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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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Overview for Request cder_mpl1r_wp130

Request ID: cder_mpl1r_wp130_nsdp_v01

Request Description: In this report we evaluated concurrent use of ticagrelor (all strength, 60mg, and 90mg) with atorvastatin or rosuvastatin in the Sentinel Distributed Database (SDD).

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 7.0.4

Data Source: We distributed this request to 17 Data Partners on January 8, 2019. The study period included data from January 1, 2012 to June 30, 2018. Please refer to Appendix A for a list of the dates of available data for each Data Partner.

Study Design: We designed this request to calculate background rates. Dispensings of ticagrelor (all strength, 60mg, and 90mg) were stratified by age, sex, and year. Dispensings of ticagrelor that had evidence of concurrent atorvatatin (10mg, 20mg, 40mg, or 80mg) and rosuvastatin (5mg, 10mg, 20mg, or 40mg) use in a window surrounding the ticagrelor dispensing date were additionally stratified by age, sex, year, and strength of the atorvastatin or rosuvastatin.

Exposure of Interest: We defined the exposure of interest, ticagrelor, using National Drug Codes (NDCs). All prevalent ticagrelor dispensings between January 1, 2012 and December 31, 2018 were used for analysis. Same-day dispensings were deduplicated. Please refer to Appendix B for the generic and brand drug names used to define the exposure.

Cohort Eligibility Criteria: We required members to be continuously enrolled in health plans with drug coverage for at least 30 days prior to their index ticagrelor dispensing date and at least 60 days post index date, during which gaps in coverage of up to 15 days were allowed.

Baseline Characteristics: We evaluated dispensings of ticagrelor for evidence of atorvastatin or rosuvastatin use in a window surrounding the ticagrelor dispensing date. Evaluation for dispensings and days supply of atorvastatin or rosuvastatin occurred within 30 days prior to through 60 days after the ticagrelor dispensing. Dispensings were evaluated by each atorvastatin (10mg, 20mg, 40mg, or 80mg) or rosuvastatin (5mg, 10mg, 20mg, or 40mg) strength. Please refer to Appendix C for generic and brand drug names of atorvastatin and rosuvastatin.

Please see the Appendices D and E for the specifications of parameters used in the analyses for this request.

Limitations: Algorithms used to define exposures are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind.

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

Sentinel

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Glossary of Terms for Analyses Using
Cohort Identification and Descriptive Analysis (CIDA) Module*

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing.

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). For laboratory results, possible care settings include: Emergency Department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). The Care Setting, along with the Principal Diagnosis Indicator (PDX), forms the Care Setting/PDX parameter.

- **Ambulatory Visit (AV) -** includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.
- **Emergency Department (ED) -** includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.
- **Inpatient Hospital Stay (IP) -** includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.
- **Non-Acute Institutional Stay (IS) -** includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.
- **Other Ambulatory Visit (OA) -** includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

Charlson/Elixhauser Combined Comorbidity Score - calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (e.g., in the 183 days prior to index).

Code Days - the minimum number of times the diagnosis must be found during the evaluation period in order to fulfill the algorithm to identify the corresponding patient characteristic.

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all valid treatment episodes during the query period until an event occurs.

Computed Start Marketing Date - represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.

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.

Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.

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

Event Deduplication - specifies how events are counted by the Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (HOI) during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

Exposure Episode Length - number of days after exposure initiation that is considered "exposed time."

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions are added after any episode gaps have been bridged.

Lookback Period - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).

Maximum Episode Duration - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

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 365.25.

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. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Monitoring Period - used to define time periods of interest for both sequential analysis and simple cohort characterization requests.

Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

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

Switch Evaluation Step Value - value used to differentiate evaluation step. Each switch pattern can support up to 2 evaluation steps (0 = switch pattern evaluation start; 1 = first evaluation; 2 = second evaluation).

Switch Gap Inclusion Indicator - indicator for whether gaps in treatment episodes that are included in a switch episode will be counted as part of the switch episode duration.

Switch Pattern Cohort Inclusion Date - indicates which date to use for inclusion into the switch pattern cohort of interest as well as optionally as the index date of the treatment episode initiating the switch pattern. Valid options are the product approval date, product marketing date, other requester defined date, or computed start marketing date.

Switch Pattern Cohort Inclusion Strategy - indicates how the switch pattern cohort inclusion date will be used: 01: used only as a switch cohort entry date. First treatment episode dispensing date is used as index for computing time to first switch; 02: used as switch cohort entry date and as initial switch step index date for computing time to first switch.

Treatment Episode Truncation Indicator - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified 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 365.25.

*all terms may not be used in this report

Table 1. Concurrent Use of All Strengths of Ticagrelor with Atorvastatin or Rosuvastatin Stratified by Year, Patient Age[1], and Strength of the HMG-CoA Reductase Inhibitor in the Sentinel Distributed Database (SDD) from January 1, 2012 to June 30, 2018

Ticagrelor Dispensings [2]	Total	2012	2013	2014	2015	2016	2017[3]	January-June 2018[3]
All Ages	1,585,475	32,465	143,860	260,384	388,174	481,298	238,626	40,668
0-64 years	514,174	9,805	39,716	72,400	109,264	146,726	116,838	19,425
65-74 years	603,502	11,088	56,029	104,353	157,141	190,734	71,782	12,375
75+ years	467,799	11,572	48,115	83,631	121,769	143,838	50,006	8,868
Atorvastatin Concurrently with Ticagrelor, by Strength	**Total**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017[3]**	**January-June 2018[3]**
All Ages								
10 mg	82,563	1,477	7,964	15,737	21,659	24,404	9,835	1,487
20 mg	164,850	2,540	14,730	28,304	42,594	51,092	21,945	3,645
40 mg	378,730	4,725	25,364	52,973	91,706	124,991	67,358	11,613
80 mg	354,127	4,374	21,002	45,359	82,469	117,043	71,508	12,372
0-64 years								
10 mg	18,702	327	1,633	3,120	4,204	5,028	3,853	537
20 mg	45,857	679	3,776	7,104	10,341	13,065	9,436	1,456
40 mg	131,425	1,618	8,055	16,295	27,421	39,544	32,983	5,509
80 mg	153,276	1,720	7,818	17,044	30,886	47,084	41,674	7,050
65-74 years								
10 mg	30,508	484	3,007	6,042	8,173	9,317	2,988	497
20 mg	63,219	859	5,715	11,184	17,033	20,471	6,831	1,126
40 mg	144,194	1,686	9,956	21,525	37,615	49,907	19,999	3,506
80 mg	130,951	1,533	7,860	18,167	33,205	46,001	20,556	3,629
75+ years								
10 mg	33,353	666	3,324	6,575	9,282	10,059	2,994	453
20 mg	55,774	1,002	5,239	10,016	15,220	17,556	5,678	1,063
40 mg	103,111	1,421	7,353	15,153	26,670	35,540	14,376	2,598
80 mg	69,900	1,121	5,324	10,148	18,378	23,958	9,278	1,693

Table 1. Concurrent Use of All Strengths of Ticagrelor with Atorvastatin or Rosuvastatin Stratified by Year, Patient Age[1], and Strength of the HMG-CoA Reductase Inhibitor in the Sentinel Distributed Database (SDD) from January 1, 2012 to June 30, 2018

Rosuvastatin Concurrently with Ticagrelor, by Strength	Total	2012	2013	2014	2015	2016	2017[3]	January-June 2018[3]
All Ages								
5 mg	28,359	809	3,258	5,192	6,848	7,948	3,656	648
10 mg	62,615	1,874	6,943	11,954	15,116	17,261	8,052	1415
20 mg	78,469	2,200	8,084	12,936	18,397	22,143	12,388	2321
40 mg	51,544	1,142	4,400	7,683	11,214	14,852	10,293	1960
0-64 years								
5 mg	6,862	218	655	1,000	1,443	1,737	1,550	259
10 mg	18,823	677	1,996	3,080	3,919	4,716	3,797	638
20 mg	29,428	814	2,818	4,421	5,923	7,739	6,528	1185
40 mg	24,223	500	1,762	3,287	4,655	6,532	6,325	1162
65-74 years								
5 mg	11,492	223	1,387	2,188	2,979	3,333	1,168	214
10 mg	25,216	650	2,806	5,129	6,414	7,189	2,557	471
20 mg	30,673	777	3,243	5,314	7,931	8,941	3,753	714
40 mg	18,773	412	1,788	3,037	4,530	5,620	2,824	562
75+ years								
5 mg	10,005	368	1,216	2,004	2,426	2,878	938	175
10 mg	18,576	547	2,141	3,745	4,783	5,356	1,698	306
20 mg	18,368	609	2,023	3,201	4,543	5,463	2,107	422
40 mg	8,548	230	850	1,359	2,029	2,700	1,144	236

[1]Aggregated results are not nationally representative when stratified by age. Further, the proportion of older adults included in this analysis varies by year. Please refer to Sentinel's Snaphot of Database Statistics (https://www.sentinelinitiative.org/sentinel/data/snapshot-database-statistics) for further details.

[2] Same-day dispensings were deduplicated

[3]A Medicare Data Partner, which primarily includes patients aged 65 years and older, did not have data available to contribute in 2017 and 2018; therefore the results should be interpreted with this limitation in mind.

Table 2. Concurrent use of 60mg Ticagrelor with Atorvastatin or Rosuvastatin Stratified by Year, Patient Age[1], and Strength of the HMG-CoA Reductase Inhibitor in the Sentinel Distributed Database (SDD) from January 1, 2012 to June 30, 2018

Ticagrelor Dispensings [2]	Total	2012	2013	2014	2015	2016	2017[3]	January-June 2018[3]
All Ages	48,127	.	.	.	942	22,586	20,490	4,109
0-64 years	18,231	.	.	.	237	6,471	9,650	1,873
65-74 years	16,943	.	.	.	383	8,971	6,297	1,292
75+ years	12,953	.	.	.	322	7,144	4,543	944
Atorvastatin Concurrently with Ticagrelor, by Strength	**Total**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017[3]**	**January-June 2018[3]**
All Ages								
10 mg	2,157	.	.	.	*****	1,126	809	*****
20 mg	5,154	.	.	.	121	2,537	2,053	443
40 mg	11,687	.	.	.	212	5,402	5,085	988
80 mg	9,354	.	.	.	152	3,828	4,409	965
0-64 years								
10 mg	611	.	.	.	*****	241	313	*****
20 mg	1,709	.	.	.	27	657	838	187
40 mg	4,635	.	.	.	55	1,638	2,486	456
80 mg	4,491	.	.	.	51	1,495	2,430	515
65-74 years								
10 mg	724	.	.	.	27	380	257	60
20 mg	1,866	.	.	.	54	1,015	655	142
40 mg	4,158	.	.	.	91	2,196	1,553	318
80 mg	3,321	.	.	.	69	1,553	1,383	316
75+ years								
10 mg	822	.	.	.	28	505	239	50
20 mg	1,579	.	.	.	40	865	560	114
40 mg	2,894	.	.	.	66	1,568	1,046	214
80 mg	1,542	.	.	.	32	780	596	134

Table 2. Concurrent use of 60mg Ticagrelor with Atorvastatin or Rosuvastatin Stratified by Year, Patient Age[1], and Strength of the HMG-CoA Reductase Inhibitor in the Sentinel Distributed Database (SDD) from January 1, 2012 to June 30, 2018

Rosuvastatin Concurrently with Ticagrelor, by Strength	Total	2012	2013	2014	2015	2016	2017[3]	January-June 2018[3]
All Ages								
5 mg	1,128	.	.	.	*****	644	383	*****
10 mg	2,408	.	.	.	*****	1,261	922	*****
20 mg	3,523	.	.	.	70	1,535	1,594	324
40 mg	2,303	.	.	.	*****	927	1,096	*****
0-64 years								
5 mg	325	.	.	.	*****	143	154	*****
10 mg	773	.	.	.	*****	298	395	*****
20 mg	1,506	.	.	.	17	522	810	157
40 mg	1,248	.	.	.	19	383	697	149
65-74 years								
5 mg	454	.	.	.	21	288	125	20
10 mg	878	.	.	.	20	510	288	60
20 mg	1,264	.	.	.	39	617	514	94
40 mg	724	.	.	.	13	355	293	63
75+ years								
5 mg	349	.	.	.	12	213	104	20
10 mg	757	.	.	.	26	453	239	39
20 mg	753	.	.	.	14	396	270	73
40 mg	331	.	.	.	*****	189	106	*****

[1]Aggregated results are not nationally representative when stratified by age. Further, the proportion of older adults included in this analysis varies by year. Please refer to Sentinel's Snaphot of Database Statistics (https://www.sentinelinitiative.org/sentinel/data/snapshot-database-statistics) for further details.

[2] Same-day dispensings were deduplicated

[3]A Medicare Data Partner, which primarily includes patients aged 65 years and older, did not have data available to contribute in 2017 and 2018; therefore the results should be interpreted with this limitation in mind.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 3. Concurrent use of 90 mg Ticagrelor with Atorvastatin or Rosuvastatin Stratified by Year, Patient Age[1], and Strength of the HMG-CoA Reductase Inhibitor in the Sentinel Distributed Database (SDD) from January 1, 2012 to June 30, 2018

Ticagrelor Dispensings [2]	Total	2012	2013	2014	2015	2016	2017[3]	January-June 2018[3]
All Ages	1,538,863	32,465	143,860	260,384	387,412	459,629	218,464	36,649
0-64 years	496,482	9,805	39,716	72,400	109,071	140,524	107,362	17,604
65-74 years	587,111	11,088	56,029	104,353	156,830	182,120	65,575	11,116
75+ years	455,270	11,572	48,115	83,631	121,511	136,985	45,527	7,929
Atorvastatin Concurrently with Ticagrelor, by Strength	**Total**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017[3]**	**January-June 2018[3]**
All Ages								
10 mg	80,482	1,477	7,964	15,737	21,602	23,330	9,039	1,333
20 mg	159,847	2,540	14,730	28,304	42,495	48,647	19,922	3,209
40 mg	367,425	4,725	25,364	52,973	91,538	119,796	62,361	10,668
80 mg	345,117	4,374	21,002	45,359	82,353	113,406	67,185	11,438
0-64 years								
10 mg	18,106	327	1,633	3,120	4,197	4,793	3,546	490
20 mg	44,196	679	3,776	7,104	10,319	12,441	8,607	1,270
40 mg	126,935	1,618	8,055	16,295	27,375	37,970	30,554	5,068
80 mg	148,943	1,720	7,818	17,044	30,847	45,654	39,300	6,560
65-74 years								
10 mg	29,814	484	3,007	6,042	8,148	8,959	2,733	441
20 mg	61,406	859	5,715	11,184	16,987	19,486	6,190	985
40 mg	140,176	1,686	9,956	21,525	37,543	47,799	1,8466	3,201
80 mg	127,750	1,533	7,860	18,167	33,149	44,524	19,196	3,321
75+ years								
10 mg	32,562	666	3,324	6,575	9,257	9,578	2,760	402
20 mg	54,245	1,002	5,239	10,016	15,189	16,720	5,125	954
40 mg	100,314	1,421	7,353	15,153	26,620	34,027	13,341	2,399
80 mg	68,424	1,121	5,324	10,148	18,357	23,228	8,689	1,557

Table 3. Concurrent use of 90 mg Ticagrelor with Atorvastatin or Rosuvastatin Stratified by Year, Patient Age[1], and Strength of the HMG-CoA Reductase Inhibitor in the Sentinel Distributed Database (SDD) from January 1, 2012 to June 30, 2018

Rosuvastatin Concurrently with Ticagrelor, by Strength	Total	2012	2013	2014	2015	2016	2017[3]	January-June 2018[3]
All Ages								
5 mg	27,277	809	3,258	5,192	6,820	7,335	3,281	582
10 mg	60,290	1874	6,943	11,954	15,075	16,060	7,138	1,246
20 mg	75,073	2,200	8,084	12,936	18,346	20,683	10,823	2,001
40 mg	49,329	1,142	4,400	7,683	11,180	13,981	9,220	1,723
0-64 years								
5 mg	6,550	218	655	1,000	1,441	1,605	1,399	232
10 mg	18,074	677	1,996	3,080	3,912	4,434	3,406	569
20 mg	27,971	814	2,818	4,421	5,913	7,244	5,730	1,031
40 mg	23,019	500	1,762	3,287	4,639	6,174	5,644	1,013
65-74 years								
5 mg	11,057	223	1,387	2,188	2,962	3,056	1,046	195
10 mg	24,369	650	2,806	5,129	6,400	6,703	2,269	412
20 mg	29,447	777	3,243	5,314	7,900	8,341	3,251	621
40 mg	18,082	412	1,788	3,037	4,521	5,289	2,534	501
75+ years								
5 mg	9,670	368	1,216	2,004	2,417	2,674	836	155
10 mg	17,847	547	2,141	3,745	4,763	4,923	1,463	265
20 mg	17,655	609	2,023	3,201	4,533	5,098	1,842	349
40 mg	8,228	230	850	1,359	2,020	2,518	1,042	209

[1]Aggregated results are not nationally representative when stratified by age. Further, the proportion of older adults included in this analysis varies by year. Please refer to Sentinel's Snaphot of Database Statistics (https://www.sentinelinitiative.org/sentinel/data/snapshot-database-statistics) for further details.

[2] Same-day dispensings were deduplicated

[3]A Medicare Data Partner, which primarily includes patients aged 65 years and older, did not have data available to contribute in 2017 and 2018; therefore the results should be interpreted with this limitation in mind.

Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (January 8, 2019)

DP ID	DP Start Date*	DP End Date*
DP01	01/01/2000	03/31/2016
DP02	06/01/2007	04/30/2018
DP03	01/01/2000	06/30/2018
DP04	01/01/2008	03/31/2018
DP05	01/01/2006	05/31/2018
DP06	01/01/2000	12/31/2016
DP07	01/01/2008	09/30/2017
DP08	01/01/2010	12/31/2016
DP09	01/01/2005	12/17/2017
DP10	01/01/2000	05/31/2015
DP11	01/01/2000	03/31/2018
DP12	01/01/2000	10/31/2017
DP13	01/01/2000	12/31/2017
DP14	01/01/2004	05/31/2018
DP15	01/01/2000	03/31/2018
DP16	01/01/2000	06/30/2018
DP17	01/01/2012	06/30/2017

* The start and end dates are based on the minimum and maximum dates within each DP. The month with the maximum date must have at least 80% of the number of records in the previous month

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

Generic Name	Brand Name
Ticagrelor	Brilinta

Appendix C. List of Generic and Brand Drug Names Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Amlodipine besylate/atorvastatin calcium	Amlodipine-Atorvastatin
Amlodipine besylate/atorvastatin calcium	Caduet
Atorvastatin calcium	Atorvastatin
Atorvastatin calcium	Lipitor
Ezetimibe/atorvastatin calcium	Liptruzet
Rosuvastatin calcium	Crestor
Rosuvastatin calcium	Rosuvastatin

Appendix D. Specifications Defining Parameters in the Request

This request utilized the Cohort Identification and Descriptive Analysis (CIDA) module, version 7.0.4, to understand dispensing patterns of ticagrelor, atorvastatin, and rosuvastatin in the Sentinel Distributed Database (SDD).

Query period: January 1, 2012 - June 30, 2018
Enrollment gap: 15 days
Age groups: 0-64, 65-74, 75+ years
Coverage requirement: Drug Coverage
Pre-index enrollment requirement: 30 days
Post-index enrollment requirement: 60 days

	Drug/Exposure						Baseline Characteristics
Scenario	Index Exposure/ Event	Cohort Definition	Washout Period (days)	Incident with Respect to:	Care Setting	Censor Episode at Evidence of	Baseline Characteristics
1	Ticagrelor, All Dispensings	Include all valid index dates during query period[1]	0	N/A	Any	Death, Data Partner End Date, Query End Date, Disenrollment	See Appendix E
2	Ticagrelor, 60mg Dispensings	Include all valid index dates during query period[1]	0	N/A	Any	Death, Data Partner End Date, Query End Date, Disenrollment	See Appendix E
3	Ticagrelor, 90mg Dispensings	Include all valid index dates during query period[1]	0	N/A	Any	Death, Data Partner End Date, Query End Date, Disenrollment	See Appendix E

[1] Same-day dispensings will be deduplicated
National Drug Codes (NDCs) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."

Appendix E. Specifications for Baseline Characteristics in this Request

This request utilized the Cohort Identification and Descriptive Analysis (CIDA) module, version 7.0.4, to understand dispensing patterns of ticagrelor, atorvastatin, and rosuvastatin in the Sentinel Distributed Database (SDD).

Overlapping Treatments

Characteristic	Care Setting	Evaluation Period Start	Evaluation Period End	Evaluate For	Number of Instances the Characteristic should be Found in Evaluation Period, at Least
Atorvastatin, 10 mg	Any	-30	60	Dispensing + Days Supply	1
Atorvastatin, 20 mg	Any	-30	60	Dispensing + Days Supply	1
Atorvastatin, 40 mg	Any	-30	60	Dispensing + Days Supply	1
Atorvastatin, 80 mg	Any	-30	60	Dispensing + Days Supply	1
Rosuvastatin, 5 mg	Any	-30	60	Dispensing + Days Supply	1
Rosuvastatin, 10 mg	Any	-30	60	Dispensing + Days Supply	1
Rosuvastatin, 20 mg	Any	-30	60	Dispensing + Days Supply	1
Rosuvastatin, 40 mg	Any	-30	60	Dispensing + Days Supply	1