,684	1,227,120	39,050,633	21,542,111	28,711,401.5
25-34	1,872,814	24,721,131	757.58	2,345,714	2,346,331	75,431,485	40,863,148	39,977,031.1
35-44	2,373,941	23,339,307	1,017.14	3,167,075	3,167,895	103,922,188	56,028,472	45,005,698.6
45-54	2,502,211	23,123,437	1,082.11	3,417,571	3,418,479	114,724,474	61,644,469	49,055,513.8
55-64	2,019,964	17,285,474	1,168.59	2,791,583	2,792,401	96,548,250	52,497,896	38,781,681.0
65-74	1,006,948	8,213,763	1,225.93	1,413,725	1,414,023	52,801,763	28,006,629	19,558,074.5
75+	580,117	4,536,137	1,278.88	849,875	850,043	31,816,095	16,674,904	14,384,970.0

¹Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on a least one day during the query period.

Table 3b. Summary of Incident Drug Exposure among Data Partners with Cause-of-Death Data in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015, by Age Group

Age Group (Years)	New Users	Eligible Members ¹	New Users per 10,000 Eligible Members	New Episodes	Dispensings	Days Supplied	Amount Supplied	Eligible Member- Years ¹
Montelukast								
0-11	284,091	4,901,758	579.57	431,754	433,820	14,793,117	17,512,799	16,726,459.0
12-17	95,674	3,323,965	287.83	127,599	127,792	4,726,629	5,054,585	9,142,424.9
18-24	37,863	3,755,588	100.82	45,009	45,192	1,737,358	1,957,538	8,497,792.0
25-34	49,799	4,627,856	107.61	60,416	60,532	2,393,596	2,704,878	11,246,085.5
35-44	60,855	4,313,446	141.08	74,529	74,667	3,121,891	3,676,291	13,104,705.1
45-54	61,637	4,041,548	152.51	74,673	74,757	3,237,395	3,443,948	14,014,854.7
55-64	52,728	3,109,593	169.57	62,614	62,688	2,771,047	3,039,118	11,745,164.0
65-74	25,766	1,580,906	162.98	29,550	29,566	1,396,841	1,671,837	6,257,555.4
75+	12,845	924,487	138.94	14,554	14,557	664,785	787,375	4,667,983.7
Zafirlukast								
0-11	201	4,901,758	0.41	214	216	5,905	10,493	16,726,459.0
12-17	373	3,323,965	1.12	407	410	11,826	20,893	9,142,424.9
18-24	355	3,755,588	0.95	386	389	11,419	20,736	8,497,792.0
25-34	722	4,627,856	1.56	806	808	22,948	41,832	11,246,085.5
35-44	1,144	4,313,446	2.65	1,268	1,274	38,169	131,026	13,104,705.1
45-54	1,336	4,041,548	3.31	1,496	1,499	48,068	88,593	14,014,854.7
55-64	1,271	3,109,593	4.09	1,408	1,411	47,398	87,141	11,745,164.0
65-74	657	1,580,906	4.16	720	721	24,782	46,805	6,257,555.4
75+	325	924,487	3.52	354	354	11,990	21,745	4,667,983.7
Inhaled Corticosteroids								
0-11	766,143	4,869,681	1,573.29	1,271,026	1,284,137	51,653,905	34,434,912	15,733,295.4
12-17	518,084	3,292,612	1,573.47	758,787	765,101	30,182,593	14,949,817	8,531,299.7
18-24	421,392	3,721,491	1,132.32	563,147	566,432	20,822,867	12,010,096	8,053,687.2
25-34	680,869	4,561,089	1,492.78	1,014,259	1,019,092	37,976,451	20,161,209	10,391,203.3
35-44	822,237	4,230,761	1,943.47	1,347,257	1,353,143	51,618,944	27,480,640	11,815,604.9
45-54	850,830	3,941,110	2,158.86	1,446,672	1,452,253	56,465,824	30,010,399	12,426,546.6
55-64	724,253	3,011,304	2,405.11	1,243,566	1,247,548	49,186,040	26,117,412	10,227,596.5
65-74	415,104	1,511,783	2,745.79	720,150	721,856	29,731,274	15,711,490	5,298,364.5
75+	260,241	888,157	2,930.12	478,190	479,025	19,841,010	10,043,241	4,001,475.3

Table 3b. Summary of Incident Drug Exposure among Data Partners with Cause-of-Death Data in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015, by Age Group

Age Group (Years)	New Users	Eligible Members ¹	New Users per 10,000 Eligible Members	New Episodes	Dispensings	Days Supplied	Amount Supplied	Eligible Member- Years ¹
Nasal Corticosteroids								
0-11	455,411	4,869,681	935.20	635,785	636,662	25,115,788	12,037,654	15,733,295.4
12-17	387,057	3,292,612	1,175.53	521,372	522,037	19,462,023	10,413,475	8,531,299.7
18-24	329,678	3,721,491	885.88	413,452	413,817	14,829,334	8,485,717	8,053,687.2
25-34	566,192	4,561,089	1,241.35	800,411	800,915	29,640,487	16,195,281	10,391,203.3
35-44	673,276	4,230,761	1,591.38	1,040,827	1,041,386	39,619,258	21,357,034	11,815,604.9
45-54	677,090	3,941,110	1,718.02	1,078,435	1,078,945	41,856,464	22,359,021	12,426,546.6
55-64	558,703	3,011,304	1,855.35	896,115	896,493	35,137,730	18,785,643	10,227,596.5
65-74	310,296	1,511,783	2,052.52	502,488	502,647	20,513,633	11,006,929	5,298,364.5
75+	189,062	888,157	2,128.70	322,001	322,080	13,195,804	6,862,222	4,001,475.3

¹Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on a least one day during the query period.

Table 4a. Summary of Incident Drug Exposure in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015, by Sex

Sex	New Users	Eligible Members ¹	New Users per 10,000 Eligible Members	New Episodes	Dispensings	Days Supplied	Amount Supplied	Eligible Member- Years ¹
Montelukast								
Female	1,675,672	60,701,643	276.05	2,109,121	2,111,556	73,359,099	76,060,166	169,228,139.7
Male	1,290,380	59,070,447	218.45	1,659,784	1,661,804	56,809,719	59,232,339	159,741,222.4
Unknown	130	6,636	195.90	159	159	5,670	5,745	17,785.0
Zafirlukast								
Female	16,708	60,701,643	2.75	18,536	18,557	629,887	1,242,856	169,228,139.7
Male	6,167	59,070,447	1.04	6,925	6,936	245,501	455,595	159,741,222.4
Unknown	2	6,636	3.01	2	2	80	260	17,785.0
Inhaled Corticosteroids								
Female	8,928,987	59,709,149	1,495.41	13,914,407	13,963,281	476,944,068	296,830,961	155,739,162.6
Male	6,925,643	58,252,666	1,188.90	10,465,306	10,505,967	361,772,921	234,002,728	149,260,127.2
Unknown	843	6,544	1,288.20	1,346	1,352	46,041	28,185	16,408.0
Nasal Corticosteroids								
Female	7,222,723	59,709,148	1,209.65	10,539,365	10,542,918	354,192,569	190,297,557	155,739,162.5
Male	5,424,440	58,252,666	931.19	7,739,991	7,742,159	262,922,323	140,068,356	149,260,127.2
Unknown	690	6,544	1,054.40	1,030	1,030	35,102	18,599	16,408.0

¹Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on a least one day during the query period.

Table 4b. Summary of Incident Drug Exposure among Data Partners with Cause-of-Death Data in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015, by Sex

Sex	New Users	Eligible Members ¹	New Users per 10,000 Eligible Members	New Episodes	Dispensings	Days Supplied	Amount Supplied	Eligible Member- Years ¹
Montelukast								
Female	349,265	10,111,923	345.40	499,653	501,128	18,991,754	21,623,795	50,604,006.6
Male	279,333	9,426,695	296.32	421,020	422,418	15,849,710	18,223,364	44,794,406.1
Unknown	17	1,098	154.83	25	25	1,195	1,210	4,611.7
Zafirlukast								
Female	4,306	10,111,923	4.26	4,890	4,906	153,777	342,938	50,604,006.6
Male	1,924	9,426,695	2.04	2,168	2,175	68,678	126,127	44,794,406.1
Unknown	1	1,098	9.11	1	1	50	200	4,611.7
Inhaled Corticosteroids								
Female	2,529,812	9,981,666	2,534.46	5,129,714	5,154,800	198,897,427	108,801,337	45,462,771.8
Male	1,916,649	9,324,858	2,055.42	3,712,962	3,733,407	148,565,148	82,110,324	41,012,027.1
Unknown	203	1,088	1,865.81	378	380	16,333	7,555	4,274.4
Nasal Corticosteroids								
Female	2,007,371	9,981,666	2,011.06	3,632,866	3,635,503	138,093,303	74,700,952	45,462,771.8
Male	1,463,462	9,324,858	1,569.42	2,577,756	2,579,215	101,265,584	52,796,171	41,012,027.1
Unknown	157	1,088	1,443.01	264	264	11,634	5,854	4,274.4

¹Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on a least one day during the query period.

Table 5a. Summary of Incident Exposures in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015, by Year

Year	New Users	Eligible Members ¹	New Users per 10,000		New Episodes	Dispensings	Days Supplied	Amount Supplied	Eligible Member-Years ¹
			Eligible Members	New Episodes					
Montelukast									
2000	8,083	6,577,950	12.29	8,083	8,095	247,850	251,010	3,037,757.0	
2001	22,400	7,159,504	31.29	22,631	22,675	672,410	678,047	6,021,898.6	
2002	27,887	7,312,924	38.13	28,220	28,265	898,305	904,536	6,118,231.0	
2003	48,779	7,307,581	66.75	49,311	49,452	1,576,968	1,596,253	6,094,375.5	
2004	60,850	7,758,398	78.43	61,569	61,866	2,027,422	6,913,367	6,347,823.0	
2005	61,144	8,005,082	76.38	61,947	62,259	2,076,586	2,086,668	6,639,164.9	
2006	124,632	19,420,903	64.17	125,564	126,002	4,354,548	4,366,359	11,664,961.4	
2007	211,254	23,688,166	89.18	213,912	214,395	7,302,392	7,319,892	17,239,972.3	
2008	306,408	44,518,419	68.83	309,116	309,491	10,402,187	10,423,093	28,200,873.6	
2009	411,389	46,023,224	89.39	416,715	416,837	13,912,273	13,932,395	35,799,710.8	
2010	380,720	44,001,608	86.52	385,604	385,737	12,910,433	12,936,341	34,418,135.2	
2011	345,752	42,735,571	80.90	350,325	350,448	11,899,620	11,919,579	33,751,474.7	
2012	379,217	43,373,356	87.43	384,019	384,212	13,148,718	13,162,788	33,963,934.9	
2013	441,167	45,640,762	96.66	446,282	446,626	15,850,835	15,872,075	35,382,020.3	
2014	486,071	47,502,943	102.32	491,704	492,249	17,663,514	17,688,283	36,559,040.8	
2015	413,235	45,276,680	91.27	414,062	414,910	15,230,427	15,247,563	27,747,773.1	
Zafirlukast									
2000	961	6,577,950	1.46	961	963	27,405	53,729	3,037,757.0	
2001	1,680	7,159,504	2.35	1,690	1,698	49,591	92,641	6,021,898.6	
2002	1,464	7,312,924	2.00	1,479	1,482	44,280	79,560	6,118,231.0	
2003	904	7,307,581	1.24	910	914	27,494	50,141	6,094,375.5	
2004	399	7,758,398	0.51	401	402	13,282	84,558	6,347,823.0	
2005	310	8,005,082	0.39	312	312	9,801	18,465	6,639,164.9	
2006	579	19,420,903	0.30	581	582	20,884	39,764	11,664,961.4	
2007	873	23,688,166	0.37	885	885	31,560	59,601	17,239,972.3	
2008	1,493	44,518,419	0.34	1,503	1,503	51,732	98,689	28,200,873.6	
2009	2,277	46,023,224	0.49	2,298	2,300	78,160	146,611	35,799,710.8	
2010	2,141	44,001,608	0.49	2,156	2,157	75,051	141,519	34,418,135.2	
2011	2,842	42,735,571	0.67	2,855	2,857	101,644	190,650	33,751,474.7	
2012	3,637	43,373,356	0.84	3,662	3,664	131,073	242,460	33,963,934.9	
2013	2,635	45,640,762	0.58	2,655	2,656	97,293	181,202	35,382,020.3	
2014	1,847	47,502,943	0.39	1,853	1,856	68,779	129,799	36,559,040.8	
2015	1,262	45,276,680	0.28	1,262	1,264	47,439	89,322	27,747,773.1	

Table 5a. Summary of Incident Exposures in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015, by Year

Year	New Users	Eligible Members ¹	New Users per 10,000		New Episodes	Dispensings	Days Supplied	Amount Supplied	Eligible Member-Years ¹
			Eligible Members	New					
Inhaled Corticosteroids									
2000	205,429	6,278,410	327.20		205,429	207,047	7,197,198	3,712,518	2,788,837.6
2001	548,845	6,942,851	790.52		561,346	568,448	21,335,629	9,954,907	5,478,559.5
2002	565,574	7,062,094	800.86		578,614	586,590	22,886,241	11,094,730	5,526,463.9
2003	571,951	7,048,459	811.46		585,614	588,837	23,051,414	13,345,299	5,488,638.7
2004	576,499	7,491,647	769.52		589,979	591,356	22,107,510	29,365,950	5,742,009.8
2005	603,447	7,730,303	780.63		617,105	619,292	24,307,788	14,296,420	6,011,408.8
2006	868,178	18,824,130	461.20		880,950	884,732	32,959,443	20,554,120	10,793,745.9
2007	1,189,003	23,027,647	516.34		1,215,612	1,219,890	42,434,462	26,666,981	16,051,769.6
2008	1,793,473	43,271,807	414.47		1,822,219	1,828,079	62,382,274	41,696,383	26,396,845.4
2009	2,431,081	44,856,404	541.97		2,484,613	2,492,781	83,660,557	55,934,635	33,468,014.7
2010	2,431,532	42,808,377	568.00		2,485,244	2,492,070	82,893,003	53,263,192	32,032,749.0
2011	2,427,407	41,560,241	584.07		2,481,657	2,488,795	82,450,172	51,811,673	31,357,003.3
2012	2,520,725	42,131,914	598.29		2,577,506	2,585,337	85,639,038	52,705,073	31,495,313.9
2013	2,707,960	44,292,798	611.38		2,768,811	2,777,655	91,974,639	56,202,693	32,723,436.3
2014	2,804,641	46,114,451	608.19		2,865,556	2,874,792	95,748,228	56,156,608	33,834,037.7
2015	1,654,682	43,951,635	376.48		1,660,804	1,664,899	57,735,434	34,100,691	25,826,863.7
Nasal Corticosteroids									
2000	147,269	6,278,410	234.56		147,269	147,583	5,344,417	2,602,094	2,788,837.6
2001	413,045	6,942,851	594.92		420,556	420,936	16,638,008	7,398,437	5,478,559.5
2002	418,065	7,062,094	591.98		425,516	425,901	17,618,578	8,061,605	5,526,463.9
2003	407,863	7,048,459	578.66		414,956	415,332	17,116,895	9,740,069	5,488,638.7
2004	405,972	7,491,647	541.90		413,037	413,203	15,872,589	15,727,486	5,742,009.8
2005	412,322	7,730,303	533.38		418,915	419,466	17,070,297	9,983,942	6,011,408.8
2006	614,832	18,824,130	326.62		621,193	622,031	23,451,508	13,394,292	10,793,745.9
2007	874,680	23,027,647	379.84		890,352	890,675	30,745,546	16,178,013	16,051,769.6
2008	1,303,808	43,271,807	301.31		1,320,945	1,321,196	43,957,596	23,256,182	26,396,845.4
2009	1,783,182	44,856,403	397.53		1,815,722	1,815,849	59,341,265	31,156,779	33,468,014.7
2010	1,838,508	42,808,377	429.47		1,873,170	1,873,527	60,503,701	31,384,382	32,032,749.0
2011	1,866,894	41,560,241	449.20		1,902,466	1,902,629	61,069,876	31,871,354	31,357,003.3
2012	1,958,463	42,131,914	464.84		1,996,518	1,996,718	64,430,111	33,751,882	31,495,313.9
2013	2,125,800	44,292,798	479.94		2,166,929	2,167,258	69,978,242	37,228,644	32,723,436.3
2014	2,219,478	46,114,451	481.30		2,261,307	2,261,967	73,581,046	38,210,706	33,834,037.7
2015	1,187,968	43,951,635	270.29		1,191,535	1,191,836	40,430,319	20,438,645	25,826,863.7

¹Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on a least one day during the query period.

Table 5b. Summary of Incident Exposures among Data Partners with Cause-of-Death Data in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, by Year

Year	New Users	Eligible Members ¹	New Users per 10,000 Eligible Members	New Episodes	Dispensings	Days Supplied	Amount Supplied	Eligible Member-Years ¹
Montelukast								
2000	7,733	6,164,253	12.54	7,733	7,745	235,192	238,166	2,849,028.9
2001	21,634	6,700,248	32.29	21,854	21,897	646,683	653,365	5,642,942.9
2002	26,806	6,838,411	39.20	27,124	27,169	862,207	867,881	5,723,848.2
2003	47,549	6,822,564	69.69	48,067	48,208	1,534,450	1,553,564	5,694,164.2
2004	59,017	7,270,091	81.18	59,714	60,009	1,959,992	6,845,396	5,942,202.9
2005	59,266	7,388,525	80.21	60,054	60,365	2,002,790	2,012,502	6,197,281.1
2006	60,162	7,243,118	83.06	61,064	61,491	2,196,189	2,204,329	6,068,837.1
2007	63,510	7,223,555	87.92	64,535	64,995	2,390,516	2,398,126	6,093,818.8
2008	58,668	7,308,769	80.27	59,634	59,960	2,206,006	2,213,846	6,154,255.4
2009	62,977	7,437,707	84.67	64,008	64,039	2,323,835	2,332,451	6,243,746.1
2010	62,868	7,571,095	83.04	63,941	63,959	2,352,516	2,361,514	6,408,348.8
2011	62,375	7,739,970	80.59	63,419	63,434	2,397,540	2,405,925	6,584,651.4
2012	65,849	7,807,408	84.34	66,957	66,976	2,597,269	2,603,106	6,685,035.8
2013	79,065	7,834,806	100.92	80,269	80,355	3,500,057	3,506,762	6,708,313.4
2014	90,066	8,179,979	110.11	91,448	91,586	3,949,757	3,956,441	6,936,317.0
2015	80,669	8,278,865	97.44	80,877	81,383	3,687,660	3,694,996	5,470,232.5
Zafirlukast								
2000	946	6,164,253	1.53	946	948	26,900	52,569	2,849,028.9
2001	1,653	6,700,248	2.47	1,663	1,671	48,703	90,896	5,642,942.9
2002	1,448	6,838,411	2.12	1,463	1,466	43,705	78,530	5,723,848.2
2003	887	6,822,564	1.30	893	897	26,749	48,715	5,694,164.2
2004	362	7,270,091	0.50	364	365	12,010	82,088	5,942,202.9
2005	291	7,388,525	0.39	293	293	9,201	17,205	6,197,281.1
2006	171	7,243,118	0.24	173	174	6,754	12,338	6,068,837.1
2007	167	7,223,555	0.23	171	171	6,396	11,785	6,093,818.8
2008	211	7,308,769	0.29	212	212	7,293	12,454	6,154,255.4
2009	204	7,437,707	0.27	205	205	6,606	10,683	6,243,746.1
2010	115	7,571,095	0.15	118	118	4,885	8,894	6,408,348.8
2011	140	7,739,970	0.18	141	141	5,866	11,236	6,584,651.4
2012	136	7,807,408	0.17	137	138	5,468	9,923	6,685,035.8
2013	105	7,834,806	0.13	105	105	4,390	8,220	6,708,313.4
2014	100	8,179,979	0.12	100	102	4,353	7,927	6,936,317.0
2015	75	8,278,865	0.09	75	76	3,226	5,802	5,470,232.5

Table 5b. Summary of Incident Exposures among Data Partners with Cause-of-Death Data in the Sentinel Distributed Database between January 1, 2000 and September 30, 2015, by Year

Year	New Users	Eligible Members ¹	New Users per		Days Supplied	Amount Supplied	Eligible Member-Years ¹	
			10,000 Eligible Members	New Episodes				
Inhaled Corticosteroids								
2000	199,779	5,872,451	340.20	199,779	201,365	7,043,854	3,609,369	2,606,423.9
2001	530,385	6,490,165	817.21	542,539	549,547	20,794,007	9,640,140	5,114,003.5
2002	541,976	6,597,739	821.46	554,337	562,230	22,201,405	10,656,919	5,155,271.3
2003	548,679	6,573,695	834.66	561,727	564,843	22,338,489	12,840,028	5,112,316.9
2004	549,350	7,014,155	783.20	562,069	563,353	21,261,286	28,744,421	5,362,266.7
2005	574,598	7,131,675	805.70	587,539	589,627	23,431,695	13,723,765	5,599,634.4
2006	560,239	7,013,378	798.81	572,047	574,899	23,670,867	13,432,548	5,509,371.2
2007	547,017	6,998,946	781.57	559,626	562,192	22,688,248	11,891,476	5,538,856.8
2008	546,968	7,080,794	772.47	558,969	561,629	23,456,495	11,417,786	5,594,798.5
2009	571,260	7,199,860	793.43	584,332	587,186	24,600,654	11,661,380	5,673,129.9
2010	575,741	7,321,733	786.35	588,538	589,957	23,626,761	10,880,970	5,809,902.7
2011	586,866	7,484,388	784.12	600,194	601,967	23,358,642	10,822,742	5,977,299.1
2012	587,215	7,548,363	777.94	601,155	602,968	22,811,985	10,594,940	6,074,901.6
2013	608,212	7,571,168	803.33	624,050	626,254	23,415,290	10,937,582	6,085,192.5
2014	618,635	7,902,862	782.80	634,290	636,864	23,580,847	11,135,974	6,304,440.6
2015	509,788	7,954,580	640.87	511,863	513,706	19,198,383	8,929,176	4,961,263.7
Nasal Corticosteroids								
2000	143,522	5,872,451	244.40	143,522	143,835	5,247,953	2,534,205	2,606,423.9
2001	400,410	6,490,165	616.95	407,718	408,097	16,270,111	7,178,346	5,114,003.5
2002	401,967	6,597,739	609.25	409,025	409,404	17,157,216	7,746,669	5,155,271.3
2003	392,471	6,573,695	597.03	399,232	399,574	16,648,463	9,380,157	5,112,316.9
2004	388,635	7,014,155	554.07	395,318	395,475	15,339,742	15,336,547	5,362,266.7
2005	393,635	7,131,675	551.95	399,878	400,422	16,516,509	9,616,011	5,599,634.4
2006	391,663	7,013,378	558.45	397,525	398,353	16,770,510	9,805,189	5,509,371.2
2007	387,375	6,998,946	553.48	393,771	394,085	15,887,539	8,355,116	5,538,856.8
2008	377,760	7,080,794	533.50	384,033	384,250	15,302,745	7,651,705	5,594,798.5
2009	387,778	7,199,860	538.59	394,413	394,453	15,383,897	7,486,990	5,673,129.9
2010	399,482	7,321,733	545.61	406,188	406,202	14,958,542	7,046,937	5,809,902.7
2011	409,680	7,484,388	547.38	416,878	416,893	14,880,235	7,052,672	5,977,299.1
2012	414,153	7,548,363	548.67	421,782	421,791	15,001,312	7,155,369	6,074,901.6
2013	429,025	7,571,168	566.66	437,721	437,806	15,500,955	7,444,357	6,085,192.5
2014	437,456	7,902,862	553.54	446,111	446,397	15,737,391	7,576,067	6,304,440.6
2015	356,606	7,954,580	448.30	357,771	357,945	12,767,401	6,136,640	4,961,263.7

¹Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on a least one day during the query period.

Appendix A. List of Dates of Available Data for Each Data Partner (DP) in the Sentinel Distributed Database (SDD) as of Request End Date (September 30, 2015)

DP ID	DP Start Date	DP End Date
DP01	6/1/2007	9/30/2015
DP02	1/1/2000	9/30/2015
DP03	1/1/2000	9/30/2015
DP04	1/1/2008	9/30/2015
DP05	1/1/2004	9/30/2015
DP06	1/1/2000	9/30/2015
DP07	1/1/2006	9/30/2015
DP08	1/1/2005	9/30/2015
DP09	1/1/2000	10/31/2014
DP10	1/1/2000	5/31/2015
DP11	1/1/2000	9/30/2015
DP12	1/1/2000	9/30/2015
DP13	1/1/2000	9/30/2015
DP14	1/1/2008	9/30/2015
DP15	1/1/2000	9/30/2015
DP16	1/1/2012	9/30/2015

Appendix A.1. List of Dates of Available Data for Each Data Partner (DP) with Cause-of-Death Data in the Sentinel Distributed Database (SDD) as of Request End Date (September 30, 2015)

Data Partner ID	Start Date	End Date
DP01	1/1/2004	9/30/2015
DP02	1/1/2000	9/30/2015
DP03	1/1/2000	9/30/2015
DP04	1/1/2000	9/30/2015
DP05	1/1/2000	9/30/2015
DP06	1/1/2000	9/30/2015
DP07	1/1/2000	9/30/2015

Appendix B. List of Generic and Brand Drug Names Used to Define Exposures in this Request

Generic Name	Brand Name
MONTELUKAST SODIUM	Singulair
MONTELUKAST SODIUM	Montelukast
ZAFIRLUKAST	Zafirlukast
BECLOMETHASONE DIPROPIONATE	Beclovent
BUDESONIDE	Budesonide
FLUTICASONE PROPIONATE	Flovent Diskus
TRIAMCINOLONE ACETONIDE	Azmacort
MOMETASONE FUROATE	Asmanex Twisthaler
FLUNISOLIDE/MENTHOL	Aerobid-M
CICLESONIDE	Alvesco
FLUTICASONE FUROATE	Arnuity Ellipta
FLUNISOLIDE	Aerospan
MOMETASONE FUROATE/FORMOTEROL FUMARATE	Dulera
FLUTICASONE PROPIONATE/SALMETEROL XINAFOATE	Advair Diskus
FLUTICASONE FUROATE/VILANTEROL TRIFENATATE	Breo Ellipta
BUDESONIDE/FORMOTEROL FUMARATE	Symbicort
BECLOMETHASONE DIPROPIONATE	Vancenase AQ
MOMETASONE FUROATE	Nasonex
FLUNISOLIDE	Nasalide
BUDESONIDE	Rhinocort Aqua
TRIAMCINOLONE ACETONIDE	Nasacort
FLUTICASONE PROPIONATE	Fluticasone
FLUTICASONE FUROATE	Veramyst
CICLESONIDE	Zetonna
FLUTICASONE PROPIONATE/SODIUM CHLORIDE/SODIUM BICARBONATE	Ticaspray

Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Characteristics in this Request

Code	Description	Code Type
Asthma		
493	Asthma	ICD-9-CM
493.0	Extrinsic asthma	ICD-9-CM
493.00	Extrinsic asthma, unspecified	ICD-9-CM
493.01	Extrinsic asthma with status asthmaticus	ICD-9-CM
493.02	Extrinsic asthma, with (acute) exacerbation	ICD-9-CM
493.1	Intrinsic asthma	ICD-9-CM
493.10	Intrinsic asthma, unspecified	ICD-9-CM
493.11	Intrinsic asthma with status asthmaticus	ICD-9-CM
493.12	Intrinsic asthma, with (acute) exacerbation	ICD-9-CM
493.2	Chronic obstructive asthma	ICD-9-CM
493.20	Chronic obstructive asthma, unspecified	ICD-9-CM
493.21	Chronic obstructive asthma with status asthmaticus	ICD-9-CM
493.22	Chronic obstructive asthma, with (acute) exacerbation	ICD-9-CM
493.8	Other forms of asthma	ICD-9-CM
493.81	Exercise induced bronchospasm	ICD-9-CM
493.82	Cough variant asthma	ICD-9-CM
493.9	Unspecified asthma	ICD-9-CM
493.90	Asthma, unspecified, unspecified status	ICD-9-CM
493.91	Asthma, unspecified with status asthmaticus	ICD-9-CM
493.92	Asthma, unspecified, with (acute) exacerbation	ICD-9-CM
Allergic Rhinitis		
477	Allergic rhinitis	ICD-9-CM
477.0	Allergic rhinitis due to pollen	ICD-9-CM
477.1	Allergic rhinitis, due to food	ICD-9-CM
477.2	Allergic rhinitis due to animal (cat) (dog) hair and dander	ICD-9-CM
477.8	Allergic rhinitis due to other allergen	ICD-9-CM
477.9	Allergic rhinitis, cause unspecified	ICD-9-CM

Appendix D. Specifications Defining Parameters in this Request

This request utilized the Cohort Identification and Descriptive Analysis (CIDA) tool, version 5.2.1 to examine patient exposure to montelukast, zafirlukast, inhaled corticosteroids, and nasal corticosteroids in the Sentinel Distributed Database (SDD).

Query Period: January 1, 2000 to September 30, 2015
Enrollment Requirement: 183 Days
Enrollment Gap: 45 Days
Coverage Requirement: Medical and Drug Coverage
Age Groups: 0-11, 12-17, 18-24, 25-34, 35-44, 45-54, 55-64, 65-74, 75+ Years
Results Stratified by: Age, Sex, and Calendar Year

Scenario	Exposure			Characteristics			
	Incident Exposure	Incidence Criteria/Incident with respect to	Washout (Days)	Cohort Definition	Characteristics	Lookback Period (Days)	Caresetting
1	Montelukast	Montelukast, Zafirlukast	183	02 (Cohort includes all valid index dates per individual during the query period)	asthma, allergic rhinitis	-183, 0	Any
2	Zafirlukast	Montelukast, Zafirlukast	183	02 (Cohort includes all valid index dates per individual during the query period)	asthma, allergic rhinitis	-183, 0	Any
3	Inhaled Corticosteroids	Montelukast, Zafirlukast, Inhaled Corticosteroids, Nasal Corticosteroids	183	02 (Cohort includes all valid index dates per individual during the query period)	asthma, allergic rhinitis	-183, 0	Any
4	Nasal Corticosteroids	Montelukast, Zafirlukast, Inhaled Corticosteroids, Nasal Corticosteroids	183	02 (Cohort includes all valid index dates per individual during the query period)	asthma, allergic rhinitis	-183, 0	Any

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes are provided by Optum360. National Drug Codes (NDCs) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."