Title	EU-Wide Cross-Sectional Observational Study of Lipid-Modifying Therapy Use in Secondary and Primary Care (DA VINCI)
Version Identifier of the Final Study Report	20150333 Version 1.0
Date of Last Version of the Study Report	NA
EU PAS Register No:	EUPAS22075
Active Substance	NA
Medicinal Product	NA
Product Reference:	evolocumab
Marketing Authorization Holder(s)	Amgen Ltd
Research Question and Objectives	Research Question: How are EU patients requiring lipid-modifying therapy routinely managed? Primary Objective: To estimate the proportion of subjects in EU primary and secondary care, with or without established ASCVD and receiving lipid lowering therapy (LLT), with LDL-C above 2016 Joint ESC Guideline-recommended levels. Secondary Objectives To assess clinical characteristics and management of subjects in EU primary and secondary care, with or without established vascular/atherosclerotic disease and receiving LLT
Country(ies) of Study	Austria, Belgium, Czech Republic, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Poland, Romania, Slovakia, Spain, Sweden, Ukraine, United Kingdom
Author	[redacted] Amgen Ltd Uxbridge, UK [redacted]

Marketing Authorization Holder(s)

Marketing Authorization Holder(s)	Amgen Ltd Sanderson Road (Uxbridge Business Park) Uxbridge UB8 1DH, UK
MAH Contact Person	[redacted]) GmbH [redacted]

TABLE OF CONTENTS

LIST OF TABLES

ABSTRACT

- **Title**

EU-Wide Cross-Sectional Observational Study of Lipid-Modifying Therapy Use in Secondary and Primary Care (DA VINCI)

- **Keywords**

Cardiovascular disease, LDL-C, lipid lowering therapy, primary prevention, secondary prevention

- **Rationale and Background**

The 2016 ESC/EAS guidelines recommend lipid-lowering therapy (LLT) for those at risk of cardiovascular disease (CVD) with or without established CVD. Lower LDL-C goals are recommended for those considered to be at the highest risk. EUROASPIRE V showed that 71% of patients with coronary disease do not reach recommended LDL-C goals despite receiving LLT. Little is known about LDL-C goal attainment among other groups of patients receiving LLT in Europe.

The DA VINCI study was designed to contribute new information on the patterns of treatment with LLT in primary and secondary care across Europe. The results will estimate the gap between treatment guidelines and clinical practice, in turn helping to inform public health initiatives across Europe; by identifying potential shortfalls in treatment the study contributes data to support policies towards rectifying suboptimal treatment, where observed.

- **Research Question and Objectives**

How are EU patients requiring lipid-modifying therapy routinely managed?

Primary Objective: To estimate the proportion of subjects in EU primary and secondary care, with or without established atherosclerotic cardiovascular disease (ASCVD) and receiving LLT, with LDL-C above 2016 Joint ESC Guideline recommended levels.

Secondary Objective: To assess clinical characteristics and management of subjects in EU primary and secondary care, with or without established vascular/atherosclerotic disease and receiving LLT.

- **Study Design**

Multicountry, cross-sectional, observational study of routine clinical management of European patients in primary and secondary care, who are prescribed LLT.

- **Setting**

Primary and secondary care clinics across 18 countries in Europe were selected to recruit subjects whose data were collected at a single visit. Site selection (secondary vs primary care physicians) and site enrolment caps were employed to facilitate enrolment of primary and secondary prevention subjects at a ratio of 1:1. Secondary care sites were selected proportionately according to speciality, to enable enrolment of a study population enriched for subjects with peripheral and cerebral disease, to reach a ratio of coronary: cerebral: peripheral of 1:2:2. Data collection occurred between June 2017 and December 2018. All participating study subjects provided individual informed consent. All relevant ethics approvals were obtained before study start in an individual country.

- **Subjects and Study Size, Including Dropouts**

The target study size was 6000 subjects. The table below illustrates expected precision of the primary outcome measure (the proportion of subjects achieving guideline-recommended LDL-C goals), assuming that 50% of subjects will achieve this goal. Sample sizes of 70-150 represent the potential size of cohorts of primary prevention or secondary prevention subjects within a country, while sample sizes of 200-300 represent the potential size of country cohorts.

Table. Estimated Precision of Primary Outcome Measure For a Range of Sample Sizes

Sample size	Half-width of 95% CI
70	11.7
100	9.8
130	8.6
150	8.0
200	6.9
250	6.2
300	5.7

Subjects were eligible on the basis of meeting all of the following inclusion criteria:

- LDL-C measurement within 14 months of enrolment, obtained independently of participation in a clinical trial
- Use of any LLT (may include statin/ezetimibe/fibrate/PCSK9 inhibitor/bile acid absorption inhibitor/nicotinic acid/other) at time of enrolment, or any LMT prescribed within 12 months prior to date of enrolment, or any LMT prescribed at date of enrolment
- Age $\geq$ 18 years at enrolment
- Provided informed consent/notified according to local requirements
- Subject expected to survive for at least 1 year after enrolment

If one or more of the following exclusion were met, the subject was not eligible to participate:

- Diagnosis of FH and with history of CV event
- Currently receiving therapy for carcinoma (except squamous epithelial cell)
- Known HIV positive status
- Pregnant or breastfeeding at time of enrolment
- Participating in an interventional clinical trial within 6 months prior to enrolment

- **Variables and Data Sources**

All data were abstracted from medical notes at a single visit, onto a structured and standardised electronic case report form (eCRF). Variables of interest included

demographics, relevant medical history, body measurements (e.g. height, weight, blood pressure), lipid profile (whereby the LDL-C value was required to be taken within the 14 months before the visit date), lipid lowering therapy at enrolment and in 12 months prior to enrolment, history of intolerance to higher doses than currently, or to other statins, reason for prescription of LLT if the subject did not have established cardiovascular disease (eg diabetic, chronic kidney disease), other concomitant therapies of interest (eg antihypertensives). Furthermore, safety events (adverse events, product complaints and other safety findings) that were suspected to be related to evolocumab and observed by the Investigator or reported by the subject that occurred in the 12 months prior to or at time of enrolment into the study were required to be collected and recorded in the subject's relevant study documentation.

All summaries of the data are descriptive in nature. For categorical variables the frequency and percentage, with 95% confidence interval, are provided. Summary statistics for continuous variables include the number of subjects, mean, median, standard deviation or standard error, 25th percentile (Q1), 75th percentile (Q3), minimum, and maximum.

Two amendments were made to the Statistical Analysis Plan (SAP): The SAP specified classification of secondary prevention patients as myocardial infarction, stroke or peripheral arterial disease according to the cardiovascular event history. These classifications were not mutually exclusive. The adhoc tables presented here instead use the mutually exclusive categories selected by the study physician: coronary, peripheral or cerebral. Furthermore, the SAP specified that subjects who were secondary prevention at the visit date but whose first ASCVD event occurred after the date of their LDL-C measurement are categorized as primary prevention subjects. This meant that the classification of primary/secondary prevention status was assessed at the time of LDL-C measurement rather than the study physician-specified status at the visit date. In contrast to what was originally planned in the SAP, the adhoc tables presented here instead use the primary/secondary prevention status at the visit date, to describe subjects' baseline characteristics. However, for the study primary endpoint (attainment of LDL-C goal) it is impoprtant to note that LDL-C goals are driven by primary/secondary prevention status. Therefore, the results of the primary endpoint are still described as originally planned, i.e. on the basis of a subject's primary/secondary prevention status at the time of their LDL-C measurement.

Data quality was monitored at regular intervals throughout the study to verify completeness, accuracy, and consistency of the data. Automated edit checks were implemented within the study database. Furthermore, manual checks were performed conducted which resulted in queries to the sites. Once these queries were addressed, data cuts were sent to the analytical team to perform further logic checks, resulting in additional queries to the study sites before the final study database was locked.

- **Results**

Between June 2017 and November 2018, 5888 eligible subjects were enrolled. Among these, 3000 (51%) were primary prevention (PP), 2794 (47%) secondary prevention (SP) and 94 (2%) did not meet the narrow definition of established ASCVD. Among SP, 622 (22%) had coronary vascular bed involvement, 1136 (41%) cerebral disease and 1036 (37%) peripheral disease. Half of PP subjects were male and the median age was 64 years (yrs). SP subjects were older (median age, 69yrs) and 66% were male. Concomitant CV risk factors included type II diabetes in 36% (PP) and 36% (SP); hypertension in 66% (PP) and 75% (SP); CKD in 9% (PP) and 14% (SP). In PP, at the

time of visit, high and moderate intensity statins were received by 23% and 63%, respectively versus 46% and 44% respectively, in SP. Use of ezetemibe was 10% in PP and 9% in SP.

For the primary endpoint, considering patients' primary/secondary prevention status at the time of LDL-C measurement, there were 2558 PP subjects with a treatment-stabilised LDL-C measurement (≥28 days after initiation of LLT). Median LDL-C was 93 mg/dL. In 2039 treatment-stabilised SP subjects the median LDL-C was 77 mg/dL. In subjects at highest risk, 61% of 2039 SP and 79% of 89 very high risk PP subjects did not achieve the recommended goal of < 70mg/dL. Among the 448 PP subjects and 858 SP who received high intensity statin at the time of the LDL-C measurement, 32% and 54% did not reach goal, respectively. Among the 47 subjects who received evolocumab, 2 non-serious adverse events were reported: myalgia and arthritis.

- **Discussion**

This cross-sectional survey highlights the gap between 2016 ESC/EAS treatment recommendations and their implementation in routine clinical practice across Europe. Among approximately half of subjects whose statin therapy is optimised, LDL-C goals are still not met. The results of this study did not alter the benefit-risk balance of evolocumab.

- **Marketing Authorization Holder(s)**

Amgen Ltd

- **Names and Affiliations of Principal Investigators**

[redacted]

Imperial College, London (UK)

SUMMARY TABLES, FIGURES, AND LISTINGS

Table 14-2.2.401. Baseline Demographics by ASCVD Status
Study 20150333 (Primary Analysis Set)

		Secondary Prevention Subjects					
	Primary Prevention Subjects (N = 3000)	Coronary (N = 622)	Peripheral (N = 1036)	Cerebral (N = 1136)	Total (N = 2794)	Other Vascular Secondary Prevention[a] (N = 94)	Total (N = 5888)
Sex - n (%)							
Male	1498 (49.9)	473 (76.0)	713 (68.8)	669 (58.9)	1855 (66.4)	60 (63.8)	3413 (58.0)
Female	1502 (50.1)	149 (24.0)	323 (31.2)	467 (41.1)	939 (33.6)	34 (36.2)	2475 (42.0)
Ethnicity - n (%)							
White	2829 (94.3)	550 (88.4)	937 (90.4)	1036 (91.2)	2523 (90.3)	83 (88.3)	5435 (92.3)
Mixed Race	14 (0.5)	3 (0.5)	1 (<0.1)	2 (0.2)	6 (0.2)	0 (0.0)	20 (0.3)
Asian	11 (0.4)	11 (1.8)	5 (0.5)	2 (0.2)	18 (0.6)	0 (0.0)	29 (0.5)
Black	7 (0.2)	1 (0.2)	3 (0.3)	1 (<0.1)	5 (0.2)	0 (0.0)	12 (0.2)
Not reported	139 (4.6)	57 (9.2)	90 (8.7)	95 (8.4)	242 (8.7)	11 (11.7)	392 (6.7)
Age (years)							
n	3000	622	1036	1136	2794	94	5888
Mean	62.5	66.6	69.0	67.4	67.8	70.3	65.1
SD	12.7	10.3	9.4	11.2	10.4	10.4	11.9
Median	64.0	67.0	70.0	68.0	69.0	70.5	66.0
Q1, Q3	55.0, 72.0	60.0, 74.0	63.0, 76.0	60.0, 75.5	61.0, 75.0	64.0, 76.0	58.0, 74.0
Min, Max	18, 93	37, 91	32, 101	27, 94	27, 101	43, 101	18, 101

N = Number of subjects enrolled in the primary analysis set (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ASCVD = Atherosclerotic Cardiovascular Disease
[a] Subjects who are not classified as primary prevention subjects and do not fulfill the criteria for secondary prevention subjects/have no CV event documented.

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/adhoc/program/t-ah-dm-sum-demo-ascvd2.sas
Output: t14-02-002-401-ah-dm-sum-demo-ascvd2.rtf (Date Generated: 14AUG19:22:46:27) Source: adam.adsl, adhoc.adslblah

Table 14-2.2.401. Baseline Demographics by ASCVD Status
Study 20150333 (Primary Analysis Set)

		Secondary Prevention Subjects					
	Primary Prevention Subjects (N = 3000)	Coronary (N = 622)	Peripheral (N = 1036)	Cerebral (N = 1136)	Total (N = 2794)	Other Vascular Secondary Prevention[a] (N = 94)	Total (N = 5888)
Age group - n (%)							
18 - 64 years	1560 (52.0)	252 (40.5)	314 (30.3)	420 (37.0)	986 (35.3)	25 (26.6)	2571 (43.7)
65 - 74 years	939 (31.3)	226 (36.3)	423 (40.8)	396 (34.9)	1045 (37.4)	38 (40.4)	2022 (34.3)
75 - 84 years	459 (15.3)	128 (20.6)	262 (25.3)	268 (23.6)	658 (23.6)	25 (26.6)	1142 (19.4)
≥85 years	42 (1.4)	16 (2.6)	37 (3.6)	52 (4.6)	105 (3.8)	6 (6.4)	153 (2.6)

N = Number of subjects enrolled in the primary analysis set (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ASCVD = Atherosclerotic Cardiovascular Disease
[a] Subjects who are not classified as primary prevention subjects and do not fulfill the criteria for secondary prevention subjects/have no CV event documented.

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/adhoc/program/t-ah-dm-sum-demo-ascvd2.sas
Output: t14-02-002-401-ah-dm-sum-demo-ascvd2.rtf (Date Generated: 14AUG19:22:46:27) Source: adam.adsl, adhoc.adslblah

Table 14-2.3.401. Baseline Physical Measurements by ASCVD Status
Study 20150333 (Primary Analysis Set)

		Secondary Prevention Subjects					
	Primary Prevention Subjects (N = 3000)	Coronary (N = 622)	Peripheral (N = 1036)	Cerebral (N = 1136)	Total (N = 2794)	Other Vascular Secondary Prevention[a] (N = 94)	Total (N = 5888)
Systolic blood pressure (mmHg)							
n	2939	601	993	1117	2711	92	5742
Mean	134.4	132.6	136.2	135.6	135.2	136.8	134.8
SD	15.8	17.9	18.9	17.4	18.1	23.0	17.1
Median	132.0	130.0	134.0	135.0	134.0	131.0	133.0
Q1, Q3	124.0, 142.0	120.0, 141.0	124.0, 146.0	122.0, 145.0	122.0, 145.0	122.0, 144.5	123.0, 143.0
Min, Max	90, 220	86, 218	69, 250	92, 201	69, 250	92, 214	69, 250
Diastolic blood pressure (mmHg)							
n	2939	601	993	1117	2711	91	5741
Mean	79.1	76.6	75.5	78.4	76.9	76.8	78.0
SD	10.1	11.3	10.8	11.0	11.1	12.9	10.7
Median	80.0	77.0	76.0	80.0	78.0	75.0	80.0
Q1, Q3	71.0, 85.0	70.0, 83.0	70.0, 81.0	70.0, 85.0	70.0, 83.0	69.0, 84.0	70.0, 85.0
Min, Max	41, 160	32, 134	38, 115	45, 120	32, 134	44, 114	32, 160

N = Number of subjects enrolled in the primary analysis set (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ASCVD = Atherosclerotic Cardiovascular Disease
[a] Subjects who are not classified as primary prevention subjects and do not fulfill the criteria for secondary prevention subjects/have no CV event documented.

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/adhoc/program/t-ah-vs-sum-bl-char-ascvd2.sas
Output: t14-02-003-401-ah-vs-sum-bl-char-ascvd2.rtf (Date Generated: 14AUG19:22:57:36) Source: adhoc.adslblah

Table 14-2.3.401. Baseline Physical Measurements by ASCVD Status
Study 20150333 (Primary Analysis Set)

		Secondary Prevention Subjects					
	Primary Prevention Subjects (N = 3000)	Coronary (N = 622)	Peripheral (N = 1036)	Cerebral (N = 1136)	Total (N = 2794)	Other Vascular Secondary Prevention[a] (N = 94)	Total (N = 5888)
Weight (kg)							
n	2947	600	988	1100	2688	87	5722
Mean	83.1	84.3	81.0	81.9	82.1	83.4	82.6
SD	17.5	15.5	16.5	16.4	16.3	16.4	17.0
Median	81.3	84.0	80.0	80.0	81.0	85.0	81.0
Q1, Q3	71.0, 93.5	73.4, 93.1	69.7, 91.0	70.8, 92.0	71.0, 92.0	73.0, 94.0	71.0, 92.7
Min, Max	40, 210	44, 155	39, 170	44, 163	39, 170	50, 124	39, 210
Height (cm)							
n	2923	600	995	1036	2631	86	5640
Mean	168.9	171.6	170.2	170.0	170.4	171.0	169.6
SD	9.9	8.8	9.0	9.2	9.1	10.2	9.6
Median	169.0	172.0	170.0	170.0	170.0	170.0	170.0
Q1, Q3	161.0, 176.0	166.0, 178.0	164.0, 176.0	164.0, 176.0	164.0, 177.0	167.0, 179.0	163.0, 176.0
Min, Max	139, 204	142, 194	143, 201	144, 196	142, 201	147, 195	139, 204

N = Number of subjects enrolled in the primary analysis set (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ASCVD = Atherosclerotic Cardiovascular Disease
[a] Subjects who are not classified as primary prevention subjects and do not fulfill the criteria for secondary prevention subjects/have no CV event documented.

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/adhoc/program/t-ah-vs-sum-bl-char-ascvd2.sas
Output: t14-02-003-401-ah-vs-sum-bl-char-ascvd2.rtf (Date Generated: 14AUG19:22:57:36) Source: adhoc.adslblah

Table 14-2.3.401. Baseline Physical Measurements by ASCVD Status
Study 20150333 (Primary Analysis Set)

		Secondary Prevention Subjects					
	Primary Prevention Subjects (N = 3000)	Coronary (N = 622)	Peripheral (N = 1036)	Cerebral (N = 1136)	Total (N = 2794)	Other Vascular Secondary Prevention[a] (N = 94)	Total (N = 5888)
Body mass index (kg/m^2)							
n	2916	596	982	1036	2614	86	5616
Mean	29.1	28.6	27.9	28.3	28.2	28.4	28.7
SD	5.3	4.7	5.0	4.8	4.9	4.8	5.1
Median	28.4	27.9	27.5	27.7	27.7	27.8	28.0
Q1, Q3	25.3, 32.1	25.3, 31.1	24.6, 30.9	24.9, 31.3	24.8, 31.1	25.2, 31.1	25.1, 31.6
Min, Max	17, 73	18, 50	16, 49	16, 50	16, 50	17, 40	16, 73
Waist circumference (cm)							
n	1917	366	476	613	1455	44	3416
Mean	99.3	100.3	101.4	99.9	100.5	101.0	99.9
SD	13.2	12.4	14.0	13.0	13.2	13.2	13.2
Median	99.0	100.5	100.5	100.0	100.0	100.5	100.0
Q1, Q3	90.0, 108.0	92.0, 108.0	92.5, 110.0	91.0, 109.0	92.0, 109.0	91.0, 109.0	91.0, 108.0
Min, Max	63, 151	70, 138	29, 145	52, 156	29, 156	80, 139	29, 156

N = Number of subjects enrolled in the primary analysis set (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ASCVD = Atherosclerotic Cardiovascular Disease
[a] Subjects who are not classified as primary prevention subjects and do not fulfill the criteria for secondary prevention subjects/have no CV event documented.

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/adhoc/program/t-ah-vs-sum-bl-char-ascvd2.sas
Output: t14-02-003-401-ah-vs-sum-bl-char-ascvd2.rtf (Date Generated: 14AUG19:22:57:36) Source: adhoc.adslblah

Table 14-2.7.401. Summary of Cardiovascular History by ASCVD Status
Study 20150333 (Primary Analysis Set)

		Secondary Prevention Subjects					
	Primary Prevention Subjects (N = 3000) n (%)	Coronary (N = 622) n (%)	Peripheral (N = 1036) n (%)	Cerebral (N = 1136) n (%)	Total (N = 2794) n (%)	Other Vascular Secondary Prevention[a] (N = 94) n (%)	Total (N = 5888) n (%)
Cardiovascular event history							
Myocardial infarction STEMI	0 (0.0)	230 (37.0)	71 (6.9)	23 (2.0)	324 (11.6)	0 (0.0)	324 (5.5)
Myocardial infarction NSTEMI	0 (0.0)	143 (23.0)	51 (4.9)	26 (2.3)	220 (7.9)	0 (0.0)	220 (3.7)
Carotid endarterectomy	0 (0.0)	2 (0.3)	47 (4.5)	45 (4.0)	94 (3.4)	0 (0.0)	94 (1.6)
Carotid surgery: stenting	0 (0.0)	12 (1.9)	17 (1.6)	18 (1.6)	47 (1.7)	0 (0.0)	47 (0.8)
Coronary artery bypass graft (CABG)	0 (0.0)	118 (19.0)	107 (10.3)	23 (2.0)	248 (8.9)	0 (0.0)	248 (4.2)
Peripheral vascular stenting	0 (0.0)	12 (1.9)	364 (35.1)	6 (0.5)	382 (13.7)	0 (0.0)	382 (6.5)
Peripheral vascular bypass	0 (0.0)	6 (1.0)	203 (19.6)	2 (0.2)	211 (7.6)	0 (0.0)	211 (3.6)
Percutaneous coronary intervention (PCI)	0 (0.0)	230 (37.0)	88 (8.5)	35 (3.1)	353 (12.6)	0 (0.0)	353 (6.0)
Ischaemic stroke	0 (0.0)	18 (2.9)	48 (4.6)	895 (78.8)	961 (34.4)	0 (0.0)	961 (16.3)
Symptomatic claudication	0 (0.0)	4 (0.6)	346 (33.4)	5 (0.4)	355 (12.7)	0 (0.0)	355 (6.0)
Claudication	0 (0.0)	4 (0.6)	298 (28.8)	8 (0.7)	310 (11.1)	0 (0.0)	310 (5.3)
Stable angina	0 (0.0)	44 (7.1)	25 (2.4)	7 (0.6)	76 (2.7)	0 (0.0)	76 (1.3)
Unstable angina	0 (0.0)	19 (3.1)	15 (1.4)	4 (0.4)	38 (1.4)	0 (0.0)	38 (0.6)
TIA	0 (0.0)	10 (1.6)	40 (3.9)	222 (19.5)	272 (9.7)	0 (0.0)	272 (4.6)
Other	0 (0.0)	11 (1.8)	125 (12.1)	22 (1.9)	158 (5.7)	94 (100.0)	252 (4.3)

N = Number of subjects enrolled in the primary analysis set (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ASCVD = Atherosclerotic Cardiovascular Disease; NSTEMI = Non-ST-elevation Myocardial Infarction; STEMI = ST-elevation Myocardial Infarction; TIA = Transient Ischemic Attack.
[a] Subjects who are not classified as primary prevention subjects and do not fulfill the criteria for secondary prevention subjects/have no CV event documented.

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/adhoc/program/t-ah-mh-sum-cvdis-ascvd2.sas
Output: t14-02-007-401-ah-mh-sum-cvdis-ascvd2.rtf (Date Generated: 14AUG19:23:24:49) Source: adhoc.adslblah

Table 14-2.7.401. Summary of Cardiovascular History by ASCVD Status
Study 20150333 (Primary Analysis Set)

		Secondary Prevention Subjects					
	Primary Prevention Subjects (N = 3000) n (%)	Coronary (N = 622) n (%)	Peripheral (N = 1036) n (%)	Cerebral (N = 1136) n (%)	Total (N = 2794) n (%)	Other Vascular Secondary Prevention[a] (N = 94) n (%)	Total (N = 5888) n (%)
Vascular beds that were involved							
Coronary	0 (0.0)	618 (99.4)	271 (26.2)	96 (8.5)	985 (35.3)	22 (23.4)	1007 (17.1)
Cerebrovascular	0 (0.0)	31 (5.0)	122 (11.8)	1124 (98.9)	1277 (45.7)	19 (20.2)	1296 (22.0)
Peripheral	0 (0.0)	24 (3.9)	1014 (97.9)	31 (2.7)	1069 (38.3)	56 (59.6)	1125 (19.1)
Medical history							
Congestive heart failure	122 (4.1)	110 (17.7)	109 (10.5)	93 (8.2)	312 (11.2)	7 (7.4)	441 (7.5)
Left ventricular hypertrophy	253 (8.4)	97 (15.6)	100 (9.7)	115 (10.1)	312 (11.2)	8 (8.5)	573 (9.7)
Atrial fibrillation	232 (7.7)	94 (15.1)	127 (12.3)	210 (18.5)	431 (15.4)	12 (12.8)	675 (11.5)
Haemorrhagic stroke	13 (0.4)	12 (1.9)	19 (1.8)	54 (4.8)	85 (3.0)	3 (3.2)	101 (1.7)
Diabetes mellitus	1169 (39.0)	238 (38.3)	473 (45.7)	371 (32.7)	1082 (38.7)	42 (44.7)	2293 (38.9)
Type I	99 (3.3)	14 (2.3)	44 (4.2)	20 (1.8)	78 (2.8)	1 (1.1)	178 (3.0)
Type II	1069 (35.6)	223 (35.9)	429 (41.4)	350 (30.8)	1002 (35.9)	41 (43.6)	2112 (35.9)
Missing	1 (<0.1)	1 (0.2)	0 (0.0)	1 (<0.1)	2 (<0.1)	0 (0.0)	3 (<0.1)
Hypertension	1976 (65.9)	455 (73.2)	809 (78.1)	826 (72.7)	2090 (74.8)	72 (76.6)	4138 (70.3)

N = Number of subjects enrolled in the primary analysis set (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ASCVD = Atherosclerotic Cardiovascular Disease; NSTEMI = Non-ST-elevation Myocardial Infarction; STEMI = ST-elevation Myocardial Infarction; TIA = Transient Ischemic Attack.
[a] Subjects who are not classified as primary prevention subjects and do not fulfill the criteria for secondary prevention subjects/have no CV event documented.

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/adhoc/program/t-ah-mh-sum-cvdis-ascvd2.sas
Output: t14-02-007-401-ah-mh-sum-cvdis-ascvd2.rtf (Date Generated: 14AUG19:23:24:49) Source: adhoc.adslblah

Table 14-2.7.401. Summary of Cardiovascular History by ASCVD Status
Study 20150333 (Primary Analysis Set)

		Secondary Prevention Subjects					
	Primary Prevention Subjects (N = 3000) n (%)	Coronary (N = 622) n (%)	Peripheral (N = 1036) n (%)	Cerebral (N = 1136) n (%)	Total (N = 2794) n (%)	Other Vascular Secondary Prevention[a] (N = 94) n (%)	Total (N = 5888) n (%)
Chronic kidney disease	282 (9.4)	70 (11.3)	194 (18.7)	116 (10.2)	380 (13.6)	18 (19.1)	680 (11.5)
Stage 1	36 (1.2)	9 (1.4)	23 (2.2)	16 (1.4)	48 (1.7)	0 (0.0)	84 (1.4)
Stage 2	66 (2.2)	15 (2.4)	41 (4.0)	28 (2.5)	84 (3.0)	7 (7.4)	157 (2.7)
Stage 3	153 (5.1)	37 (5.9)	96 (9.3)	60 (5.3)	193 (6.9)	5 (5.3)	351 (6.0)
Stage 4	17 (0.6)	6 (1.0)	19 (1.8)	8 (0.7)	33 (1.2)	2 (2.1)	52 (0.9)
Stage 5	9 (0.3)	3 (0.5)	9 (0.9)	4 (0.4)	16 (0.6)	4 (4.3)	29 (0.5)
Missing	1 (<0.1)	0 (0.0)	6 (0.6)	0 (0.0)	6 (0.2)	0 (0.0)	7 (0.1)
Rheumatoid arthritis	40 (1.3)	5 (0.8)	22 (2.1)	16 (1.4)	43 (1.5)	1 (1.1)	84 (1.4)

N = Number of subjects enrolled in the primary analysis set (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ASCVD = Atherosclerotic Cardiovascular Disease; NSTEMI = Non-ST-elevation Myocardial Infarction; STEMI = ST-elevation Myocardial Infarction; TIA = Transient Ischemic Attack.
[a] Subjects who are not classified as primary prevention subjects and do not fulfill the criteria for secondary prevention subjects/have no CV event documented.

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/adhoc/program/t-ah-mh-sum-cvdis-ascvd2.sas
Output: t14-02-007-401-ah-mh-sum-cvdis-ascvd2.rtf (Date Generated: 14AUG19:23:24:49) Source: adhoc.adslblah

Table 14-2.9.403. Summary of Statin Background Therapy Intensity at Visit by ASCVD Status Study 20150333 (Primary Analysis Set)

		Secondary Prevention Subjects					
	Primary Prevention Subjects (N = 3000) n (%)	Coronary (N = 622) n (%)	Peripheral (N = 1036) n (%)	Cerebral (N = 1136) n (%)	Total (N = 2794) n (%)	Other Vascular Secondary Prevention[a] (N = 94) n (%)	Total (N = 5888) n (%)
Statin therapy intensity per ACC/AHA definition							
High intensity statin	700 (23.3)	349 (56.1)	421 (40.6)	527 (46.4)	1297 (46.4)	31 (33.0)	2028 (34.4)
Medium intensity statin	1880 (62.7)	225 (36.2)	497 (48.0)	507 (44.6)	1229 (44.0)	55 (58.5)	3164 (53.7)
Low intensity statin	157 (5.2)	12 (1.9)	27 (2.6)	27 (2.4)	66 (2.4)	3 (3.2)	226 (3.8)
Unknown[b]	81 (2.7)	16 (2.6)	23 (2.2)	13 (1.1)	52 (1.9)	3 (3.2)	136 (2.3)
None[c]	182 (6.1)	20 (3.2)	68 (6.6)	62 (5.5)	150 (5.4)	2 (2.1)	334 (5.7)

N = Number of subjects enrolled in the primary analysis set (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ACC = American College of Cardiology; AHA = American Heart Association; ASCVD = Atherosclerotic Cardiovascular Disease.
[a] Subjects who are not classified as primary prevention subjects and do not fulfill the criteria for secondary prevention subjects/have no CV event documented.
[b] Subjects receiving statin combinations with unknown intensities.
[c] Subjects not receiving any statins.

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/adhoc/program/t-ah-cm-sum-stat-intens-ascvd2.sas
Output: t14-02-009-403-ah-cm-sum-stat-intens-ascvd2.rtf (Date Generated: 14AUG19:23:43:41) Source: adhoc.adslblah

Table 14-2.15.400. LDL-C Status by LMT Duration/Stabilization by ASCVD Status
Study 20150333 (Primary Analysis Set)

		Secondary Prevention Subjects					
	Primary Prevention Subjects (N = 3142) n (%)	Coronary (N = 593) n (%)	Peripheral (N = 970) n (%)	Cerebral (N = 1096) n (%)	Total (N = 2659) n (%)	Unclassified[a] (N = 87) n (%)	Total (N = 5888) n (%)
LMT-stabilized LDL-C measurement							
Group A[b]	2378 (75.7)	441 (74.4)	766 (79.0)	688 (62.8)	1895 (71.3)	65 (74.7)	4338 (73.7)
Group B[c]	180 (5.7)	29 (4.9)	52 (5.4)	63 (5.7)	144 (5.4)	6 (6.9)	330 (5.6)
LMT-naïve LDL-C measurement							
Group C[d]	487 (15.5)	66 (11.1)	70 (7.2)	254 (23.2)	390 (14.7)	9 (10.3)	886 (15.0)
Group D[e]	5 (0.2)	1 (0.2)	3 (0.3)	5 (0.5)	9 (0.3)	0 (0.0)	14 (0.2)
LMT-not-stabilized LDL-C measurement							
Group E[f]	51 (1.6)	35 (5.9)	26 (2.7)	74 (6.8)	135 (5.1)	1 (1.1)	187 (3.2)
Unknown[g]	41 (1.3)	21 (3.5)	53 (5.5)	12 (1.1)	86 (3.2)	6 (6.9)	133 (2.3)

N = Number of subjects enrolled in the primary analysis set (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ASCVD = Atherosclerotic Cardiovascular Disease; LDL-C = Low Density Lipoprotein Cholesterol; LMT = Lipid Modifying Therapy
[a] Subjects who are not classified as primary prevention subjects and do not fulfill the criteria for secondary prevention subjects/have no CV event documented.
[b] Subjects have their LDL-C measurements taken at least 28 days after the most recent LMT is initiated.
[c] Subjects not stabilized on the most current LMT but is stabilized on any one of the previous LMTs.
[d] Subjects have their LDL-C measurements taken before any LMT is initiated.
[e] Subjects not stabilized on any LMT, and with LDL-C measurement taken within 28 days of the start of a previous LMT.
[f] Subjects have their LDL-C measurement taken after the most recent LMT but less than 28 days.
[g] Subjects who cannot be classified into any of the groups due to partial/missing LMT date(s).

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/adhoc/program/t-ah-dm-sum-ldlc-strata-ascvd.sas
Output: t14-02-015-400-ah-dm-sum-ldlc-strata-ascvd.rtf (Date Generated: 27MAY19:23:41:08) Source: adhoc.adslblah

Table 14-4.1.400. Summary of LDL-C Measurements in Conventional Units by ASCVD Status Study 20150333 (Primary Analysis Set)

		Secondary Prevention Subjects					
	Primary Prevention Subjects (N = 3142)	Coronary (N = 593)	Peripheral (N = 970)	Cerebral (N = 1096)	Total (N = 2659)	Unclassified[a] (N = 87)	Total (N = 5888)
Full study population (mg/dL)							
n	3142	593	970	1096	2659	87	5888
Mean	106.8	83.8	87.7	96.4	90.4	92.1	99.2
SD	44.5	37.1	40.7	41.3	40.5	39.7	43.4
SE	0.8	1.5	1.3	1.2	0.8	4.3	0.6
Median	99.0	77.0	80.0	89.0	82.0	77.0	91.0
Q1, Q3	77.0, 130.0	59.0, 100.0	62.0, 108.0	67.0, 120.0	63.0, 112.0	64.0, 116.0	69.0, 122.0
Min, Max	9, 459	8, 331	6, 378	4, 480	4, 480	30, 205	4, 480

N = Number of subjects enrolled in the primary analysis set (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ASCVD = Atherosclerotic Cardiovascular Disease; LDL-C = Low Density Lipoprotein Cholesterol; LMT = Lipid Modifying Therapy
[a] Subjects who are not classified as primary prevention subjects and do not fulfill the criteria for secondary prevention subjects/have no CV event documented.
[b] Subjects who are stabilized on the most current or any one of the previous LMT.
[c] Subjects who are not stabilized on any LMT or have their LDL-C measurement taken before any LMT is initiated.
[d] Subjects who have their LDL-C measurement taken after the most recent LMT but less than 28 days.
[e] Subjects who cannot be classified into any of the groups due to partial/missing LMT date(s).

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/adhoc/program/t-ah-lb-sum-ldlc-cnunit-ascvd.sas
Output: t14-04-001-400-ah-lb-sum-ldlc-cnunit-ascvd.rtf (Date Generated: 27MAY19:23:41:15) Source: adhoc.adslblah

Table 14-4.1.400. Summary of LDL-C Measurements in Conventional Units by ASCVD Status Study 20150333 (Primary Analysis Set)

		Secondary Prevention Subjects					
	Primary Prevention Subjects (N = 3142)	Coronary (N = 593)	Peripheral (N = 970)	Cerebral (N = 1096)	Total (N = 2659)	Unclassified[a] (N = 87)	Total (N = 5888)
LMT stabilized subjects[b] (mg/dL)							
n	2558	470	818	751	2039	71	4668
Mean	98.0	77.8	84.7	84.7	83.1	89.5	91.4
SD	37.3	33.1	37.9	33.0	35.2	38.1	37.1
SE	0.7	1.5	1.3	1.2	0.8	4.5	0.5
Median	93.0	73.0	77.0	79.0	77.0	77.0	85.0
Q1, Q3	72.0, 117.0	58.0, 91.0	61.0, 102.0	62.0, 102.0	61.0, 100.0	64.0, 109.0	66.0, 111.0
Min, Max	9, 358	8, 331	9, 378	4, 205	4, 378	33, 205	4, 378

N = Number of subjects enrolled in the primary analysis set (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ASCVD = Atherosclerotic Cardiovascular Disease; LDL-C = Low Density Lipoprotein Cholesterol; LMT = Lipid Modifying Therapy
[a] Subjects who are not classified as primary prevention subjects and do not fulfill the criteria for secondary prevention subjects/have no CV event documented.
[b] Subjects who are stabilized on the most current or any one of the previous LMT.
[c] Subjects who are not stabilized on any LMT or have their LDL-C measurement taken before any LMT is initiated.
[d] Subjects who have their LDL-C measurement taken after the most recent LMT but less than 28 days.
[e] Subjects who cannot be classified into any of the groups due to partial/missing LMT date(s).

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/adhoc/program/t-ah-lb-sum-ldlc-cnunit-ascvd.sas
Output: t14-04-001-400-ah-lb-sum-ldlc-cnunit-ascvd.rtf (Date Generated: 27MAY19:23:41:15) Source: adhoc.adslblah

Table 14-4.1.400. Summary of LDL-C Measurements in Conventional Units by ASCVD Status
Study 20150333 (Primary Analysis Set)

		Secondary Prevention Subjects					
	Primary Prevention Subjects (N = 3142)	Coronary (N = 593)	Peripheral (N = 970)	Cerebral (N = 1096)	Total (N = 2659)	Unclassified[a] (N = 87)	Total (N = 5888)
LMT-naïve subjects[c] (mg/dL)							
n	492	67	73	259	399	9	900
Mean	151.7	121.5	117.8	127.2	124.5	121.4	139.3
SD	51.2	39.8	51.2	39.6	42.0	43.1	49.2
SE	2.3	4.9	6.0	2.5	2.1	14.4	1.6
Median	151.5	122.0	112.0	124.0	122.0	126.0	139.0
Q1, Q3	120.0, 184.0	90.0, 151.0	81.0, 154.0	100.0, 153.0	96.0, 153.0	103.0, 151.0	106.0, 169.5
Min, Max	14, 459	42, 203	8, 262	41, 264	8, 264	54, 184	8, 459

N = Number of subjects enrolled in the primary analysis set (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ASCVD = Atherosclerotic Cardiovascular Disease; LDL-C = Low Density Lipoprotein Cholesterol; LMT = Lipid Modifying Therapy
[a] Subjects who are not classified as primary prevention subjects and do not fulfill the criteria for secondary prevention subjects/have no CV event documented.
[b] Subjects who are stabilized on the most current or any one of the previous LMT.
[c] Subjects who are not stabilized on any LMT or have their LDL-C measurement taken before any LMT is initiated.
[d] Subjects who have their LDL-C measurement taken after the most recent LMT but less than 28 days.
[e] Subjects who cannot be classified into any of the groups due to partial/missing LMT date(s).

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/adhoc/program/t-ah-lb-sum-ldlc-cnunit-ascvd.sas
Output: t14-04-001-400-ah-lb-sum-ldlc-cnunit-ascvd.rtf (Date Generated: 27MAY19:23:41:15) Source: adhoc.adslblah

Table 14-4.1.400. Summary of LDL-C Measurements in Conventional Units by ASCVD Status Study 20150333 (Primary Analysis Set)

		Secondary Prevention Subjects					
	Primary Prevention Subjects (N = 3142)	Coronary (N = 593)	Peripheral (N = 970)	Cerebral (N = 1096)	Total (N = 2659)	Unclassified[a] (N = 87)	Total (N = 5888)
LMT not-stabilized subjects[d] (mg/dL)							
n	51	35	26	74	135	1	187
Mean	117.6	95.1	106.2	107.4	104.0	116.0	107.7
SD	50.2	40.9	45.2	60.1	53.0	-	52.3
SE	7.0	6.9	8.9	7.0	4.6	-	3.8
Median	111.0	85.0	96.5	104.0	96.0	116.0	99.0
Q1, Q3	81.0, 161.0	62.0, 135.0	77.0, 142.0	66.0, 132.0	69.0, 135.0	116.0, 116.0	71.0, 139.0
Min, Max	43, 255	27, 176	34, 210	23, 480	23, 480	116, 116	23, 480
Unknown[e]	41 (1.3)	21 (3.5)	53 (5.5)	12 (1.1)	86 (3.2)	6 (6.9)	133 (2.3)

Page 4 of 4

N = Number of subjects enrolled in the primary analysis set (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ASCVD = Atherosclerotic Cardiovascular Disease; LDL-C = Low Density Lipoprotein Cholesterol; LMT = Lipid Modifying Therapy
[a] Subjects who are not classified as primary prevention subjects and do not fulfill the criteria for secondary prevention subjects/have no CV event documented.
[b] Subjects who are stabilized on the most current or any one of the previous LMT.
[c] Subjects who are not stabilized on any LMT or have their LDL-C measurement taken before any LMT is initiated.
[d] Subjects who have their LDL-C measurement taken after the most recent LMT but less than 28 days.
[e] Subjects who cannot be classified into any of the groups due to partial/missing LMT date(s).

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/adhoc/program/t-ah-lb-sum-ldlc-cnunit-ascvd.sas
Output: t14-04-001-400-ah-lb-sum-ldlc-cnunit-ascvd.rtf (Date Generated: 27MAY19:23:41:15) Source: adhoc.adslblah

Table 14-4.2.3. Achievement of LMT Stabilized LDL-C Below Target by ASCVD Status
Study 20150333 (Primary Analysis Set)

	Total (N = 4668)
Achievement of LDL-C below the 2016 Joint ESC Guideline-recommended level	
Primary prevention subjects - n (%)	2558 (54.8)
Low or moderate risk subjects - n (%)	1391 (29.8)
High-risk subjects - n (%)	593 (12.7)
Very high-risk subjects - n (%)	89 (1.9)
Unclassified subjects[a] - n (%)	485 (10.4)
Secondary prevention subjects - n (%)	2039 (43.7)
Subjects who are neither primary prevention nor secondary prevention[b] - n (%)	71 (1.5)
Primary prevention subjects	
Low or moderate risk subjects[c] - n	1391
Achieved target LDL-C level-115 mg/dL (3.0 mmol/L) - n (%)	1025 (73.7)
95% CI[d]	(71.3, 75.9)
Not achieved target LDL-C level-115 mg/dL (3.0 mmol/L) - n (%)	366 (26.3)
95% CI[d]	(24.1, 28.7)

N = Number of subjects enrolled in the primary analysis set and with treatment stabilized LDL-C (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ASCVD = Atherosclerotic Cardiovascular Disease; ESC = European Society of Cardiology; LDL-C = Low Density Lipoprotein Cholesterol; LMT = Lipid Modifying Therapy.
Subjects who were secondary prevention at the visit date but whose first ASCVD event occurred after the date of their stabilized LDL-C are categorized as primary prevention in this table.
[a] Primary prevention subjects who have missing SCORE and/or GFR and cannot have their risk levels defined.
[b] Subjects who are not classified as primary prevention subjects and do not fulfill the criteria for secondary prevention subjects/have no CV event documented.
[c] Number of subjects in the category with non-missing target LDL-C data.
[d] 95% Confidence interval is calculated using the Wilson Score method.

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/tables/program/t-lb-sum-ach-ascvd.sas
Output: t14-04-002-003-lb-sum-ach-ascvd.rtf (Date generated: 13MAR2019:02:14) Source data: adam.adslbl

Table 14-4.2.3. Achievement of LMT Stabilized LDL-C Below Target by ASCVD Status
Study 20150333 (Primary Analysis Set)

	Total (N = 4668)
High-risk subjects[c] - n	593
Achieved target LDL-C level-100 mg/dL (2.6 mmol/L) - n (%)	373 (62.9)
95% CI[d]	(58.9, 66.7)
Not achieved target LDL-C level-100 mg/dL (2.6 mmol/L) - n (%)	220 (37.1)
95% CI[d]	(33.3, 41.1)
Very high-risk subjects[c] - n	89
Achieved target LDL-C level-70 mg/dL (1.8 mmol/L) - n (%)	19 (21.3)
95% CI[d]	(14.1, 31.0)
Not achieved target LDL-C level-70 mg/dL (1.8 mmol/L) - n (%)	70 (78.7)
95% CI[d]	(69.0, 85.9)
Secondary prevention subjects[c] - n	2039
Achieved target LDL-C level-70 mg/dL (1.8 mmol/L) - n (%)	801 (39.3)
95% CI[d]	(37.2, 41.4)
Not achieved target LDL-C level-70 mg/dL (1.8 mmol/L) - n (%)	1238 (60.7)
95% CI[d]	(58.6, 62.8)

N = Number of subjects enrolled in the primary analysis set and with treatment stabilized LDL-C (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ASCVD = Atherosclerotic Cardiovascular Disease; ESC = European Society of Cardiology; LDL-C = Low Density Lipoprotein Cholesterol; LMT = Lipid Modifying Therapy.
Subjects who were secondary prevention at the visit date but whose first ASCVD event occurred after the date of their stabilized LDL-C are categorized as primary prevention in this table.
[a] Primary prevention subjects who have missing SCORE and/or GFR and cannot have their risk levels defined.
[b] Subjects who are not classified as primary prevention subjects and do not fulfill the criteria for secondary prevention subjects/have no CV event documented.
[c] Number of subjects in the category with non-missing target LDL-C data.
[d] 95% Confidence interval is calculated using the Wilson Score method.

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/tables/program/t-lb-sum-ach-ascvd.sas
Output: t14-04-002-003-lb-sum-ach-ascvd.rtf (Date generated: 13MAR2019:02:14) Source data: adam.adslbl

Table 14-4.2.400. Achievement of LMT Stabilized LDL-C Below Target by ASCVD Types Study 20150333 (Primary Analysis Set)

	Coronary (N = 470)	Peripheral (N = 818)	Cerebral (N = 751)	Total (N = 2039)
Achievement of LDL-C below the 2016 Joint ESC Guideline-recommended level				
Secondary prevention subjects[a] - n	470	818	751	2039
Achieved target LDL-C level-70 mg/dL (1.8 mmol/L) - n (%)	207 (44.0)	326 (39.9)	268 (35.7)	801 (39.3)
95% CI[b]	(39.6, 48.6)	(36.6, 43.2)	(32.3, 39.2)	(37.2, 41.4)
Not achieved target LDL-C level-70 mg/dL (1.8 mmol/L) - n (%)	263 (56.0)	492 (60.1)	483 (64.3)	1238 (60.7)
95% CI[b]	(51.4, 60.4)	(56.8, 63.4)	(60.8, 67.7)	(58.6, 62.8)

N = Number of secondary prevention subjects enrolled in the primary analysis set and with treatment stabilized LDL-C (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ASCVD = Atherosclerotic Cardiovascular Disease; ESC = European Society of Cardiology; LDL-C = Low Density Lipoprotein Cholesterol; LMT = Lipid Modifying Therapy
Subjects who were secondary prevention at the visit date but whose first ASCVD event occurred after the date of their stabilized LDL-C are categorized as primary prevention subjects and not included in this table.
[a] Number of subjects in the category with non-missing target LDL-C data.
[b] 95% Confidence interval is calculated using the Wilson Score method.
NOTE: draft, QC not yet done.

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/adhoc/program/t-ah-lb-sum-ach-ascvt.sas
Output: t14-04-002-400-ah-lb-sum-ach-ascvt.rtf (Date generated: 29MAY2019:01:24) Source data: adhoc.adslblah

Table 14-4.2.401. Achievement of LMT Stabilized LDL-C Below Target by Statin Intensities Study 20150333 (Primary Analysis Set)

	High intensity statin (N = 1424)	Moderate intensity statin (N = 2627)	Low intensity statin (N = 194)	Unknown[c] (N = 117)	Total (N = 4362)
Achievement of LDL-C below the 2016 Joint ESC Guideline-recommended level					
Number of subjects taking statins[a]	1306	2279	171	100	3856
Achieved target LDL-C level - n (%)	701 (53.7)	1299 (57.0)	82 (48.0)	68 (68.0)	2150 (55.8)
95% CI[b]	(51.0, 56.4)	(55.0, 59.0)	(40.6, 55.4)	(58.3, 76.3)	(54.2, 57.3)
Not achieved target LDL-C level - n (%)	605 (46.3)	980 (43.0)	89 (52.0)	32 (32.0)	1706 (44.2)
95% CI[b]	(43.6, 49.0)	(41.0, 45.0)	(44.6, 59.4)	(23.7, 41.7)	(42.7, 45.8)

N = Number of subjects enrolled in the primary analysis set and with treatment stabilized LDL-C and are taking statins (one subject is excluded from the analysis set due to withdrawal of consent for their data to be used).
ESC = European Society of Cardiology; LDL-C = Low Density Lipoprotein Cholesterol; LMT = Lipid Modifying Therapy.
Subjects who were secondary prevention at the visit date but whose first ASCVD event occurred after the date of their stabilized LDL-C are categorized as primary prevention subjects.
This table presents the statin intensities at LDL-C measurement.
[a] Number of subjects in the category with non-missing target LDL-C data.
[b] 95% Confidence interval is calculated using the Wilson Score method.
[c] Unknown: patients with combination of therapies/unclassified therapies.

Program: /userdata/stat/amg145/lipid/20150333/analysis/final/adhoc/program/t-ah-lb-sum-ach-inten.sas
Output: t14-04-002-401-ah-lb-sum-ach-inten.rtf (Date generated: 28MAY2019:18:52) Source data: adhoc.adslblah

ANNEX

Investigator Signature

STUDY NUMBER: 20150333

STUDY REPORT TITLE: EU-Wide Cross-Sectional Observational Study of Lipid-Modifying Therapy Use in Secondary and Primary Care (DA VINCI)

I have read the above named Observational Research Study Report Abstract and signify my agreement with the overall conclusions.

Name of Coordinating Investigator:	[redacted]
Institution:	Imperial College
Signature of Investigator:	[redacted]
Date:	28/8/19