

SUPPLEMENTAL MATERIAL

Supplemental Table 1. Baseline characteristics of the USA and non-USA subgroups (overall and by treatment).

	USA (N=3146)			Non-USA (N=5033)			Overall (N=8179)		
	Icosapent Ethyl (N=1548)	Placebo (N=1598)	P-value*	Icosapent Ethyl (N=2541)	Placebo (N=2492)	P-value*	Icosapent Ethyl (N=3146)	Placebo (N=5033)	P-value*
Age (years), Median (Q1-Q3)	65.0 (59.0-71.0)	65.0 (59.0-71.0)	0.56	63.0 (56.0-68.0)	63.0 (56.0-68.0)	0.82	65.0 (59.0-71.0)	63.0 (56.0-68.0)	<0.0001
Age ≥65 years, n (%)	808 (52.2%)	866 (54.2%)	0.26	1049 (41.3%)	1040 (41.7%)	0.75	1674 (53.2%)	2089 (41.5%)	<0.0001
Female, n (%)	487 (31.5%)	528 (33.0%)	0.34	675 (26.6%)	667 (26.8%)	0.87	1015 (32.3%)	1342 (26.7%)	<0.0001
Hispanic or Latino Ethnicity, n (%)	165 (10.7%)	141 (8.8%)	0.08	23 (0.9%)	16 (0.6%)	0.29	306 (9.7%)	39 (0.8%)	<0.0001
Race, n (%) [†]			0.29			0.98			<0.0001
White	1437 (92.8%)	1474 (92.2%)		2254 (88.7%)	2214 (88.8%)		2911 (92.5%)	4468 (88.8%)	<0.0001
Black or African American	52 (3.4%)	72 (4.5%)		17 (0.7%)	17 (0.7%)		124 (3.9%)	34 (0.7%)	
Asian	35 (2.3%)	34 (2.1%)		190 (7.5%)	187 (7.5%)		69 (2.2%)	377 (7.5%)	
Other or Multiple	24 (1.6%)	18 (1.1%)		80 (3.1%)	73 (2.9%)		42 (1.3%)	153 (3.0%)	
BMI (kg/m ²), Median (Q1-Q3)	32.3 (28.8-36.5)	32.2 (28.7-36.6)	0.54	30.0 (27.2-33.3)	30.2 (27.4-33.5)	0.09	32.3 (28.8-36.5)	30.1 (27.3-33.4)	<0.0001
BMI ≥30, n (%) [†]	1055 (68.2%)	1053 (65.9%)	0.32	1276 (50.2%)	1309 (52.5%)	0.08	2108 (67.0%)	2585 (51.4%)	<0.0001
Stratification Factors Other than Geography									
CV Risk Category - As Randomized, n (%)			0.87			0.86			<0.0001
CV Risk Category 1 (Secondary Prevention)	908 (58.7%)	942 (58.9%)		1984 (78.1%)	1951 (78.3%)		1850 (58.8%)	3935 (78.2%)	
CV Risk Category 2 (Primary Prevention)	640 (41.3%)	656 (41.1%)		557 (21.9%)	541 (21.7%)		1296 (41.2%)	1098 (21.8%)	
Ezetimibe Use, n (%)	94 (6.1%)	108 (6.8%)	0.43	168 (6.6%)	154 (6.2%)	0.53	202 (6.4%)	322 (6.4%)	0.97
Statin Intensity and Diabetes Status									
Statin Intensity, n (%)			0.64			0.32			<0.0001
Low	152 (9.8%)	153 (9.6%)		102 (4.0%)	114 (4.6%)		305 (9.7%)	216 (4.3%)	
Moderate	871 (56.3%)	923 (57.8%)		1662 (65.4%)	1652 (66.3%)		1794 (57.0%)	3314 (65.8%)	
High	518 (33.5%)	511 (32.0%)		772 (30.4%)	715 (28.7%)		1029 (32.7%)	1487 (29.5%)	
Missing	7 (0.5%)	11 (0.7%)		5 (0.2%)	11 (0.4%)		18 (0.6%)	16 (0.3%)	
Diabetes, n (%)			0.37			0.63			<0.0001
Type I	12 (0.8%)	20 (1.3%)		15 (0.6%)	10 (0.4%)		32 (1.0%)	25 (0.5%)	
Type II	1078 (69.6%)	1095 (68.5%)		1289 (50.7%)	1268 (50.9%)		2173 (69.1%)	2557 (50.8%)	
No Diabetes at Baseline	458 (29.6%)	483 (30.2%)		1237 (48.7%)	1211 (48.6%)		941 (29.9%)	2448 (48.6%)	
Missing	0	0		0	3 (0.1%)		0	3 (0.1%)	
Laboratory Measurements									
hsCRP (mg/L), Median (Q1-Q3)	2.5 (1.2-5.0)	2.4 (1.2-5.1)	0.71	2.0 (1.0-4.2)	2.0 (1.0-4.1)	0.81	2.5 (1.2-5.1)	2.0 (1.0-4.2)	<0.0001
Triglycerides (mg/dL), Median (Q1-Q3)	217.0 (177.5-271.0)	217.5 (175.0-273.5)	0.93	216.0 (175.8-272.5)	215.0 (175.5-274.0)	0.82	217.0 (176.5-272.5)	215.5 (175.5-272.5)	0.7
Triglycerides Category, n (%)			0.92			0.84			0.27
< 150 mg/dL	161 (10.4%)	172 (10.8%)		251 (9.9%)	257 (10.3%)		333 (10.6%)	508 (10.1%)	
150 - <200 mg/dL	439 (28.4%)	446 (27.9%)		754 (29.7%)	745 (29.9%)		885 (28.1%)	1499 (29.8%)	
≥200 mg/dL	945 (61.0%)	979 (61.3%)		1536 (60.4%)	1490 (59.8%)		1924 (61.2%)	3026 (60.1%)	
Triglycerides Tertiles, n (%)			0.72			0.67			0.37

	USA (N=3146)			Non-USA (N=5033)			Overall (N=8179)		
	Icosapent Ethyl	Placebo	P-value*	Icosapent Ethyl	Placebo	P-value*	Icosapent Ethyl	Placebo	P-value*
	(N=1548)	(N=1598)		(N=2541)	(N=2492)		(N=3146)	(N=5033)	
Lowest (≥ 81.25 - ≤ 190 mg/dL)	510 (32.9%)	527 (33.0%)		868 (34.2%)	854 (34.3%)		1037 (33.0%)	1722 (34.2%)	
Middle (>190 - ≤ 250 mg/dL)	532 (34.4%)	531 (33.2%)		838 (33.0%)	795 (31.9%)		1063 (33.8%)	1633 (32.4%)	
Upper (>250 - ≤ 1401 mg/dL)	503 (32.5%)	539 (33.7%)		835 (32.9%)	843 (33.8%)		1042 (33.1%)	1678 (33.3%)	
Triglycerides ≥ 200 mg/dL and HDL-C ≤ 35 mg/dL, n (%)	351 (22.7%)	349 (21.8%)	0.54	472 (18.6%)	445 (17.9%)	0.51	700 (22.3%)	917 (18.2%)	<0.0001
HDL-C (mg/dL), Median (Q1-Q3)	39.5 (34.0-45.5)	40.0 (34.5-46.5)	0.06	40.0 (35.0-46.0)	40.0 (35.5-46.0)	0.68	39.5 (34.5-46.0)	40.0 (35.0-46.0)	0.006
LDL-C (mg/dL), Median (Q1-Q3)	72.0 (60.0-85.0)	73.0 (61.0-85.0)	0.27	77.0 (63.0-90.0)	78.0 (64.0-92.0)	0.04	72.0 (60.0-85.0)	77.0 (63.0-91.0)	<0.0001
LDL-C Tertiles, n (%)			0.31			0.05			<0.0001
Lowest (≥ 1 - ≤ 67 mg/dL)	639 (41.3%)	620 (38.8%)		842 (33.1%)	766 (30.7%)		1259 (40.0%)	1608 (31.9%)	
Middle (>67 - ≤ 84 mg/dL)	517 (33.4%)	568 (35.5%)		830 (32.7%)	796 (31.9%)		1085 (34.5%)	1626 (32.3%)	
Upper (>84 - ≤ 222 mg/dL)	389 (25.1%)	409 (25.6%)		869 (34.2%)	930 (37.3%)		798 (25.4%)	1799 (35.7%)	
EPA ($\mu\text{g/mL}$), Median (Q1-Q3)	20.8 (15.1-28.4)	21.9 (15.5-29.1)	0.04	32.7 (20.0-48.5)	31.6 (19.4-47.2)	0.33	21.3 (15.3-28.7)	32.3 (19.7-47.8)	<0.0001
Cardiovascular Disease History [§]									
Prior Atherosclerotic Cardiovascular Disease (ASCVD), n (%)	878 (56.7%)	925 (57.9%)	0.51	1938 (76.3%)	1910 (76.6%)	0.75	1803 (57.3%)	3848 (76.5%)	<0.0001
Prior Atherosclerotic Coronary Artery Disease and Related Morbidities	712 (46.0%)	734 (45.9%)	0.97	1675 (65.9%)	1659 (66.6%)	0.62	1446 (46.0%)	3334 (66.2%)	<0.0001
Myocardial Infarction	558 (36.0%)	566 (35.4%)	0.71	1380 (54.3%)	1315 (52.8%)	0.27	1124 (35.7%)	2695 (53.5%)	<0.0001
Unstable Angina	354 (22.9%)	360 (22.5%)	0.82	663 (26.1%)	655 (26.3%)	0.88	714 (22.7%)	1318 (26.2%)	0.0004
Ischemic Dilated Cardiomyopathy	84 (5.4%)	69 (4.3%)	0.15	53 (2.1%)	40 (1.6%)	0.21	153 (4.9%)	93 (1.8%)	<0.0001
Prior Atherosclerotic Cerebrovascular Disease and Related Morbidities	273 (17.6%)	300 (18.8%)	0.41	368 (14.5%)	362 (14.5%)	0.96	573 (18.2%)	730 (14.5%)	<0.0001
Carotid Disease	169 (10.9%)	197 (12.3%)	0.22	174 (6.8%)	175 (7.0%)	0.81	366 (11.6%)	349 (6.9%)	<0.0001
Ischemic Stroke	76 (4.9%)	76 (4.8%)	0.84	191 (7.5%)	166 (6.7%)	0.24	152 (4.8%)	357 (7.1%)	<0.0001
Transient Ischemic Attack	100 (6.5%)	97 (6.1%)	0.65	94 (3.7%)	84 (3.4%)	0.53	197 (6.3%)	178 (3.5%)	<0.0001
Prior Atherosclerotic Peripheral Artery Disease	131 (8.5%)	160 (10.0%)	0.13	256 (10.1%)	228 (9.1%)	0.27	291 (9.2%)	484 (9.6%)	0.58
Peripheral Artery Disease	128 (8.3%)	158 (9.9%)	0.11	249 (9.8%)	219 (8.8%)	0.22	286 (9.1%)	468 (9.3%)	0.75
ABI <0.9 Without Symptoms of Intermittent Claudication	17 (1.1%)	26 (1.6%)	0.2	80 (3.1%)	50 (2.0%)	0.01	43 (1.4%)	130 (2.6%)	0.0002
Prior Non-Atherosclerotic Cardiovascular Disease, n (%)	1470 (95.0%)	1501 (93.9%)	0.21	2179 (85.8%)	2144 (86.0%)	0.77	2971 (94.4%)	4323 (85.9%)	<0.0001
Prior Structural Cardiac Disorders	205 (13.2%)	245 (15.3%)	0.09	622 (24.5%)	621 (24.9%)	0.72	450 (14.3%)	1243 (24.7%)	<0.0001
Heart Failure	155 (10.0%)	187 (11.7%)	0.13	548 (21.6%)	556 (22.3%)	0.52	342 (10.9%)	1104 (21.9%)	<0.0001
Hypertrophic Cardiomyopathy	11 (0.7%)	11 (0.7%)	0.94	12 (0.5%)	9 (0.4%)	0.54	22 (0.7%)	21 (0.4%)	0.09
Non-Ischemic Dilated Cardiomyopathy	24 (1.6%)	25 (1.6%)	0.97	11 (0.4%)	4 (0.2%)	0.08	49 (1.6%)	15 (0.3%)	<0.0001
Non-Rheumatic Valvular Heart Disease	45 (2.9%)	61 (3.8%)	0.16	105 (4.1%)	102 (4.1%)	0.94	106 (3.4%)	207 (4.1%)	0.09
Rheumatic Valvular Heart Disease	8 (0.5%)	2 (0.1%)	0.05	9 (0.4%)	7 (0.3%)	0.64	10 (0.3%)	16 (0.3%)	>0.99
Prior Cardiac Arrhythmias	86 (5.6%)	100 (6.3%)	0.4	143 (5.6%)	143 (5.7%)	0.87	186 (5.9%)	286 (5.7%)	0.66
Atrio-Ventricular Block Above First Degree	18 (1.2%)	24 (1.5%)	0.41	33 (1.3%)	30 (1.2%)	0.76	42 (1.3%)	63 (1.3%)	0.74
Sick Sinus Syndrome	17 (1.1%)	19 (1.2%)	0.81	13 (0.5%)	13 (0.5%)	0.96	36 (1.1%)	26 (0.5%)	0.001
Supra-Ventricular Tachycardia	24 (1.6%)	31 (1.9%)	0.4	50 (2.0%)	46 (1.8%)	0.75	55 (1.7%)	96 (1.9%)	0.6

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Other Than Atrial Fibrillation/Atrial Flutter									
Sustained Ventricular Tachycardia	17 (1.1%)	17 (1.1%)	0.93	17 (0.7%)	17 (0.7%)	0.95	34 (1.1%)	34 (0.7%)	0.05
Torsades De Pointes	0 (0.0%)	0 (0.0%)		1 (0.0%)	3 (0.1%)	0.31	0 (0.0%)	4 (0.1%)	0.11
Ventricular Fibrillation	18 (1.2%)	21 (1.3%)	0.7	43 (1.7%)	44 (1.8%)	0.84	39 (1.2%)	87 (1.7%)	0.08
Prior Non-Cardiac/Non Atherosclerotic Vascular Disorders	1461 (94.4%)	1486 (93.0%)	0.11	2107 (82.9%)	2080 (83.5%)	0.6	2947 (93.7%)	4187 (83.2%)	<0.0001
Hypotension	25 (1.6%)	22 (1.4%)	0.58	20 (0.8%)	11 (0.4%)	0.12	47 (1.5%)	31 (0.6%)	<0.0001
Hypertension	1455 (94.0%)	1480 (92.6%)	0.12	2086 (82.1%)	2063 (82.8%)	0.52	2935 (93.3%)	4149 (82.4%)	<0.0001
Non-Ischemic Stroke	48 (3.1%)	50 (3.1%)	0.96	31 (1.2%)	34 (1.4%)	0.65	98 (3.1%)	65 (1.3%)	<0.0001
Hemorrhagic Stroke	8 (0.5%)	10 (0.6%)	0.69	10 (0.4%)	12 (0.5%)	0.64	18 (0.6%)	22 (0.4%)	0.39
Stroke of Unknown Origin	40 (2.6%)	40 (2.5%)	0.89	23 (0.9%)	22 (0.9%)	0.93	80 (2.5%)	45 (0.9%)	<0.0001
Arterial Embolism	2 (0.1%)	4 (0.3%)	0.44	10 (0.4%)	5 (0.2%)	0.21	6 (0.2%)	15 (0.3%)	0.35
Deep Vein Thrombosis	31 (2.0%)	29 (1.8%)	0.7	39 (1.5%)	31 (1.2%)	0.38	60 (1.9%)	70 (1.4%)	0.07
Pulmonary Embolism	11 (0.7%)	15 (0.9%)	0.48	20 (0.8%)	27 (1.1%)	0.27	26 (0.8%)	47 (0.9%)	0.62
Other Prior Conditions or Investigations Influencing Cardiovascular Risk, n (%)	1326 (85.7%)	1362 (85.2%)	0.73	1718 (67.6%)	1693 (67.9%)	0.8	2688 (85.4%)	3411 (67.8%)	<0.0001
Prior Metabolic Disorders	1118 (72.2%)	1155 (72.3%)	0.97	1362 (53.6%)	1360 (54.6%)	0.49	2273 (72.3%)	2722 (54.1%)	<0.0001
Type 1 Diabetes ^l	13 (0.8%)	20 (1.3%)	0.26	15 (0.6%)	10 (0.4%)	0.34	33 (1.0%)	25 (0.5%)	0.004
Type 2 Diabetes ^l	1078 (69.6%)	1095 (68.5%)	0.5	1289 (50.7%)	1268 (50.9%)	0.91	2173 (69.1%)	2557 (50.8%)	<0.0001
Baseline Laboratory Abnormalities	836 (54.0%)	813 (50.9%)	0.08	947 (37.3%)	894 (35.9%)	0.3	1649 (52.4%)	1841 (36.6%)	<0.0001
Renal Disorders	214 (13.8%)	201 (12.6%)	0.3	256 (10.1%)	228 (9.1%)	0.27	415 (13.2%)	484 (9.6%)	<0.0001
Creatinine Clearance (CrCl) >30 And <60 ml/min	150 (9.7%)	136 (8.5%)	0.25	159 (6.3%)	150 (6.0%)	0.72	286 (9.1%)	309 (6.1%)	<0.0001
Proteinuria	33 (2.1%)	24 (1.5%)	0.19	42 (1.7%)	39 (1.6%)	0.8	57 (1.8%)	81 (1.6%)	0.49
Macroalbuminuria	12 (0.8%)	7 (0.4%)	0.22	22 (0.9%)	17 (0.7%)	0.46	19 (0.6%)	39 (0.8%)	0.37
Microalbuminuria	68 (4.4%)	63 (3.9%)	0.53	78 (3.1%)	71 (2.8%)	0.64	131 (4.2%)	149 (3.0%)	0.004
Other Morbidities	38 (2.5%)	43 (2.7%)	0.68	135 (5.3%)	130 (5.2%)	0.88	81 (2.6%)	265 (5.3%)	<0.0001
Pancreatitis	6 (0.4%)	3 (0.2%)	0.29	8 (0.3%)	6 (0.2%)	0.62	9 (0.3%)	14 (0.3%)	0.95
Retinopathy	32 (2.1%)	40 (2.5%)	0.41	129 (5.1%)	127 (5.1%)	0.97	72 (2.3%)	256 (5.1%)	<0.0001
Carotid Stenosis			0.59			0.47			0.08
N	155	178		161	168		333	329	
Mean (SD)	61.5(20.27)	59.3(21.68)		56.5(21.55)	54.3(24.09)		60.3(21.03)	55.4(22.88)	
Median	59.5	59.8		60	55		59.5	57	
Min, Max	15.0,100.0	0.0,100.0		0.0,100.0	0.0,100.0		0.0,100.0	0.0,100.0	
Medications Take at Baseline, n (%)									
Anti-Diabetic	1020 (65.9%)	1056 (66.1%)	0.91	1170 (46.0%)	1140 (45.7%)	0.83	2076 (66.0%)	2310 (45.9%)	<0.0001
Anti-Hypertensive	1468 (94.8%)	1515 (94.8%)	0.97	2427 (95.5%)	2380 (95.5%)	0.99	2983 (94.8%)	4807 (95.5%)	0.15
Anti-Platelet [#]	1220 (78.8%)	1228 (76.8%)	0.18	2037 (80.2%)	2008 (80.6%)	0.71	2448 (77.8%)	4045 (80.4%)	0.005
One Anti-platelet	861 (55.6%)	867 (54.3%)	0.44	1555 (61.2%)	1541 (61.8%)	0.64	1728 (54.9%)	3096 (61.5%)	<0.0001
Two or more Anti-platelets	359 (23.2%)	361 (22.6%)	0.69	482 (19.0%)	467 (18.7%)	0.84	720 (22.9%)	949 (18.9%)	<0.0001

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	Icosapent Ethyl (N=1548)	Placebo (N=1598)	P-value*	Icosapent Ethyl (N=2541)	Placebo (N=2492)	P-value*	Icosapent Ethyl (N=3146)	Placebo (N=5033)	P-value*
Anticoagulant	139 (9.0%)	164 (10.3%)	0.22	246 (9.7%)	226 (9.1%)	0.46	303 (9.6%)	472 (9.4%)	0.7
Anticoagulant plus Anti-platelet	71 (4.6%)	85 (5.3%)	0.34	66 (2.6%)	52 (2.1%)	0.23	156 (5.0%)	118 (2.3%)	<0.0001
No Antithrombotic	260 (16.8%)	291 (18.2%)	0.3	324 (12.8%)	310 (12.4%)	0.74	551 (17.5%)	634 (12.6%)	<0.0001
ACE Inhibitors	804 (51.9%)	838 (52.4%)	0.78	1308 (51.5%)	1293 (51.9%)	0.77	1642 (52.2%)	2601 (51.7%)	0.65
ARB	396 (25.6%)	395 (24.7%)	0.58	712 (28.0%)	701 (28.1%)	0.93	791 (25.1%)	1413 (28.1%)	0.004
ACE Inhibitors or ARB	1178 (76.1%)	1217 (76.2%)	0.97	1986 (78.2%)	1959 (78.6%)	0.7	2395 (76.1%)	3945 (78.4%)	0.02
Beta Blockers	1036 (66.9%)	1030 (64.5%)	0.14	1866 (73.4%)	1850 (74.2%)	0.52	2066 (65.7%)	3716 (73.8%)	<0.0001
Statin	1541 (99.5%)	1587 (99.3%)	0.38	2536 (99.8%)	2481 (99.6%)	0.12	3128 (99.4%)	5017 (99.7%)	0.08

Abbreviations: ABI = ankle brachial index; ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blockers, BMI = body mass index, CV = cardiovascular, EPA = eicosapentaenoic acid, HDL-C = high-density lipoprotein cholesterol; hsCRP = high-sensitivity C-reaction protein, LDL-C = low-density lipoprotein cholesterol, N = number, SD = standard deviation.

In general, the baseline value is defined as the last non-missing measurement obtained prior to the randomization. The baseline LDL-C value obtained via Preparative Ultracentrifugation was used, unless this value was missing. If the LDL-C Preparative Ultracentrifugation value was missing, then another LDL-C value was used, with prioritization of values obtained from LDL-C Direct measurements, followed by LDL-C derived by the Friedewald calculation method (only for subjects with triglycerides < 400 mg/dL), and finally LDL-C derived using the calculation published by Johns Hopkins University investigators (1). For all other lipid and lipoprotein marker parameters, wherever possible, baseline was derived as the arithmetic mean of the Visit 2 (Day 0) value and the preceding Visit 1 (or Visit 1.1) value. If only one of these values was available, the single available value was used as baseline. Tertiles for LDL-C Derived and Triglycerides are based on the overall ITT population.

* P-values are reported from a chi square test for categorical variables and Wilcoxon test for continuous variables. Missing categories are excluded from any comparisons.

† P-value is based on the race categories as listed herein. The category 'Other or Multiple' also includes American Indian, Alaskan Native, Native Hawaiian, and Other Pacific Islander.

‡ P-value is based on BMI categories of ≥30 kg/m², ≥25 - <30 kg/m² and <25 kg/m².

§ The summary is based on the data collected from CV history Case Report Form (CRF).

|| Several patients reported having a cardiovascular history of both Type I and Type II diabetes.

Anti-platelet medications were classified as dual if both components have a regulatory approval affirming anti-platelet effects. Combinations where one element lacks such regulatory approval were excluded (e.g. aspirin + magnesium oxide is classified as a single agent because the latter component is not approved as an anti-platelet agent).

Notes: Percentages are based on the number of subjects randomized to each treatment group in the USA (N). Non-USA includes the following countries: Australia, Canada, India, New Zealand, Poland, Romania, Russian Federation, South Africa, The Netherlands, and Ukraine.

Supplemental Table 2. Treatment emergent adverse events in the USA subgroup of the safety population.

	Icosapent Ethyl (N=1548)	Placebo (N=1598)	P-value[‡]
Subjects with at Least One TEAE, n(%)	1354 (87.5)	1387 (86.8)	0.59
Severe TEAE	436 (28.2)	458 (28.7)	0.78
Drug-Related TEAE*	188 (12.1)	183 (11.5)	0.58
Serious TEAE	533 (34.4)	571 (35.7)	0.46
Drug-Related Serious TEAE*	5 (0.3)	2 (0.1)	0.28
TEAE Leading to Withdrawal of Study Drug [†]	145 (9.4)	170 (10.6)	0.26
Drug-Related TEAE Leading to Withdrawal of Study Drug ^{*,†}	56 (3.6)	75 (4.7)	0.15
Serious TEAE Leading to Withdrawal of Study Drug [†]	31 (2.0)	48 (3.0)	0.09
Serious TEAE Leading to Death	36 (2.3)	53 (3.3)	0.11
Drug-Related Serious TEAE Leading to Withdrawal of Study Drug ^{*,†}	1 (0.1)	2 (0.1)	>0.99

ITT = intent to treat. TEAE = treatment emergent adverse event.
 Note: A treatment-emergent adverse event (TEAE) is defined as an event that first occurs or worsens in severity on or after the date of dispensing study drug and within 30 days after the completion or withdrawal from study. Percentages are based on the number of subjects randomized to each treatment group in the Safety population (N). Events that were positively adjudicated as clinical endpoints are not included.
 All adverse events are coded using the Medical Dictionary for Regulatory Activities (MedDRA Version 20.1).
 * Drug-related TEAEs include those characterized as related, probably related, or possibly related.
 † Withdrawal of study drug excludes subjects who were off drug in study (ODIS) for 30 days or more, and restarted study drug.
 ‡ Fisher's Exact test.

Supplemental Table 3. Incidence of atrial fibrillation or flutter in the USA subgroup of the ITT population.

	Icosapent Ethyl (N=1548)	Placebo (N=1598)	p-Value
Treatment Emergent Atrial Fibrillation/Flutter*	102 (6.6%)	72 (4.5%)	0.01
Serious Treatment Emergent Atrial Fibrillation/Flutter†	11 (0.7%)	5 (0.3%)	0.14
Positively Adjudicated Atrial Fibrillation/Flutter Requiring ≥24 Hours Hospitalization‡	56 (3.6%)	47 (2.9%)	0.35
<p>Note: Percentages are based on the number of subjects in the ITT Population within each treatment group (N). All adverse events are coded using the Medical Dictionary for Regulatory Activities (MedDRA Version 20.1). * Includes Atrial Fibrillation/Flutter treatment emergent adverse events and excludes positively adjudicated events. P value is based on Fisher's Exact test. † Includes Atrial Fibrillation/Flutter treatment emergent adverse events meeting seriousness criteria. P value is based on Fisher's Exact test. ‡ Includes endpoints of Atrial Fibrillation/Flutter requiring ≥24 hours of hospitalization, positively adjudicated by the Clinical Endpoint Committee (CEC). P value is based on stratified log-rank test.</p>			

Supplemental Table 4. Bleeding treatment emergent adverse events in the USA subgroup of the safety population.

Category Preferred Term	Icosapent Ethyl (N=1548)	Placebo (N=1598)	P-value*
Subjects with any bleeding	258 (16.7%)	218 (13.6%)	0.02
Subjects with CNS bleeding	11 (0.7%)	7 (0.4%)	0.35
Subdural hematoma	6 (0.4%)	3 (0.2%)	0.34
Subarachnoid hemorrhage	3 (0.2%)	1 (0.1%)	0.37
Extradural hematoma	2 (0.1%)	0 (0.0%)	0.24
Hemorrhagic transformation stroke	1 (0.1%)	0 (0.0%)	0.49
Subdural hemorrhage	1 (0.1%)	1 (0.1%)	>0.99
Cerebral hemorrhage	0 (0.0%)	1 (0.1%)	>0.99
Hemorrhage intracranial	0 (0.0%)	1 (0.1%)	>0.99
Subjects with GI bleeding	75 (4.8%)	69 (4.3%)	0.50
Gastrointestinal hemorrhage	29 (1.9%)	21 (1.3%)	0.25
Rectal hemorrhage	14 (0.9%)	15 (0.9%)	>0.99
Hematochezia	9 (0.6%)	11 (0.7%)	0.82
Melena	6 (0.4%)	3 (0.2%)	0.34
Hematemesis	5 (0.3%)	2 (0.1%)	0.28
Hemorrhoidal hemorrhage	5 (0.3%)	6 (0.4%)	>0.99
Lower gastrointestinal hemorrhage	4 (0.3%)	7 (0.4%)	0.55
Occult blood positive	4 (0.3%)	6 (0.4%)	0.75
Upper gastrointestinal hemorrhage	4 (0.3%)	2 (0.1%)	0.45
Diverticulum intestinal hemorrhagic	2 (0.1%)	1 (0.1%)	0.62
Diarrhea hemorrhagic	1 (0.1%)	1 (0.1%)	>0.99
Gastric ulcer hemorrhage	1 (0.1%)	2 (0.1%)	>0.99
Gastrointestinal angiodysplasia hemorrhagic	1 (0.1%)	0 (0.0%)	0.49
Mallory-Weiss syndrome	1 (0.1%)	0 (0.0%)	0.49
Ulcer hemorrhage	1 (0.1%)	0 (0.0%)	0.49

TEAE = treatment-emergent adverse event.
 Note: A TEAE is defined as an event that first occurs or worsens in severity on or after the date of dispensing study drug and within 30 days after the completion or withdrawal from study. For each subject, multiple TEAEs of the same Preferred Term were counted only once within each Preferred Term. TEAEs are listed in descending order of icosapent ethyl frequency. Percentages are based on the number of subjects randomized to each treatment group in the Safety population (N). Events that were positively adjudicated as clinical endpoints are not included. All adverse events are coded using the Medical Dictionary for Regulatory Activities (MedDRA Version 20.1).
 * Fisher's Exact test.

Supplemental Table 5. Bleeding results that were treatment emergent serious adverse events in the USA patients in the safety population.

Category Preferred Term	Icosapent Ethyl (N=1548)	Placebo (N=1598)	P-value*
Subjects with any serious bleeding	55 (3.6%)	53 (3.3%)	0.77
Subjects with serious CNS bleeding	8 (0.5%)	5 (0.3%)	0.42
Subdural hematoma	5 (0.3%)	2 (0.1%)	0.28
Hemorrhagic transformation stroke	1 (0.1%)	0 (0.0%)	0.49
Subarachnoid hemorrhage	1 (0.1%)	1 (0.1%)	>0.99
Subdural hemorrhage	1 (0.1%)	1 (0.1%)	>0.99
Cerebral hemorrhage	0 (0.0%)	1 (0.1%)	>0.99
Subjects with serious GI bleeding	36 (2.3%)	32 (2.0%)	0.54
Gastrointestinal hemorrhage	21 (1.4%)	18 (1.1%)	0.63
Lower gastrointestinal hemorrhage	4 (0.3%)	4 (0.3%)	>0.99
Diverticulum intestinal hemorrhagic	2 (0.1%)	1 (0.1%)	0.62
Hematemesis	2 (0.1%)	0 (0.0%)	0.24
Hemorrhoidal hemorrhage	2 (0.1%)	1 (0.1%)	0.62
Rectal hemorrhage	2 (0.1%)	4 (0.3%)	0.69
Upper gastrointestinal hemorrhage	2 (0.1%)	1 (0.1%)	0.62
Gastric ulcer hemorrhage	1 (0.1%)	1 (0.1%)	>0.99
Gastrointestinal angiodysplasia hemorrhagic	1 (0.1%)	0 (0.0%)	0.49
Hematochezia	1 (0.1%)	2 (0.1%)	>0.99
Mallory-Weiss syndrome	1 (0.1%)	0 (0.0%)	0.49
Ulcer hemorrhage	1 (0.1%)	0 (0.0%)	0.49
Diverticulitis intestinal hemorrhagic	0 (0.0%)	1 (0.1%)	>0.99
Melena	0 (0.0%)	1 (0.1%)	>0.99
Esophageal hemorrhage	0 (0.0%)	1 (0.1%)	>0.99
Subjects with other serious bleeding	16 (1.0%)	16 (1.0%)	>0.99
Hematuria	4 (0.3%)	3 (0.2%)	0.72

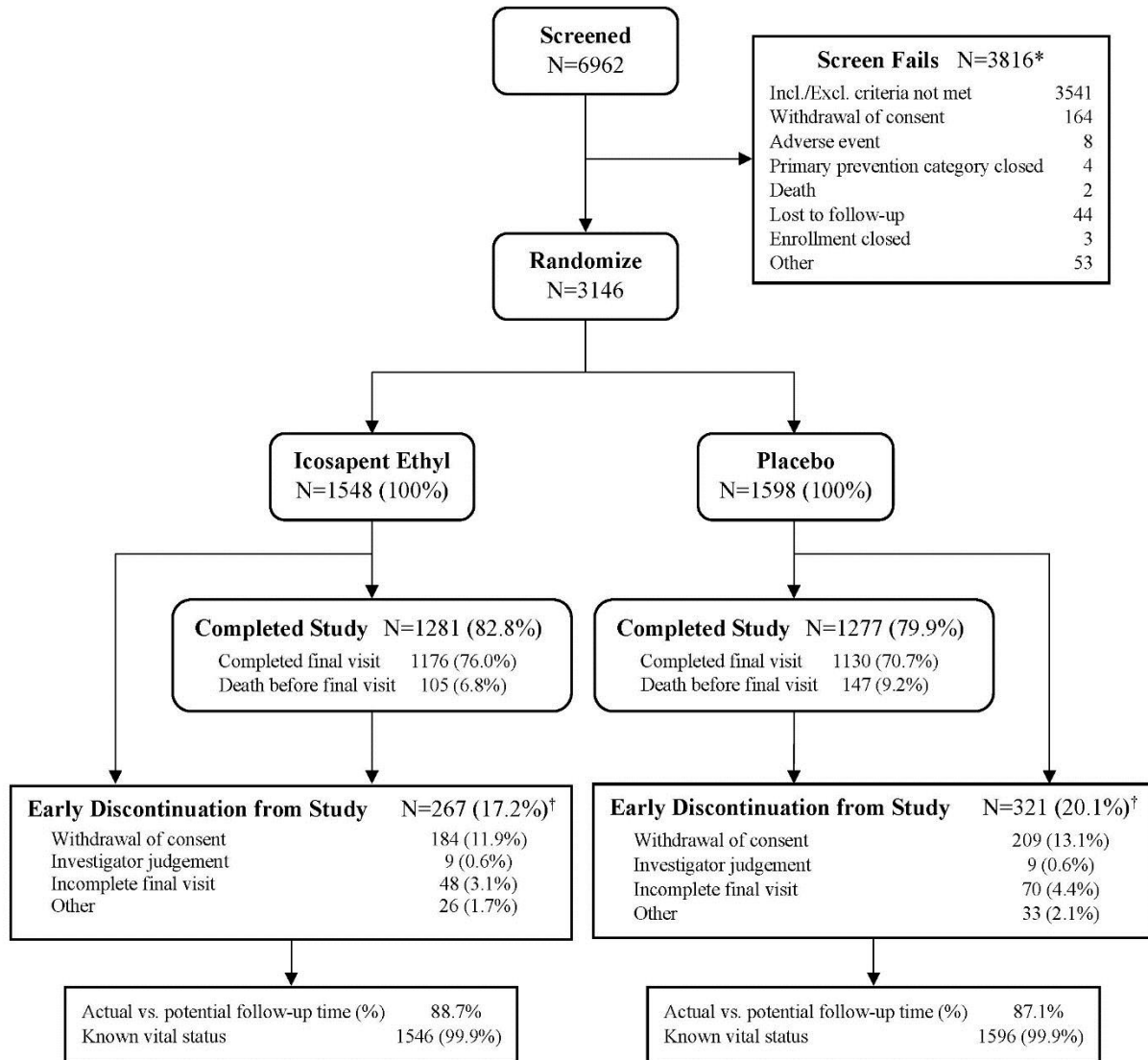
TEAE = treatment-emergent adverse event

Note: A TEAE is defined as an event that first occurs or worsens in severity on or after the date of dispensing study drug and within 30 days after the completion or withdrawal from study. For each subject, multiple TEAEs of the same Preferred Term will be counted only once within each Preferred Term. TEAEs are listed in descending order of icosapent ethyl frequency. Percentages are based on the number of subjects randomized to each treatment group in the Safety population (N). Events that were positively adjudicated as clinical endpoints are not included.

All adverse events are coded using the Medical Dictionary for Regulatory Activities (MedDRA Version 20.1).

* Fisher's Exact test.

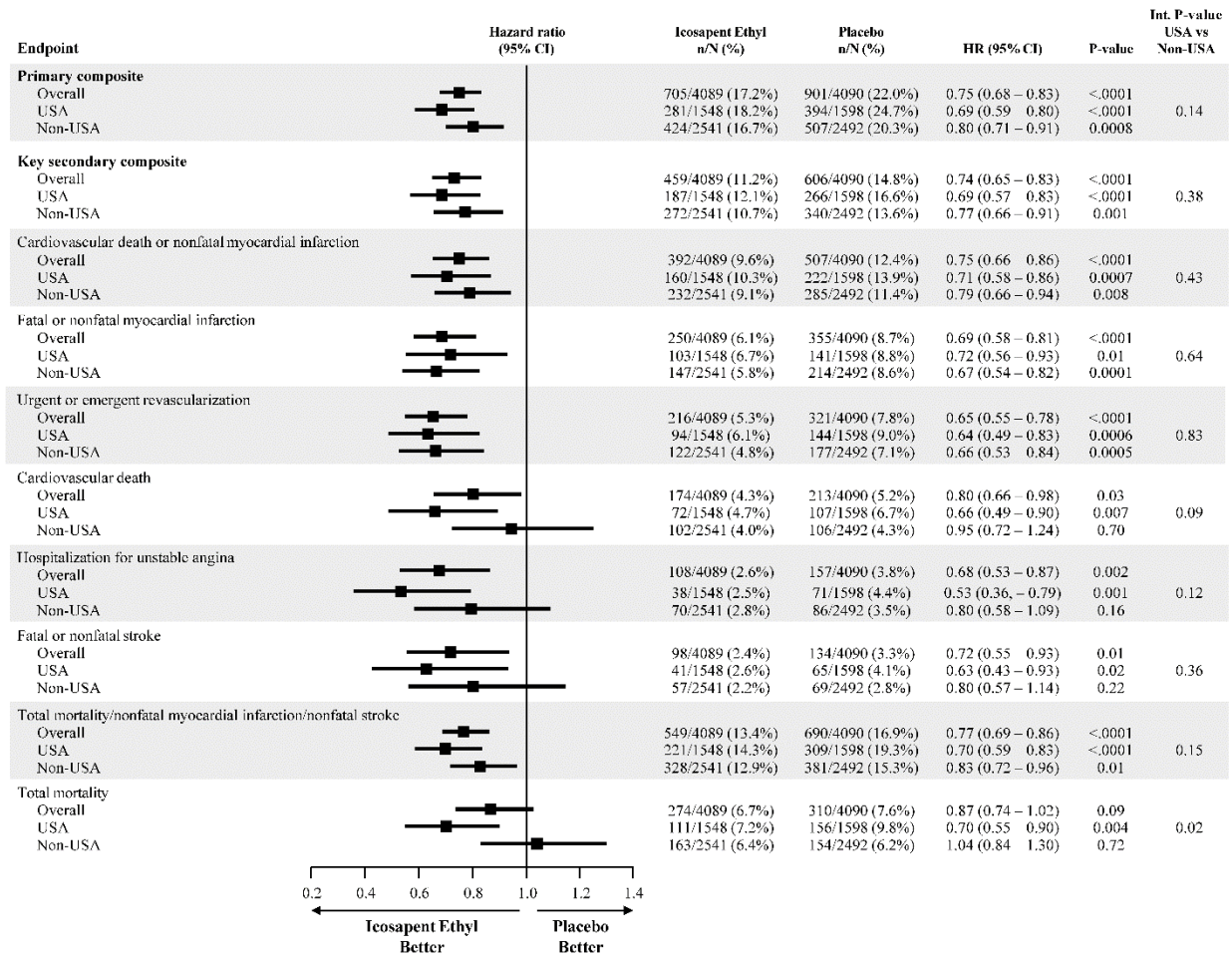
Supplemental Figure 1. CONSORT diagram for patients from the United States of America.



* 3 patients presented 2 screen failure reasons.

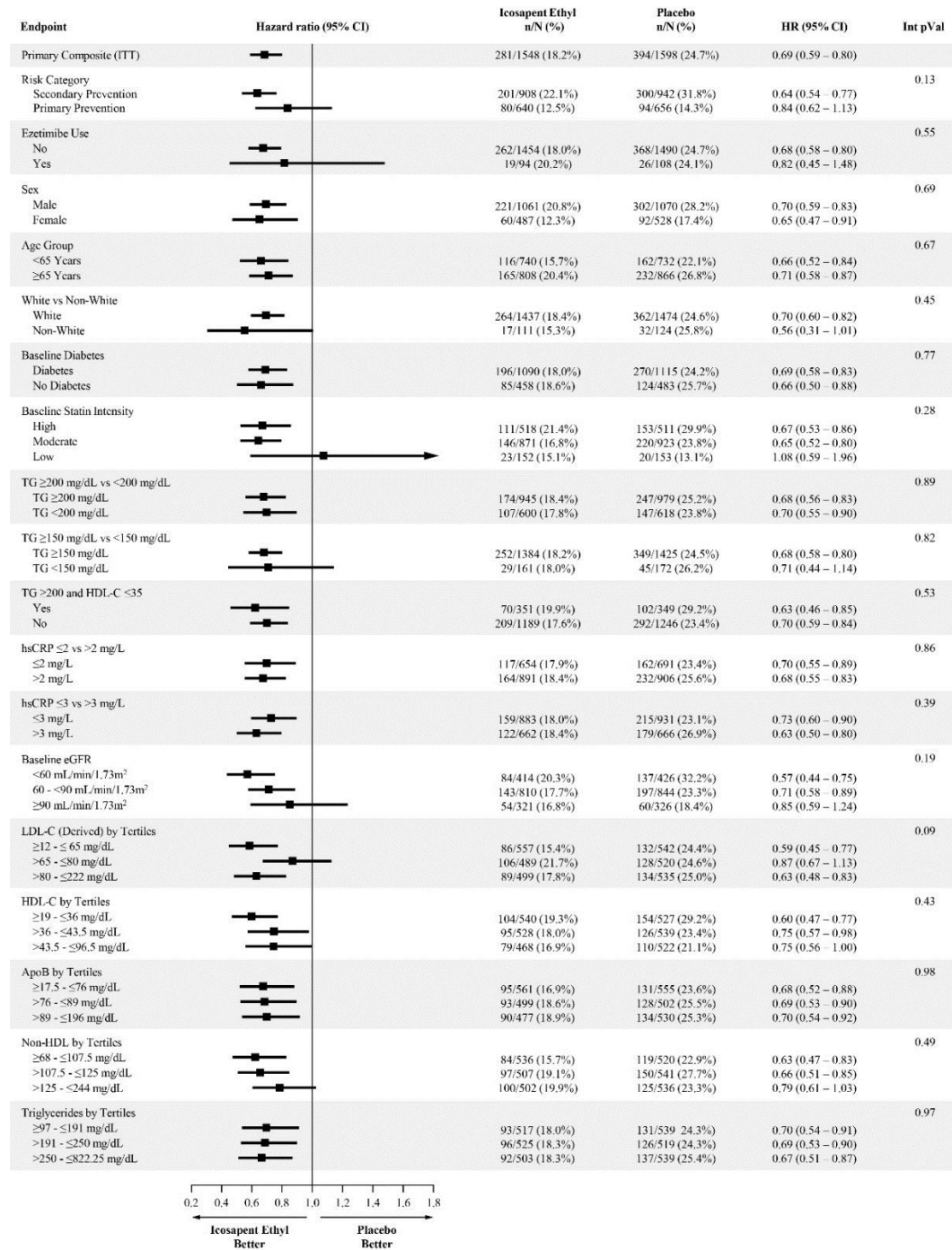
† Early discontinuation from study (17.2% icosapent ethyl; 20.1% placebo) includes patients who discontinued after having a primary event (15 [1.0%] icosapent ethyl; 34 [2.1%] placebo) and prior to having an event (252 [16.3%] icosapent ethyl; 287 [18.0%] placebo).

Supplemental Figure 2. Hazard ratios for efficacy endpoints in hierarchical testing order in the overall study and the USA and non-USA subgroups, ITT population.



Abbreviations: Int p value = interaction p-value, USA = United States of America.

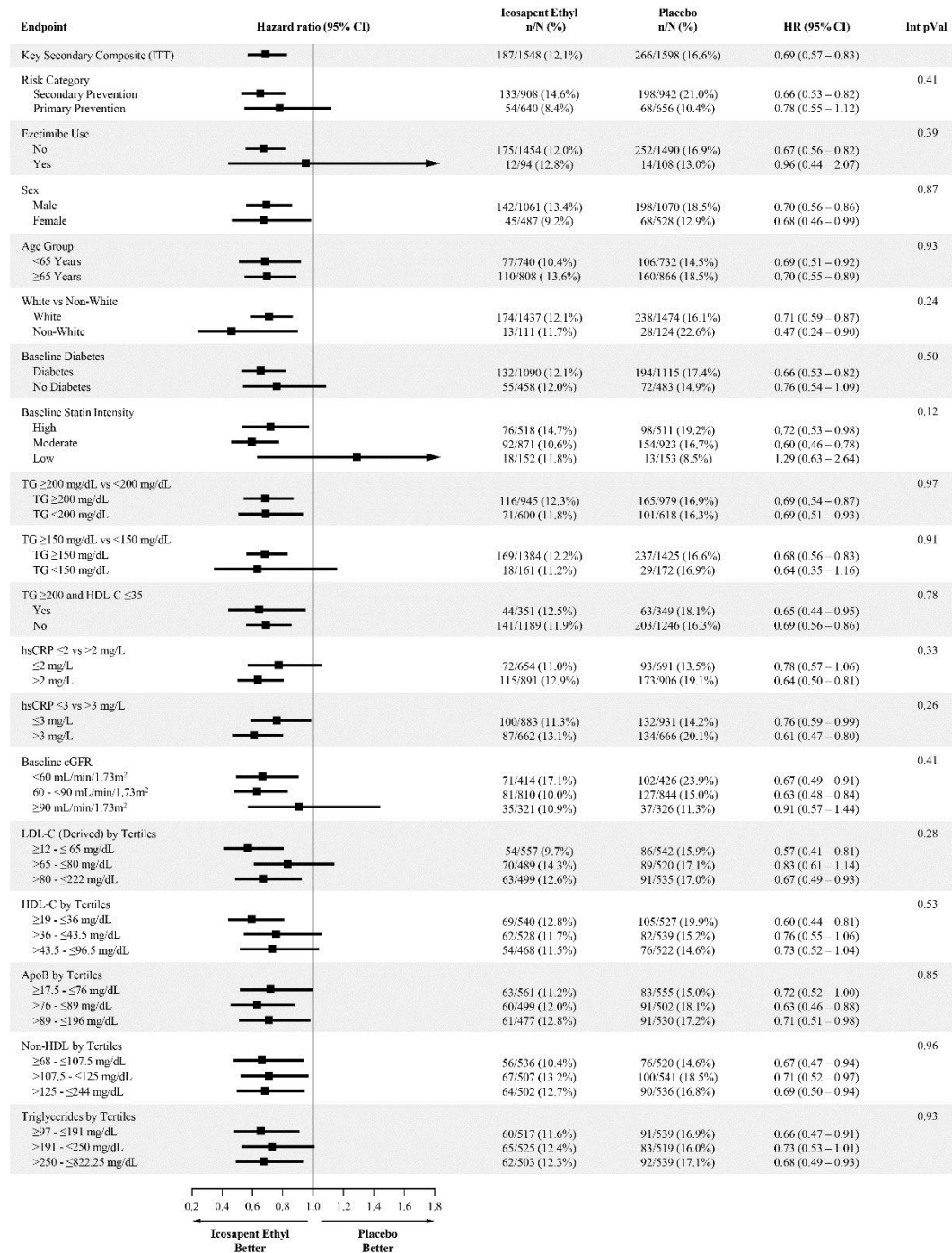
Supplemental Figure 3. Primary efficacy endpoint results for USA subgroup by baseline characteristics.



ApoB = apolipoprotein B, eGFR = estimated glomerular filtration rate, HDL-C = high-density lipoprotein cholesterol; hsCRP = high-sensitivity C-reaction protein, LDL-C = low-density lipoprotein cholesterol, TG = triglyceride.

Primary composite endpoint events: cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, and hospitalization for unstable angina.

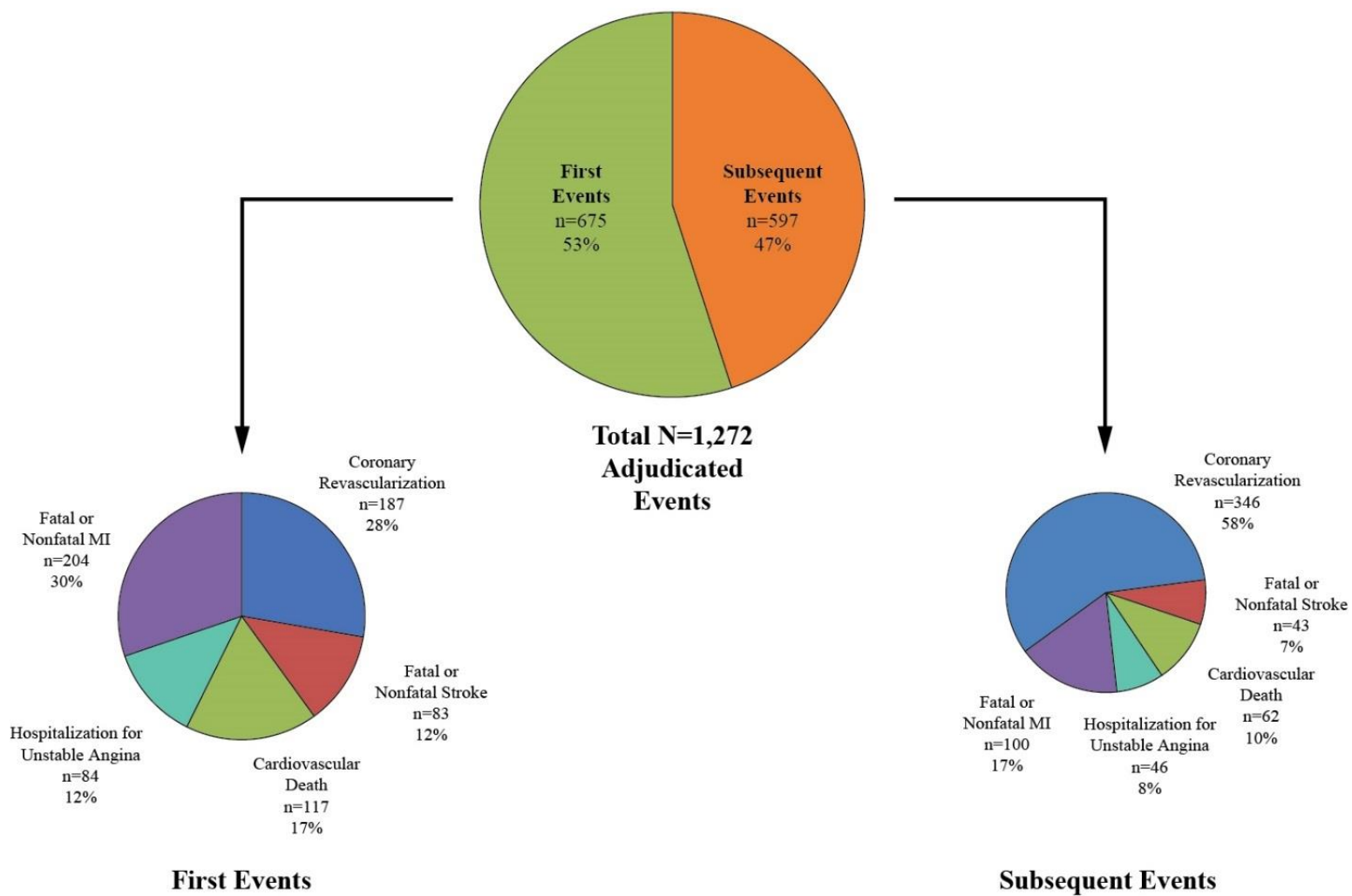
Supplemental Figure 4. Key secondary efficacy endpoint results for the USA subgroup by baseline characteristics.



ApoB = apolipoprotein B, eGFR = estimated glomerular filtration rate, HDL-C = high-density lipoprotein cholesterol; hsCRP = high-sensitivity C-reaction protein, LDL-C = low-density lipoprotein cholesterol, TG = triglyceride.

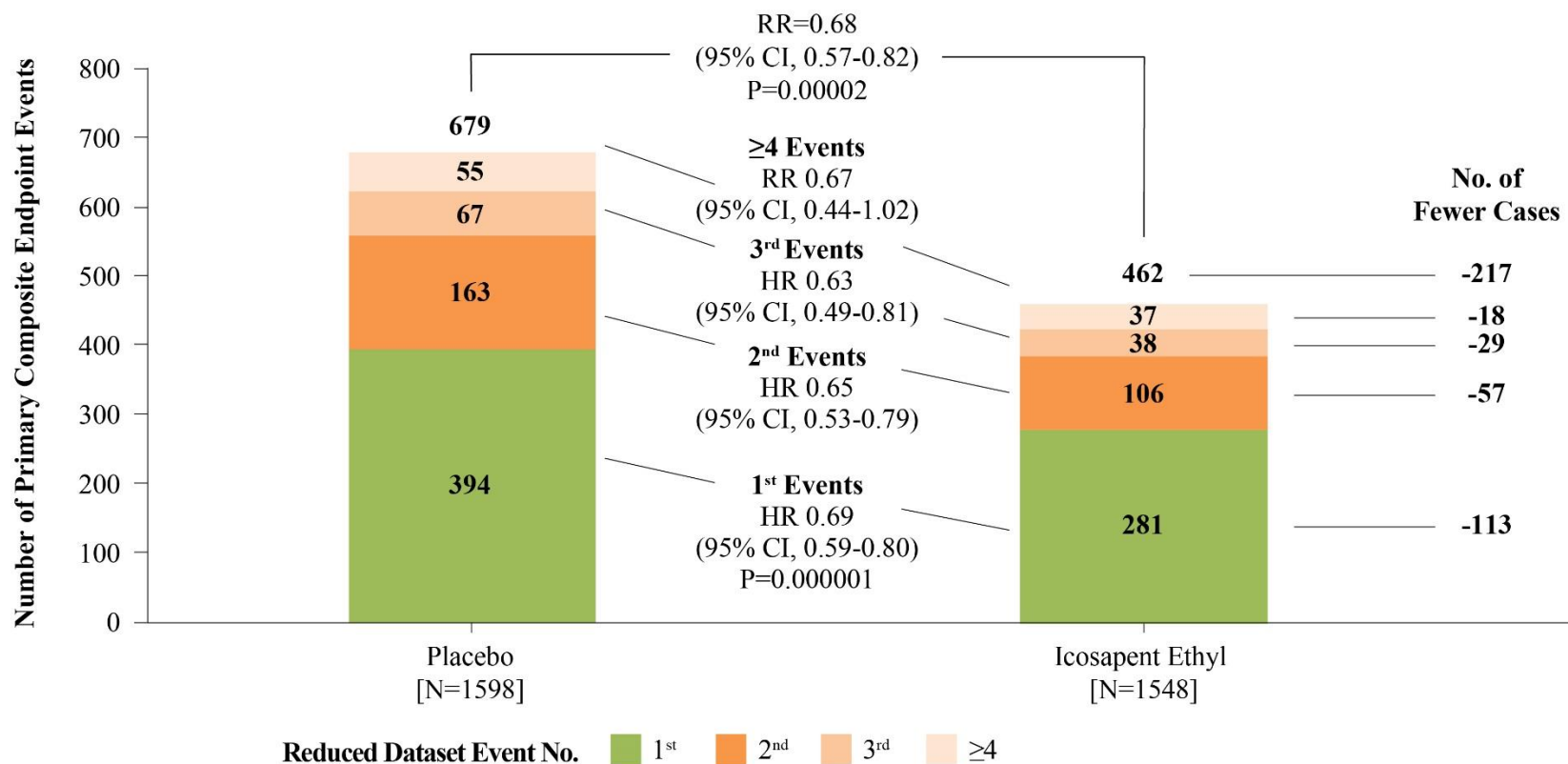
Key secondary composite endpoint events: cardiovascular death, nonfatal myocardial infarction, nonfatal stroke.

Supplemental Figure 5. Proportion of first and recurrent ischemic events in the USA subgroup.



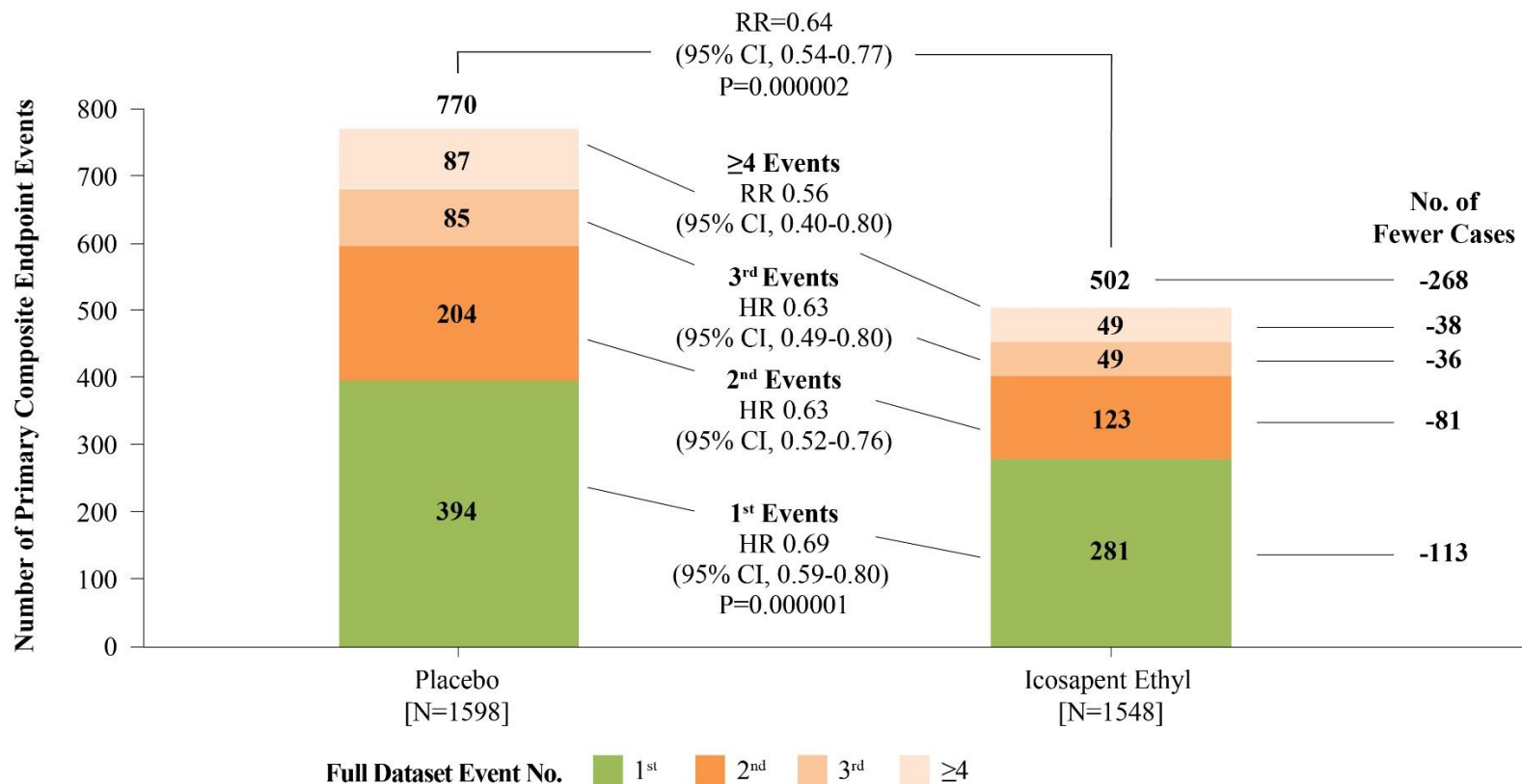
Analyses are based on total adjudicated event dataset without accounting for multiple endpoints occurring in a single calendar day by counting as a single event.

Supplemental Figure 6. Distribution of first and subsequent primary endpoint events in the reduced dataset for the USA subgroup.



Abbreviations: CI = confidence interval; HR = hazard ratio; RR = rate ratio. Hazard ratios (HR) and 95% confidence intervals (CI) for between treatment group comparisons were generated using Li-Lagakos-modified Wei-Lin-Weissfeld (WLW) method for the 1st event, 2nd event, and 3rd event categories. Rate ratio (RR) and 95% CI for between group comparisons used a negative binomial model for additional events beyond 1st, 2nd, 3rd occurrences, i.e., 4th event or more and overall treatment comparison. Analyses are based on reduced dataset accounting for statistical handling of multiple endpoints occurring in a single calendar day by counting as a single event.

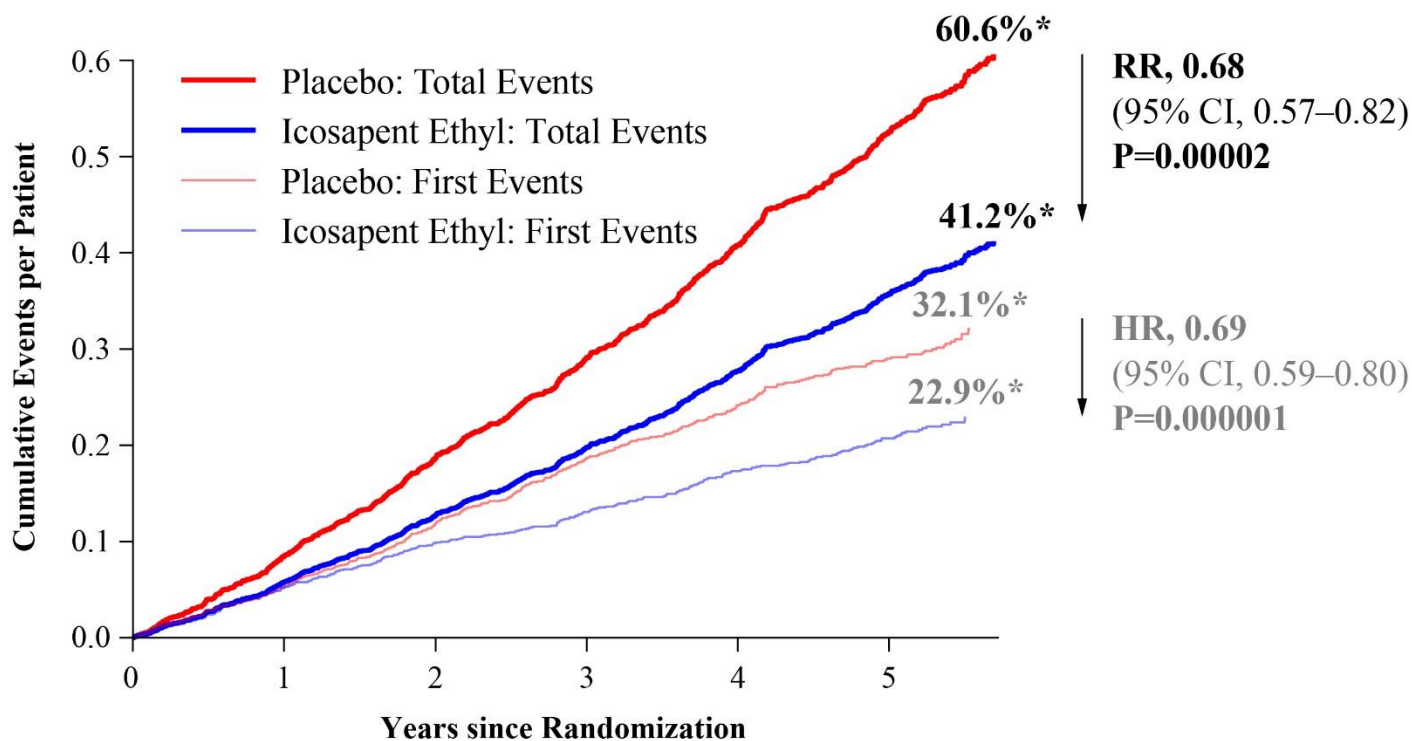
Supplemental Figure 7. Distribution of first and subsequent primary composite endpoint events in the full dataset for the USA subgroup.



Abbreviations: CI = confidence interval; HR = hazard ratio; RR = rate ratio. Hazard ratios (HR) and 95% confidence intervals (CI) for between treatment group comparisons were generated using Li-Lagakos-modified Wei-Lin-Weissfeld (WLW) method for the 1st event, 2nd event, and 3rd event categories. Rate ratio (RR) and 95% CI for between group comparisons used a negative binomial model for additional events beyond 1st, 2nd, 3rd occurrences, i.e., 4th event or more and overall treatment comparison. Analyses are based on full dataset accounting for statistical handling of multiple endpoints occurring in a single calendar day by counting as a single event.

Supplemental Figure 8. Total (First and Subsequent) and Time to the First Primary Composite Endpoint Events for the USA subgroup.

Primary Composite Endpoint



No. at Risk

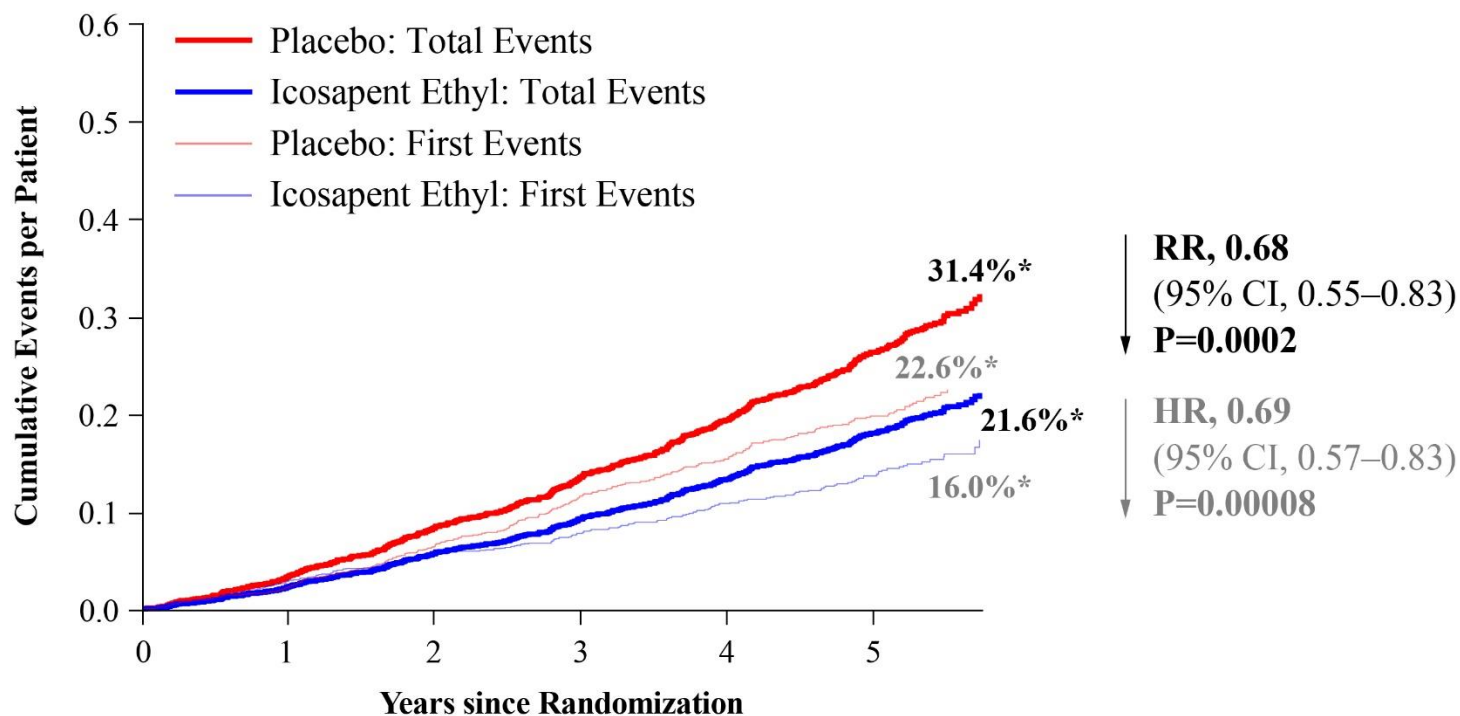
Placebo	1598	1474	1365	1179	1019	668
Icosapent Ethyl	1548	1446	1347	1196	1043	693

Abbreviations: CI = confidence interval; HR = hazard ratio; RR = rate ratio. No. at Risk = Number of patients at risk for recurrent events.

*Cumulative event rate for total events analysis; estimated Kaplan-Meier event rate at approximately 5.7 years for time to first event analysis. The number of patients at risk for the first occurrence of an endpoint event are presented in Figure 1. Primary composite endpoint events: cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, and hospitalization for unstable angina. Analyses are based on reduced dataset accounting for statistical handling of multiple endpoints occurring in a single calendar day by counting as a single event.

Supplemental Figure 9. Total (First and Subsequent) and Time to the Key Secondary Composite Endpoint Events for the USA subgroup.

Key Secondary Composite Endpoint

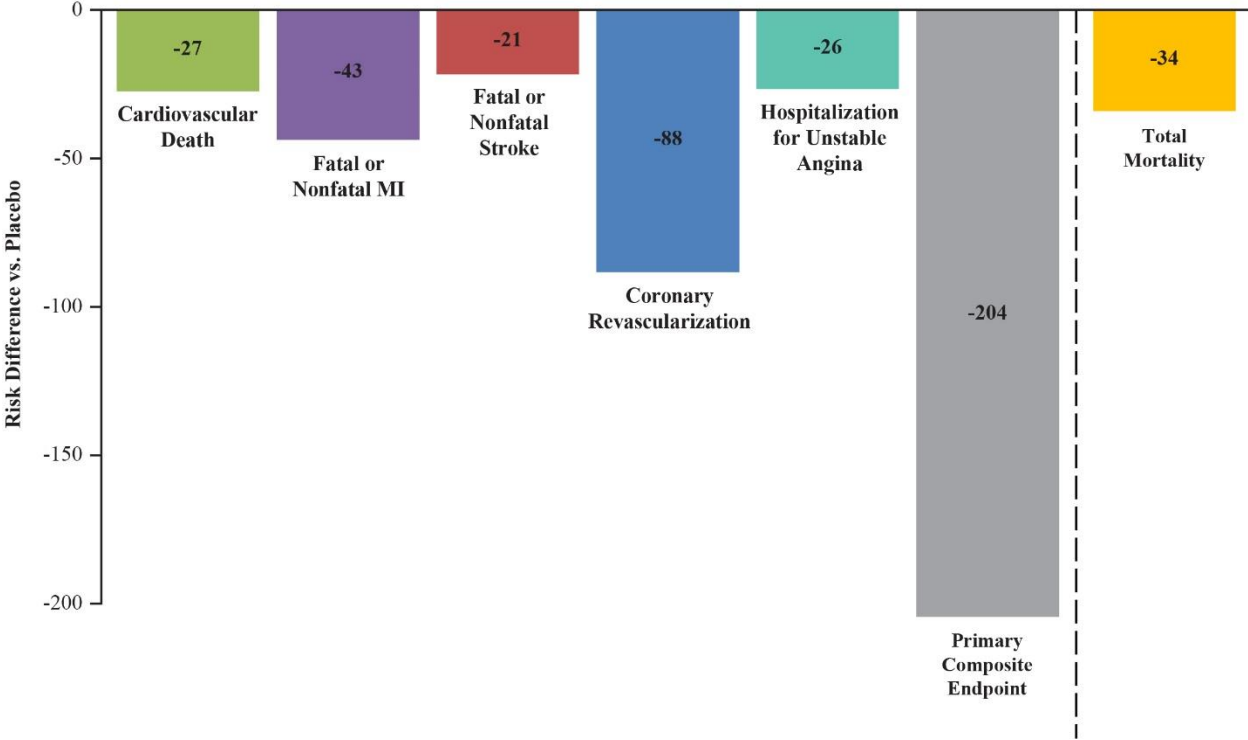


No. at Risk

Placebo	1598	1474	1365	1179	1019	668
Icosapent Ethyl	1548	1446	1347	1196	1043	693

Abbreviations: CI = confidence interval; HR = hazard ratio; RR = rate ratio. No. at Risk = Number of patients at risk for recurrent events. * Cumulative event rate for total events analysis; estimated Kaplan-Meier event rate at approximately 5.7 years for time to first event analysis. The number of patients at risk for the first occurrence of an endpoint event are presented in Figure 2. Key secondary composite endpoint events: cardiovascular death, nonfatal myocardial infarction, nonfatal stroke. Analyses are based on reduced dataset accounting for statistical handling of multiple endpoints occurring in a single calendar day by counting as a single event.

Supplemental Figure 10. Risk differences for 1000 patients from the USA treated for 5 years with icosapent ethyl versus placebo for the primary endpoint and individual components, and for total mortality.



Analyses are based on total adjudicated event dataset without accounting for multiple endpoints occurring in a single calendar day by counting as a single event.

Supplemental References

1. Martin SS, Blaha MJ, Elshazly MB, et al. Comparison of a novel method vs the Friedewald equation for estimating low density lipoprotein cholesterol levels from the standard lipid profile. JAMA 2013;310: 2061-8.

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N=number of participants; (site number)

N=3146 (100) / Joanne Ladner, (101) / Lily Kakish, Ashley Kakish, (102) / Amy L. Little, (103) Jaime Gerber / Nancy J. Hinchion, Janet Guarino, (104) Denise Raychok / Susan Budzinski, (105) Kathleen Kelley-Garvin / April Beckord, Jessica Schlinder, (107) Arthur Schwartzbard / Stanley Cobos, (108) Deborah Freeman, David Abisalih, Dervilla McCann / Kylie Guy, Jennifer Chase, Stacey Samuelson, Madeline Cassidy, Marissa Tardif, Jaime Smith, (110) / Brenna Sprout, (111) Nanette Riedeman / Julie Goza, Lori Johnson, (114) Chad Kraske, Sheila Hastings / Chris Dutka, Stephanie Smith, Toni McCabe, (115) / Kathleen Maloney, (116) Paul Alfieri, Vinay Hosemane, Chanhsamone Syrvanh, / (117) Cindy Pau, April Limcoiloc, Tabitha Carreira, Taryn S. Kurosawa / Taryn S. Kurosawa, (118) Razmig Krumian, Krista Preston, Ashraf Nashed, Daria Schneidman-Fernandez, Jack Patterson, John Tsakonas / Jennifer Esaki, Lynn Sprafka, Porous Patel, (119) / Brian Mitchell, Erin M. Ross, (120) / Donna Miller, Akash Prashad, (121) / Kristina M. Feyler, Natasha Juarbe, Sandra Herrera, (122) / Sarah M. Keiran, Becky Whitehead, Whitney Asher, Coury Hobbs, (124) / Abbey Elie, Jean Brooks, (125) / Amanda L. Zaleski, Brenda Foxen, (129) / Barb Lapke, (130) / Philippa Wright, (131) Bristol Pavol / Gwen Carangi, (132) / Marla Turner, (135) Howard S. Ellison, Katharine W. Sanders / Rikita S. Delamar, Virginia L. Wilson, Sarah M. Harvel, Alison M. Cartledge, Kaitlyn R. Bailey, (136) Kathleen Mahon, Timothy Schuchard / Jen Humbert, (137) Mark C. Hanson, Michael P. Cecil, James S. Abraham / Lorie Benedict, Claudia Slayton, (138) Curtis S. Burnett / Rachel W. Ono-Lim, (139) / Sharon Budzinski, (140) / Shubi A. Khan, (141) / Sharon Goss, Terry

Techmanski, (142) Farida Valliani / Rimla Joseph, (143) / Edith Flores, Laurn Contreras, Ana Aguillon, (144) / Carrie-Ann Silvia, Maria Martin, (146) Edmund K. Kerut, Leslie W. Levenson, Louis B. Glade, Brian J. Cospolich, Maureen W. Stein, Stephen P. LaGuardia, Thelma L. Sonza, Tracy M. Fife / Melissa Forschler, Jasmyne Watts, (147) / Judy Fritsch, (149) / Emese Futchko, (151) / Sarah Utech, (152) Scott B. Baker, Miguel F. Roura, David R. Sutton, Scott A. Segel, James S. Magee / Cathy Jackson, Rebecca F. Goldfaden, (154) / Liudmila Quas, (155) / Elizabeth C. Ortiz, (156) Michael Simpson, Robert Foster, C. Brian, James Trimm, Michael Bailey, Brian Snoddy, Van Reeder, Rachel Wilkinson, Harold Settle, Cynthia Massey, Angela Maiola, Michele Hall / Shelly Hall, Wanda Hall, (158) Mark Xenakis / Janet Barrett, (161) Giovanni Campanile, David Anthou / Susan F. Neill, (162) Steven Karas, Enrique Polanco, Norberto Schechtman / Grace Tischner, Kay Warren, Cynthia St Cyr, Menna Kuczinski, Latrina Alexander, (164) / Maricruz Ibarra, (165) Barry S. Horowitz, Jaime Steinsapir / Jeanette Mangual-Coughlin, Brittany Mooney, (166) / Precilia Vasquez, Kathleen Rodkey, Alexandria Biberstein, Christine Ignacio, (167) Irina Robinson / Marcia Hibberd, (169) Lisa B. Hoffman, Daniel J. Murak, Raghupathy Varavenkataraman / Theresa M. Ohlson Elliott, Linda A. Cunningham, Heather L. Palmerton, Sheri Poole, (171) / Jeannine Moore, Helene Wallace, (185) Ted Chandler, Robert Riley, Farah Dawood, Amir Azeem, Michael Cammarata, Ashleigh Owen, Shivani Aggarwal, Waqas Qureshi, Mohamed Almahmoud, Abdullahi Oseni, Adam Leigh, Erin Barnes, Adam Pflum, Amer Aladin / Karen Blinson, Vickie Wayne, Lynda Doomy, Michele Wall, Valerie Bitterman, (186) /Cindi Young, Rachel Grice, Liubov Poliakova, (189) Jorge Davalos, David Rosenbaum, Mark Boulware, Heather Mazzola, J. Russell Strader, Russell Linsky, David Schwartz / Elizabeth Graf, Alicia Gneiting, Melissa Palmblad, Ashley Donlin, Emily Ensminger, Hillary Garcia, (190) Dawn Robinson, Carolyn Tran, Jeffrey Jacqmein, Darlene Bartilucci, Michael Koren / Barbara Maluchnik, Melissa Parks, Jennifer Miller, (191) / Cynthia DeFosse, (192) Albert B. Knouse, Jr / Amy Delancey, (193) Stephanie Chin, Thomas Stephens / Mag Sohal, Juana Ingram, (194) Swarooparani Kumar / Heather Foley, Nina Smith, (196) / Vera McKinney, Linda Schwarz, Judith Moore, (197) H.V. Anderson, Stefano Sdringola-Maranga, Ali Denktas / Elizabeth Turrentine, Rhonda Patterson, (199) John Marshall / Terri Tolar, Donna Patrick, (203) / Pamela Schwartzkopf, (204) Anthony M. Fletcher, Frances R. Harris / Sherry Clements, Tiffany Brown, (205) William Smith / Stacey J. Baehl, Robin Fluty, (206) Daniel VanHamersveld, Dennis Breen, Nancy Bender / Beverly Stafford, Tamika Washington, (207) / Margaret N. Pike, (208) Mark A. Stich, / (209) Evyan Jawad, Amin Nadeem / Jill Nyland, (211) / Rhonda Hamer, Kendra Calhoun, Charlotte Mall, Samuel Cadogan, Kati Raynes, (212) Richard Katz / Lorraine Marshall, (213) Rashida Abbas, Jay L. Dinerman, John T. Hartley, III / Beth Lamb, Lisa Eskridge, Donna Raymond, (214) / Kristy Clemmer, (215) / Denise M. Fine, Paula Beardsley, (216) / Janet Werner, Bette Mahan, Courtney VanTol, (217) Robert Herman / Christine Raiser-Vignola, Felicia McShan, (220) Stefanie A. Neill, David R. Blick, Michael J. Liston / Denetta K. Nelson, Sandra K. Dorrell, Patricia Wyman, (221) Ambereen Quraishi, Fernando Ferro, Frank Morris / Vicki J. Coombs, Autumn M. Mains, Austin A. Campbell, Jeanne Phelps, Cheryl A. Geary, Ellen G. Sheridan, Jean M. Downing, (222) Arie Swatkowski, Tish Redden / Brian Dragutsky, Susan Thomas, Candace Mitchell, Diana Barker, Elanie Turcotte, Deborah Segerson, Jill Guy, (223) / Karena De La Mora, Jennifer Hong, Dennis Do, Rose Norris, (224) Faisal Khan / Hector Montero, (225) Stacy Kelly-White, Alan Cleland,

Rosalyn Alcalde-Crawford, Melissa Morgan, Brijmohan Sarabu, Megan Minor / Shweta Kamat, Stephanie M. Estes, Nancee Harless, Alicia Disney, (226) / Jodi L. Pagano, (227) Chad M. Alford, Noel W. Bedwell, Warren D. Hardy, Kevin DeAndrade / Jessica G. Elmore, (228) Eric G. Auerbach, Anthony W. Haney / Miriam H. Brooks, (229) Jose Torres, Lois Roper, Terry Backer, Katie Backer / Lois Roper, (230) John G. Evans, James S. Magee, Ricardo A. Silva, Lorraine H. Dajani, Scott A. Segel / Veronica Yousif, Tammy Ross, Rebecca F. Goldfaden, (231) Sion K. Roy, Ronald Oudiz / Sajad Hamal, Ferdinand Flores, (233) / Amor Leahy, Debra Ayer, (234) Swapna George / Chrisi Carine Stewart, Elvira Orellana, (235) Cristina Boccalandro / Mary Rangel, (237) Suzanne Hennings, Carl Vanselow, Teri Victor, Darlene Birdwell, Paul Haas, Anthony Sandoval / Gina Ciavarella, Caroline Saglam, (239) / Amy Bird, (240) Keith Beck, Brian Poliquin, David Dominguez, Brittany Tenorio / Harvonya Perkins, Esther San Roman, (241) Paris Bransford, Christy Lowrance, Marcy Broussard / Mary Ellis, Bobbi Skiles, Jessica Hamilton, Kathryn Hall, Diego Olvera, (243) / Kathleen Maloney, (244) / Julee A. Hartwell, (246) / Nevien Sorial, (248) Kishlay Anand, Mary Rickman, Kevin Berman, Nirav Mehta / Annie Laborin, Caroline Saglam, (249) Rodger Rothenberger / Sarah Beauvilliers, (250) / Kathy Morrell, (251) Michael P. Schachter, Cindy L. Perkins, Elizabeth A. Gordon / Jennifer Lauer, Kim Bichsel, Kelly Oliver, (252) / Leslie J. Mellor, (253) Candice Demattia / Jennifer Schomburg, Yennifer Moreno, Eduardo Mansur-Garza, (255) Lena Rippstein / Lorie Chacon, Andrea Pena, (256) Michelle King / Susan Richardson, Annette Jessop, Nicole Tucker, Whitney Royer, (257) Gilbert Templeton, Ann Moell, Christine Weller / Melissa J. Botts, Gretel Hollon, (258) / Elsa Homberg-Pinassi, (259) Paula Forest, Aref Bin Abhulhak / Devona Chun-Furlong, Deborah Harrington, Emily Harlynn, Marjorie Schmitt, Constance Shelsky, Patricia Feldick, Mary Cherrico, (260) Courtney Jagle, Nicholas Warnecke, Debra Myer / Deanna J. Ruder, Albina Underwood, (261) Alan Rauba, George Carr / Barbara Oberhaus, Jessica Vanderfeltz, (263) Mary Jo Stucky-Heil, Dale R. Gibson / Vonnie Fuentes, (264) Kimberly L. Talbot, William C. Simon / Katlyn J. Grimes, Christina R. Wheeler, Cassaundra Shultz, Rhonda A. Metcalf, Jennifer L. Hill, Michelle R. Oliver, (265) / Basharat Ahmad, Fouzal Azeem, Abdul Rahim, (267) George H. Freeman, Dawn Bloch / Heather Freeman, (268) Jamie Brown / Sarah Rosbach, Pamela Melander, Nick Taralson, Alex Liu, Katlyn Harms, (269) Mahfouz Michale / Jose Lopez, (270) Maria Revoredo, / (272) / Shari Edevane, Sarah Shawley, (273) Timothy L. Jackson, Michael J. Oliver / Dina DeSalle, (274) Patricia J. Matlock, Ionna M. Beraun / Heather Hendrix, Garrett Bromley, Ashley Niemerski, Gabby Teran, Sonia Guerrero, Murtaza Marvi, Zehra Palanpurwala, Andrea Torres, Patty Gloyd, Michelle Conger, Andrea Pena, (275) Aziz Laurent / Olia Naylor, (277) Catalina S. Villanueva, (278) Munira Khambati / Tabetha J. Mumford, Melanie J. Castillo, (279) Taddese Desta, Jerome Robinson / La Shawn Woods, Anita H. Bahri, Nancy Herrera, (280) Cecilia Casaclang, Jeffrey R. Unger, Geraldine Martinez, Mia K. Moon, Stephen M. Mohaupt / Larry Sandoval, Louisito Valenzuela, Victora Ramirez, Nelly Mata, Veronica Avila, Marisol Patino, Cynthia Montano-Pereira, Omar Barnett, (281) William M. Webster / Lorraine M. Christensen, Leighna Bofman, Melanie Livingston, Stacey Adams, (283) Joseph Hobbs / Stacey Adams, Leesa Koskela, Mia Katz, (284) Samuel Mujica-Trenche / Franklin Cala, Noreen T. Rana, Jennifer Scarlett, Milagros Cala Anaya, (285) / Marsha R. Jones, Kelly D. Hollis, Debbie Roth, Kristin Eads, Tina Watts, (287) / Judy Perkins, (289) / Alice Arnold, (290) Daniel C. Ginsberg / Denise Quinn, (291) / Nicole Cureton, (292) David B.

Fittingoff, Mohammed I. Iqbal, Stephen R. White / Edith Sisneros, Michelle Ducca, David Streja, Danny Campos, (293) / Jennifer L. Boak, (295) / Farzeen Amir, (296) / Felice Anderson, (297) James J. Kmetzo / Mary O. Bongarzone, Dawn Scott, (298) / Mary Grace De Leon, (299) / Cynthia Buda, (350) William Graettinger, Michelle Alex, William Graettinger, / (353) Erika Hess, James Govoni / Melissa Bartel, (356) Travis L. Monchamp / Julie S. Roach, Sara Gibson, (357) / Amy M. Allfrey, Kristen Timpy, Kathy Bott, Karin A. Soucy, (358) / Jean Willis, (359) / Cecilia A. Valerio, Anusha Chunduri, (360) / Rebecca Coker, Nicole Vidrine, (362) Ellen A. Thompson, Mark A. Studeny / Melissa K. Marcum, Tammy S. Monway, (363) Douglas L. Kosmicki / Melissa J. Kelley, Corey M. Godfrey, Susan L. Krenk, Randy R. Holcomb, Deb K. Baehr, Mary K. Trauernicht, (364) David Rowland Lowry, Betty Bondy Herts, Jeanne E Phelps, Jean-Marie Downing, Carol Gamer Dignon, (365) / Elisabeth S. Cockrill, (367) Pravinchandra G. Chapla / Diane Fera, (368) Margaret Chang, Patricia Fredette / Tamie Ashby, Renee Bergin, (370) Zebediah A. Stearns, David B. Ware / Rachael M. Boudreaux, (371) Francisco G. Miranda / Joanna Rodriguez, (373) Robert McKenzie, Amanda Huber, Rebecca Sommers, Heather Rowe, Stacy McLallen, Michale Haynes / Ashley Adamson, Janice Henderson, Lori McClure, (374) / Beverly A. Harris, (375) / Laura Ference, Sue Meissner-Dengler, (376) / Lisa Treasure, Doreen Nicely, (377) Timothy L. Light / Tracey A. Osborn, Kimberly J. Mai, (379) Pablo Vivas, Jose Rios / Dunia Rodriguez, (380) Roger DeRaad, James Walder, Oscar Bailon / Denice Hockett, Debbie Anderson, Kelli McIntosh, Amber Odegard, Andrew Shepherd, Mary Seifert, (381) Laurence Kelley, Rajendra Shetty, Michael Castine, David Brill, Gregory Fisher / Nicole Richmond, Kathleen Gray, Patricia Miller, (383) / Charlene Coneys, (384) / Yarixa Chanza, Monica Sumoza, (386) Victoria M. Caudill, Kelly D. Harris, Courtney A. Manion / Melody J. Lineberger-Moore, Julie J. Wolfe, Barbara J. Rosen, (387) / Patricia DiVito, (388) / Janet L. Moffat, (389) Christina Michaelis, Prashant Koshy / Diana Perea, Ghaith Al Yacoub, Stephanie Sadeghi, (393) Thomas D. LeGalley, Rudolph F. Evonich, William J. Jean, Gary M. Friesen, John M. Pap, David A. Pesola, Mark D. Cowan, Kristofer M. Dosh / Dianna Larson, Adele M. Price, Jodi A. Nease, Jane E. Anderson, Lori A. Piggott, (394) Robert Iwaoka, Kevin Sharkey, Edward McMillan / Laurie Lowder, Latisha Morgan, Kyle Davis, Tara Caldwell, Erica Breglio, Jasmine Summers, Rachel Poulimas, (396) / Muhammad Zahid, Hamid Syed, Maria Escobar, Jacob Levy, Rahma Warsi, (398) Carol Ma, Puxiao Cen / Kimberly A. Cawthon, Delores B. Barnes, Deanna G. Allen, Margaret L. Warrington, Carol R. Stastny, Robin J. Michaels, (399) / Mohamad Saleh, (653) John Sorin / Sunny Rathod, Urakay Juett, (654) Steven Spencer, Aziza Keval, Jill McBride, Shane Young, Catherine Baxter, Carol Rasmussen, Shari L. Coxe / (655) Luis Campos, Shahin Tavackoli / Diana Beckham, Darlynee Sanchez, (656) Karanjit Basrai / Dorian Helms, Erica Clinton, Kasie Smith, (657) Arnold Ghitis, Henry Cusnir / Mary Klaus Clark, (661) Madhavagopal V. Cherukuri / Ameta Scarfaru, (662) Stephen D. Nash / Jeannine Moore, Helene Wallace, (663) Loretta C. Grimm, / (664) / Anna Grace, Kylie McElheran, (665) / Dino Subasic, (668) / Zedrick Buhay, (669) / Janet Litvinoff, Tamika Washington, (670) Deepak Shah / Shannon Cervantes, Freda Usher, (671) Farra Yasser, Theodore Trusevich, Ronnie L. Garcia, Jamison Wyatt, Rahul Bose / Hollililyn Miska, Traci Spivey, (672) Amy B. Wren, Katie E. Vance / Lani L. Holman, Pam Gibbons, (678) / Elaine Eby, Sandra Shepard, (679) Soratree Charoenthongtrakul, (680) / Brett Snodgrass, Mohammed Nazem, Shelly Keteenburg, Prathima Murthy, (681) Frederic Prater / Ashley Rumfelt, (683) / Christina

Eizensmits, (685) / Lisa Iannuzzi, (686) / Pourus R. Patel, (687) / Clellia Bergamino, Elizabeth McFeaters, (688) Botros Rizk, Emiljia Pflaum / Danny Kalish, (690) / Rex Ambatali, Mona Ameli, Delaina Sanguinetti / Mona Ameli, (691) Rakesh Vaidya / Karen Blinson, Lynda Doomy, Vickie Wayne

United States Institutions

N=number of participants randomized; (site number)

N=3146 (100) The Center for Clinical Trials, Inc., Biloxi, MS, (101) The Center for Clinical Trials, Mobile, AL, (102) Velella Research, Sarasota, FL, (103) Yale New Haven Health, North Haven, CT, (104) Nature Coast Clinical Research, Inverness, FL, (105) Biofortis, Inc, Addison, IL, (106) North Ohio Heart Center, Sandusky, OH, (107) New York University School of Medicine, New York, NY, (108) Maine Research Associates, Lewiston, ME, (110) Heartland Research Associates, LLC, Wichita, KS, (111) Merced Heart Associates, Merced, CA, (114) Aurora Denver Cardiology, Aurora, CO, (115) Clearwater Cardiovascular Consultants, Clearwater, FL, (116) Alfieri Cardiology, Wilmington, DE, (117) East-West Medical Research Institute, Honolulu, HI, (118) Westlake Medical Research, Westlake Village, CA, (119) Ventura Cardiology Consultants Medical Group, Inc., Ventura, CA, (120) Ocala Research Institute, Inc, Ocala, FL, (121) Altus Research, Inc, Lake Worth, FL, (122) L-Marc Research Center, Louisville, KY, (124) Carient Heart & Vascular, Manassas, VA, (125) Hartford Hospital, Hartford, CT, (129) Chi Health Research Center, Omaha, NE, (130) John Muir Physician Network Clinical Research Center, Concord, CA, (131) New West Physicians, Golden, CO, (132) St. Vincent's Research - Southside, Jacksonville, FL, (135) Rockdale Medical Research Associates, Conyers, GA, (136) Centracare Heart & Vascular Center, St. Cloud, MN, (137) Georgia Heart Specialists, LLC, Covington, GA, (138) Daniel W. Gottlieb, M.D., P.S., Buriem, WA, (139) Cardiology Consultants of Philadelphia, Yardley, PA, (140) Duke University Medical Center, Durham, NC, (141) Baylor College of Medicine, Houston, TX, (142) Trinity Clinical Research Associates, Inc., Carrollton, TX, (143) Westside Medical Associates of Los Angeles, Beverly Hills, CA, (144) Jellinger and Lerman, MD PA DBA The Center for Diabetes and Endocrine Care, Fort Lauderdale, FL, (146) West Jefferson Heart Clinic of Louisiana, Marrero, LA, (147) North Ohio Heart Center, Lorain, OH, (149) Penn State Health Medical Group - Berks Cardiology, Wyomissing, PA, (151) PMG Research of Raleigh, Raleigh, NC, (152) East Coast Institute for Research, LLC, Jacksonville, FL, (154) Gables Research, Miami, FL, (155) Steljes Cardiology, Henderson, NV, (156) Birmingham Heart Clinic, Birmingham, AL, (158) Cardiovascular Associates of Virginia, Bon Secours St. Mary's Hospital, Midlothian, VA, (161) Foundation Research, Key West, FL, (162) Melbourne Internal Medicine Associates, Melbourne, FL, (164) Cardiovascular Research Institute of Dallas, Dallas, TX, (165) Metabolic Research Institute, Inc., West Palm Beach, FL, (166) Legacy Heart Center, Plano, TX, (167) Longmont Medical Research Network, Longmont, CO, (169) Southgate Medical Group, LLP, West Seneca, NY, (171) Syracuse Preventive Cardiology, Syracuse, NY, (185) Wake Forest University Health Sciences, Winston-Salem, NC, (186) University of Maryland School of Medicine, Baltimore, MD, (189) Memorial Hospital, University of Colorado Health, Colorado Springs, CO, (190) Jacksonville Center for Clinical Research Ltd, Jacksonville, FL, (191) The Lindner Research

Center, Cincinnati, OH, (192) Capital Area Research, Newport, PA, (193) University Healthcare Alliances/Cardiology Consultants Medical Group, Walnut Creek, CA, (194) Nature Coast Clinical Research, Crystal River, FL, (196) Doylestown Health Cardiology, Doylestown, PA, (197) University of Texas Health Science Center of Houston, Houston, TX, (199) Northeast Georgia Heart Center, Gainesville, GA, (203) Advocate Medical Group Cardiology/Pulmonology, Normal, IL, (204) Cardiology and Medicine Clinic, P.A., Little Rock, AR, (205) Research Institute of Deaconess Clinic, Evansville, IN, (206) Sacramento Heart and Vascular Research, Sacramento, CA, (207) University of Alabama at Birmingham, Birmingham, AL, (208) Westside Center for Clinical Research, Jacksonville, FL, (209) Captain James A. Lovell Federal Health Care Center, North Chicago, IL, (211) Atlanta Heart Specialists, LLC, Cumming, GA, (212) George Washington University School of Medicine and Health Sciences - Medical Faculty Associates, Washington, DC, (213) Heart Center Research, LLC, Huntsville, AL, (214) Baptist Heart Specialists, Jacksonville, FL, (215) Boston Medical Center, Boston, MA, (216) San Diego Cardiac Center, San Diego, CA, (217) Long Island Gastrointestinal Research Group LLP, Great Neck, NY, (220) Kansas City Cardiology, Lee's Summit, MA, (221) Spectrum Clinical Research at Overlea Personal Physicians, Baltimore, MD, (222) Stern Cardiovascular Foundation, Germantown, TN, (223) Orange County Heart Institute & Research Center, Orange, CA, (224) Metabolic Clinic and Research Center, Los Angeles, CA, (225) Baptist Endocrinology, Jacksonville, FL, (226) Washington University School of Medicine, St. Louis, MO, (227) Mobile Heart Specialists, Mobile, AL, (228) Oklahoma Heart Institute, Tulsa, OK, (229) Atlanta Cardiology Consultants, Roswell, GA, (230) East Coast Institute for Research, LLC, Jacksonville, FL, (231) Los Angeles Biomedical Research Institute at Harbor UCLA Medical Center, Torrance, CA, (233) Broward Health, Fort Lauderdale, FL, (234) Seven Corners Medical Research Center, Falls Church, VA, (235) Office of Dr. Alan S. Hoffman, Houston, TX, (237) Clinical Research Advantage Inc., Glendale, AZ, (239) New Mexico Heart Institute, PA, Albuquerque, NM, (240) BFHC Research, San Antonio, TX, (241) Southeast Texas Clinical Research Center, Beaumont, TX, (243) Clearwater Cardiovascular Consultants, Safety Harbor, FL, (244) United Medical Associates, Vestal, NY, (246) N & N Research and Management Corp., Fall River, MA, (248) Clinical Research Advantage, Phoenix, AZ, (249) PMA Medical Specialists, LLC, Phoenixville, PA, (250) PMG Research of Bristol, Bristol, TN, (251) Prime Care Research, LLC, Florissant, MS, (252) Med Center Medical Clinic, Carmichael, CA, (253) DM Clinical Research, Houston, TX, (255) Texas Medical Research Associates, LLC, San Antonio, TX, (256) Advanced Clinical Research, West Jordan, UT, (257) Primed Clinical Research, Dayton, OH, (258) NYU Langone Medical Associates Chelsea, New York, NY, (259) University of Iowa, College of Public Health, Preventive Intervention Center, Iowa City, IA, (260) Methodist Medical Center of Illinois, Peoria, IL, (261) Jefferson City Medical Group, P.C., Jefferson City, MS, (263) Cardiovascular Associates of Mesa, Mesa, AZ, (264) Professional Research Network of Kansas, LLC, Wichita, KS, (265) DiGiovanna Institute for Medical Education & Research, North Massapequa, NY, (267) Health Research of Hamilton Roads, Newport News, VA, (268) Lillestol Research LLC, Fargo, ND, (269) Clinica Medica San Miguel, Los Angeles, CA, (270) Pembroke Clinical Trials, Miami Lakes, FL, (272) Clinical Research Associates of Central PA, LLC, Altoona, PA, (273) Heritage Valley Medical Group, Inc., Beaver, PA, (274) Martin Diagnostic Clinic/DM Clinical Research, Tomball, TX, (275)

Austin Center for Clinical Research, Austin, TX, (277) Center for Clinical Trials, LLC, Paramount, CA, (278) Family Practice Center South, Austin, TX, (279) Precision Research Institute, San Diego, CA, (280) Catalina Research Institute, LLC, Montclair, CA, (281) Sierra Clinical Research, Roseville, CA, (283) Clinical Trials Research, Lincoln, CA, (284) Viable Research Management; Alas Science Clinical Research, Las Vegas, NV, (285) Cardiology Associates Research, LLC, Tupelo, MS, (287) Arcturus Healthcare, Plc, Troy Internal Medicine Research Division, Troy, MI, (289) Terence Hart MD, Tuscumbia, AL, (290) Multicare Research Institute, Tacoma, WA, (291) Quality Clinical Research, Omaha, NE, (292) Infosphere Clinical Research, INC., Omaha, NE, (293) Sparrow Clinical Research Institute, Lansing, MI, (295) Dairy Ashford Family Practice, Houston, TX, (296) Eclipse Clinical Research, Tucson, AZ, (297) Doylestown Health Cardiology, Doylestown, PA, (298) American Clinical Trials, Hawaiian Gardens, CA, (299) Fleming Island Center for Clinical Research, Fleming Island, FL, (350) Reno Clinical Trials, Sparks, NV, (353) Panacea Clinical Research, San Antonio, TX, (356) Endocrinology Services Northwest, Bend, OR, (357) Monmouth Cardiology Associates, Eatontown, NJ, (358) Christiana Care Health System, Newark, DE, (359) Angiocardiac Care of Texas, Houston, TX, (360) Alexandria Cardiology Clinic/Cambridge Medical Trials, Alexandria, LA, (362) Marshall Cardiology, Huntington, WV, (363) Nebraska Heart Institute, Hastings, NE, (364) Lutherville Personal Physicians, Lutherville, MD, (365) Hillcrest Clinical Research, LLC, Simpsonville, SC, (367) Lycoming Internal Medicine, Inc., Jersey Shore, PA, (368) Riverside Clinical Research, Edgewater, FL, (370) Horizon Research Group of Opelousas, LLC, Eunice, LA, (371) New Horizon Research Center, Miami, FL, (373) HCCA Clinical Research Solutions, Smyrna, TN, (374) HCCA Clinical Research Solutions, Columbia, TN, (375) Grandview Lehigh Valley Health Services, Buxmont Cardiology Division, Sellersville, PA, (376) Cardiovascular Research of Knoxville, Knoxville, TN, (377) Innovative Research of West Florida, Clearwater, FL, (379) Research Physicians Network Alliance, Miami Beach, FL, (380) Black Hills Cardiovascular Research, Rapid City, SD, (381) Adventist Health Care Inc., Takoma Park, MD, (383) Joslin Diabetes Center, Boston, MA, (384) Research Physicians Network Alliance, Pembroke, FL, (386) CaroMont Heart & Vascular, Gastonia, NC, (387) Penn Presbyterian Medical Center, Philadelphia, PA, (388) Dupage Medical Group Cardiology, Winfield, IL, (389) Endocrine IPS, PLLC, Houston, TX, (393) UP Health System Marquette, Marquette, MI, (394) Novant Health Clinical Research, Charlotte, NC, (396) VA Medical Center, Philadelphia, Philadelphia, PA, (398) Florida Hospital, Orlando, FL, (399) Beth Israel Deaconess Medical Center, Boston, MA, (653) Diverse Clinical Research Center of Chicago, LLC, Chicago, IL, (654) Exodus Healthcare Network, Magna, UT, (655) Med-Tech LP, Houston, TX, (656) Trinity Medical Research, Inc, Roseville, CA, (657) Heart & Health Institute Westside, Plantation, FL, (661) Biltmore Cardiology, Phoenix, AZ, (662) SJH Cardiology, Liverpool, NY, (663) Albany Medical Center, Division of Community Endocrine, Albany, NY, (664) Oregon Health and Science University, Portland, OR, (665) Triwest Research Associates, El Cajon, CA, (668) Mercury Clinical Research, Inc, Houston, TX, (669) Shahram Jacobs, MD Inc, Sherman Oaks, CA, (670) Carolina Heart Specialists, LLC, Lancaster, SC, (671) Mission Research Institute, New Braunfels, TX, (672) Apex Cardiology, P.C., Jackson, TN, (678) Nova Clinical Research, Bradenton, FL, (679) Professional Health Care of Pinellas, St. Petersburg, FL, (680) Center for Advanced Medicine and Research, St. Peters, MO, (681) Clinical Research Professionals,

Chesterfield, MO, (683) Protenium Clinical Research, Hurst, TX, (685) Endocrine Associates of Long Island, PC, Smithtown, NY, (686) Synergist Research, LLC, Lancaster, CA, (687) Geodysey Research, LLC, Vero Beach, FL, (688) The Center for Clinical Trials, Saraland, AL, (690) Manshadi Heart Institute, Inc, Stockton, CA, (691) W.G. (Bill) Hefner Salisbury VA Medical Center/ Kernersville Health Care Center, Kernersville, NC

Non-United States Investigators and Institutions:

Non-United States Principal Investigators and Previous Principal Investigators

Country listing by enrollment; N=number of participants randomized per country; (site number)

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Gramzyna Latocha Korecka, Ewa Gulaj, (608) / Jolanta Sopa, (609) Bogusław Derlaga, / (610) Marcin Baisiak, / (612) Allicia Kowalisko, Edyta Stainszewska-Marasazlek, Bartosz Szafran / Malgorzata Swiatkiewicz, (613) Artur Racewicz, Sławomir Grycel, Jerzy Supronik / Sylwia Walendziuk, Magdalena Tarantowicz, Agata Stasiak, (614) Anna Sidorowicz-Białynicka, Marek Dwojak, Ewa Jaźwińska-Tarnawska / Katarzyna Kupeczyk, Kamila Martowska, Kamila Kulon, (617) / Katarzyna Gajda

India N=262 (501) Bivin Wilson / Krithika Velusamy, Swaidha S. Sadhiq, (502) / Bhavani Siddeshi, (503) M Bhanukumar / Abhishek Srivatsav, Madhan Ramesh, Sri Harsha Chalasani, Mini Johnson, Prashanth Gopu, Jeesa George, Sowmya Reddy, Swetha Tessy Thara Eleena (504) Damodara Rao Kodem / Haritha N. Nakkella, Padma Kumari Mandula, Anjan Kumar Vuriya, Syamala Rajana, (505) / Aruna Kale, (506) Tiwari Rajeev / Raina Jain, Vipin Jain, (507) Srilakshmi Mandayam Adhyapak / Lumin Sheeba, Uma C R, Ramya R, (509) Aditya V. Kulkarni / M S. Ganachari, Ruma Sambrekar, (510) / Mohammad Bilal, Nungshijungla (511) Kalyan Chakravarthy / Ravi Badhavath, Sravan Kumar, Meenakshi Simhadri, Farooque Salamuddin, Venkat Prasad, (513) Vivek Dwivedi, Sudha Sarna / Tilak Arora, Deepak Chawla, (514) Archana Sathe / Chaware Gayatree, (515) / Ajeet Nanda, Ram Avtar, Jyoti Sharma, (516) Vaibhavi P S Sasirekha D, Deepthi Kobbajji / Ramya Ningappa, Shwetha Shree, Chandrashekar K Nandini M R Sowjanya S Devika I G Yashaswini N Sonika G Rathna L Priyanka R (517) / Rupal J. Shrimanker, (518) Lakshmi Vinutha Reddy, K Sumathi, Babitha Devi / Bina N. Naik, Rohini Manjunath, Rajeshwari Ashok, (524) / Tony V. Kunjumon, Jesline Thomas, (525) / Shaik Samdhani, (526) Kasthuri Selvam / Poongothai Subramani, Nandakumar Parthasarathy, (527) Nirmal K. Bohra / Anvesh K. Gatla

Canada N=250 (172) / Cheryl Horbatuk, (173) / Julie Sills, (175) E B. Davey / Liz Paramonczyk, Olga Racanelli, (176) David Crowley / Sandy Strybosch, (177) Andre Belanger, Jean Palardy, Alicia Schiffrin / Sylvie Gauthier, (178) Norman Kalyniuk, Shawn D. Whatley / Heather Lappala, Grishma Patel, Matthew Reeve, (181) Catherine Moran / Jody Everitt, (182) / Teresa Ferrari, (188) / Christine Bouffard, (200) Jirir Frohlich, Gordon Francis, John Mancini, Gregory Bondy, Debbie DeAngelis, Patricia Fulton / Debbie DeAngelis, Patricia Fulton, (201) David W. Blank / Angela Lombardo, Mylène Roy, (202) / Jackie Chow, (219) Hyman Fox, William J. Grootendorst, Angela Hutchinson, Hyman Fox / Sharon M. Chan, (271) / Christie Fitzgerald, (361) / Teresa Ferrari, (395) / Lynn Wilkins, Rebecca L. Raymond, Arlene Reyes (397) Lavoie Marc André / Denis Fortin, (659) Hélène Ouimet, Thanh-Thao Tô-n-Nu, Martine Dussureault, Marie-Hélène Blain / Madeleine Roy, Nathalie Kopajko, Chantal Fleury, (660) / Karine Maheux

Romania N=202 (801) Gabriela Valentina Ciobotaru, / (803) Maria C. Constantinescu / Carmen-Lucia Gherghinescu, (804) Ana-Maria Avram, / (805) Ioan Manitiu / Radu I. Cojan, (806) Octavian M. Pirvu, (808) Aura Sinpetrean, Lucian Pop, Delia Lupu, / (809) Radu Usvat, Ana Petrisor, / (810) Nicoleta Dumitru, / (811) Camelia Moruju, / (812) / Adelina Gheorghita, (813) Magda V. Mitu, / (814) Cosmin Macarie, / (815) Ana Maria Pop, / (816) Maria-Catalina Diaconu, / (817) Iulia Grancea, / (818) Mihaela Cosma / Mihaela Cosma, (819) Mihaela Crisan /

Australia N=189 (301) / Elizabeth Herron, (302) Anthony M. Dart, Paul Nestel / Sally B. Kay, Kaye S. Carter, (303) Imran Badshah, Ashley Makepeace / Jocelyn Drinkwater, Michelle England, (304) / Azette Rafei, Kylie Patterson, (305) Alicia Jenkins, Sybil McAuley / Sue M. Kent, (306) / Joy E. Vibert, Leonie Perrett, (307) Thomas David / Samantha L. Kaye, Monika O'Connor, (308) Nimalie J. Perera / Nicole T. Lai, Kerry A. Kearins, (309) Christinia Dicamillo, Heather Anderson / Louise Ferguson, (310) / Sharon D. Radtke, (311) Charles T. Thamarappillil / Janice M. Boys, (312) / Anita K. Long, Toni Shanahan, (313) Michael Nyguyen / Nicole Forrest, Gill Tulloch, Della Greenwell, (314) Sarah L. Price, Aye N. Tint, Priya K. Sumithran / Tamara L. Debreceni, Lisa Walker, Mary Caruana, Kira Edwards, Maria Stathopoulos, Cilla Haywood, (316) Dimitar Sajkov / Sharen Pringle, Anne Tabner, Kathrina Bartolay, Chamindi Abeyratne, Kylie Bragg, (317) Patrick Mulhern, Peter Purnell, Randall Hendriks / Gill Tulloch, (319) Lyn Williams, Jane Hamlyn / Aurelia Connelly, Jan Hoffman

New Zealand N=134 (402) Samantha Bailey, Jane Kerr / Zarnia Morrison, Sarah Maeder, Roberta McEwan, Prasanna Kunasekera, Patrice McGregor, Jo Young, Sharon Berry, (405) Rick Cutfield, Michelle Choe, Catherine McNamara / Narrinder K. Shergill, (406) / Petra Crone, (408) Miles G. Williams, Keith Dyson / Diana H. Schmid, Audrey C. Doak, Melissa Spooner, (411) Colin Edwards / Anne Turner, Grainne M. McAnnalley, (414) Raewyn A. Fisher, Fraser B. Hamilton, Denis H. Friedlander / Melissa R. Kirk, Jayne E. Scales, (415) / Marguerite A. McLelland, (442) Neelam A. Dalman / Cathy E. Vickers, Carolyn Jackson, (444) / Wendy Coleman, (445) Phillip I. Garden / Wendy F. Arnold

Non-United States Institutions

Country listing by enrollment; N=number of participants randomized per country; (site number)

The Netherlands N=1678 WCN (701) Bravis Hospital, Roosendaal, (702) Deventer Hospital, Cardiology Department, Deventer, (703) Spaarnegasthuis, Hoofddorp, (704) Gelre Ziekenhuis, Zutphen, (705) Tweesteden Ziekenhuis, Tilburg, (706) Admiraal De Ruyter Ziekenhuis, Goes, (707) Tergooi, Blaricum, (708) Canisius Wilhelmina Ziekenhuis, Nijmegen, (709) Alrijne Hospital, Leiderdorp, (719) HMC Bronovo, Den Haag, (720) Stichting CRE Enschede, Thoraxcentrum Twente, Medisch Spectrum Twente, Enschede, (721) Beatrix Hospital, Gorinchem, (722) Langeland Ziekenhuis, Cardiology Department, Zoetermeer, (723) Medisch Centrum Leeuwarden, Leeuwarden, (724) Spaarne Gasthuis, Haarlem, (725) St Elisabeth Hospital, Tilburg, (726) Bernhoven Hospital, Uden, (727) Franciscus Gasthuis & Vlietland, Schiedam, (728) Noordwest Ziekenhuis, Den Helder, (729) Jeroen Bosch Hospital, Hertogenbosch, (731) Groene Hart Ziekenhuis, Gouda, (732) Meander Medical Center, Amersfoort, (733) Ikazia Hospital Rotterdam, Rotterdam, (734) Máxima Medisch Centrum, Veldhoven, (735) Ziekenhuis Stjansdal, Harderwijk, (736) Tjongerschans Ziekenhuis, Cardiology Department, Heerenveen, (737) Franciscus Gasthuis, Rotterdam, (738) ZGT, Almelo and Hengelo, (739) D & A Research, Sneek, (740) Zuyderland Mc, Heerlen, (741) Martini Ziekenhuis, Groningen, (742) Gelderse Vallei Ziekenhuis, EDE, (743) Ijsselland Ziekenhuis, Capelle aan den IJssel; **non-WCN** (710) Andromed Rotterdam, Rotterdam, (711) Andromed Eindhoven, Eindhoven, (712) Andromed Leiden, Leiderdorp, (713) Andromed Oost BV, Velp,

(714) Andromed Zoetermeer BV, Zoetermeer, (715) Andromed Noord, Groningen, (716) Andromed Breda, Breda, (718) Gemini Ziekenhuis, Den Helder

Ukraine N=836 (885) State Institutio, D.F.Chebotarev Institute of Gerontology of NAMS, Kiev, (886) Department of Internal Diseases-1 of Zaporizhzhya State Medical University, Zaporizhzhya City Clinical Hospital of Emergency Care, Zaporizhzhya, (887) The State Institute of Therapy, L.T. Malaya of Ukrainian National Academy of Medical Science, Kharkov, (888) Polyclinic of Administration of Medical Services and Rehabilitation of Artem State Holding, Kiev, (889) State Institution, Ukrainian State Scientific and Research Institute of Medical and Social Problems of Disability of Ministry of Health of Ukraine, Dnipro, (890) National Scientific Center M.D. Strazhesko Institute of Cardiology, Kiev, (891) Communal Institution, Central Clinical Hospital #4 of Zavodsky District, Zaporizhzhia, (892) Kiev City Clinical Hospital #7, Therapeutic dpt #2, Kiev, (893) Medical Center, Desna, Ltd, Ternopil, (894) LTD Cardiology Clinic, Heart and Vessels, Kiev, (895) Clinic of State Institution, Ukrainian State Institute of Medical and Social Problems of Disability Ministry of Public Health, Dnipro, (897) State Institute, Zaporizhzhia Medical Academy of Postgraduate Education of Ministry of Health of Ukraine, Department of Family Medicine With Course of Dermatovenereology and Psychiatry Based On Municipal Institution: Zaporyzhzhya 9th City Multidisciplinary Clinical Hospital, Cardiology Department, Zaporizhzhia, (898) Volyn Regional Clinical Hospital, Department of Cardiosurgery, Lutsk, (899) Zakarpatskyi Oblasnyi Klinichnyi Kardiologichnyi Dyspanser, m. Uzhhorod, (900) Infarction Dprt of City Clinic Hosp. #6, Simferopol, AR Crimea, (937) Zakarpattyia Regional Clinical Cardiology Dispensary, Dept. of General Cardiology, Uzhhorod National University, Chair of Hospital Therapy, Uzhhorod, (938) City Clinical Hospital #1, Vinnitsa, (939) State Institution, National Scientific Center, NAMS Institute of Cardiology M.D. Strazhesko, Department of Essential Hypertension, Kiev, (940) Kharkiv Medical Academy of Postgraduate Education, City Clinical Hospital #8, Kharkiv, (941) Lutsk City Clinical Hospital, Lutsk, (942) Kharkiv City Clinical Hospital #27, Kharkiv, (943) Kharkiv Medical Academy of Postgraduate Education, Kharkiv, (944) Lugansk Regional Cardiological Dispensary, Luhansk, (945) Dnipropetrovsk Medical Academy, Dnipropetrovsk Joint Emergency Hospital, Dnipro, (946) State Institution, National Scientific Center, The M.D. Strazhesko Institute of Cardiology, National Academy of Medical Sciences of Ukraine, Kiev, (947) City Clinical Hospital №3, Chernivtsi, (948) National Institute of Therapy N.A. L. Malaya NAMS, Kharkiv, (949) National Pirogov Memorial Medical University, Vinnytsya, (951) Clinic of State Institution, Institute of Therapy NAMS Ukraine L.T. Maloy, Kharkiv, (952) HSEE of Ukraine, Ukrainian Medical Stomatological Academy, Poltava, (953) Odessa National Medical University, Center of Reconstructive and Recovery Medicine (University Clinic), Odessa, (954) Institute of Urgent and Recovery Surgery, Donetsk, (955) State Institution National Scientific Centre, Acad. M.D. Strazhesko Institute of Cardiology of Nacional Ams of Ukraine, Kiev, (956) Kiev Municipal Clinical Hospital #12, Department of Cardiology; O. O. Bogomolets National Medical University, Kiev, (957) Saint Catherine Odessa, Treatment and Diagnostic Center LLC, Odesa, (958) Central City Clinical Hospital #1, Donetsk, (959) Communal Institution, Odesa Regional Cardiological Dispensary, Odesa, (960) Zaporizhzhia Regional Clinical Hospital, Zaporizhzhia, (961) National Scientific Center, NAMS Strazhesko Institute of Cardiology, Kiev, (962) Communal City Clinical Hospital #8, Lviv, (963) Ivano-Frankivsk Regional Clinical

Cardiological Center, Ivano-Frankivsk, (964) City Clinical Hospital #9, Department of Cardiology; State Institution, Dnipropetrovsk Medical Academy of Moh, Dnipro, (965) Kyiv City Clinical Hospital #1, Department of Emergency Cardiology, Kiev, (985) Kyiv City Oleksandrivska Clinical Hospital, Kiev, (992) Cherkasy Regional Cardiological Center, Cherkasy, (994) Kyiv Emergency Care Hospital, Infarction Department, Kiev, (996) The Institute of Gerontology NAMS D.F.Chebotarev, Kiev, (997) D.F. Chebotarev Institute of Gerontology, National Academy of Medical Sciences, Kiev, (998) Odesa Regional Clinical Hospital, Department of Cardiosurgery, Odesa, (999) Ivano-Frankivsk National Medical University, Ivano-Frankivsk

Russian Federation N=709 (850) State Budget Healthcare Institution of City Moscow, City Clinical Hospital N.A. M.P. Konchalovskogo of Healthcare Department, Zelenograd, (851) Saint Petersburg State Budget Healthcare Institution, City Consultative and Diagnostic Center #1, Saint Petersburg, (901) State Health Care Institution City Hospital #117, Saint Petersburg, (902) State Budget Healthcare Institution of Moscow, City Clinical Hospital #4 of The Healthcare Department, Moscow, (903) First Saint Petersburg State Medical University N.A.Acad.I.P.Pavlov of The Ministry of Healthcare of Russian Federation, Saint Petersburg, (904) Pirogov Russian National Research Medical University, Moscow, (905) City Clinical Emergency Hospital#2, Novosibirsk, (906) State Inst City Multidiscipline Hospital# 2, Saint Petersburg, (908) Almazov National Medical Research Centre, Saint Petersburg, (909) Autonomous Non-Profit Organization: Medical Center Alliance, Kirovsk, (910) Central Clinical Hospital of The Russian Academy of Sciences, Moscow, (911) Saint Petersburg State Budget Institution of Healthcare, City Hospital #15, Saint Petersburg, (912) City Clinical Hospital #15 O.M.Filatov, Moscow, (913) FSBHI Clinical Hospital #123 of FMBA, Moscow, (914) Kazan State Medical University, Kazan, (915) Scientific Research Medical Complex, State Budget Institution of Healthcare Clinical Hospital #2, LLC, Kazan, (916) Saint Petersburg State Budget Institution of Healthcare, City Hospital #9, Saint Petersburg, (917) State Budget Healthcare Institution of City Moscow, City Clinical Hospital N.A. V.V.Vinogradova of Healthcare Department, Moscow, (918) International Clinic MEDEM, LLC, Saint Petersburg, (919) Almazov National Medical Research Centre, Saint Petersburg, (921) Saint Petersburg State Budget Institution of Healthcare, City Outpatient Clinic #109, Saint Petersburg, (922) Novosibirsk State Medical University, Novosibirsk, (923) Medinet, LLC, Saint Petersburg, (924) Research Institute of Internal and Preventive Medicine, Branch of The Institute of Cytology and Genetics, Siberian Branch of Russian Academy of Sciences, Novosibirsk, (925) Almazov National Medical Research Centre, Saint Petersburg, (926) Saint Petersburg State Budgetary Healthcare Institution, City Pokrovskaya Hospital, Saint Petersburg, (927) Saratov Regional Veterans Hospital, Saratov, (928) State Healthcare Institution of Yaroslavl Region, Clinical Hospital #8, Yaroslavl, (929) Federal State Budget Military Educational Institution of Higher Professional Education, Military Medical Academy, S.M. Kirov of Ministry of Defence of Russian Federation, Saint Petersburg, (930) The Federal State Autonomous Educational Institution of Higher Education I.M. Sechenov First Moscow State Medical University of Ministry of Healthcare of The Russian Federation (Sechenovskiy University), Moscow, (931) Moscow State Medical and Dental University N.A A.I. Evdokimov of The Ministry of Health, Moscow, (932) FGBU, National Medical Research Center of Cardiology, Ministry of Health

Care of Russia, Moscow, (933) State Budget Institution of Healthcare, Republican Hospital V.A. Baranov, of The Ministry of Healthcare of Karelia Republic, Petrozavodsk, (934) State Budget Healthcare Institution of Arkhangelsk Region, Arkhangelsk Regional Clinical Hospital, Arkhangelsk, (935) Leningrad Regional Clinical Hospital, Saint Petersburg, (936) Science and Research Institute of Experimental Medicine, Saint Petersburg, (966) Saint Petersburg State Budget Healthcare Institution, City Hospital #40 of Kurortniy District, Saint Petersburg, (967) Federal State Budget Institution of Healthcare, Clinical Hospital #122 N.A. L.G. Sokolov Under Federal Medical and Biological Agency of Russia, Saint Petersburg, (968) City Hospital # 38 N A Semashko, Saint Petersburg, (969) State Budget Institution of Healthcare of Arkhangelsk Region, The First City Clinical Hospital E.E. Volosevich, Arkhangelsk, (970) Cardio-Centre, Chernaya Rechka, Saint Petersburg, (971) Central Outpatient Department at Federal State Budget Institution of Healthcare, Northern Medical Clinical Center N.A. Semashko of Federal Medical-Biological Agency, Arkhangelsk, (972) Saint Petersburg State Official Institution of Healthcare, Mariinskaya Ambulatory, Saint Petersburg, (973) Sanatorium Chernaya Rechka, Saint Petersburg, (974) State Healthcare Institution, Regional Clinical Cardiology Dispensary, Saratov, (975) Cardiology Research Institute, Tomsk National Research Medical Center of Russian Academy of Sciences, Tomsk, (976) Research Institute of Complex Issues of Cardiovascular Diseases (NII KPSSZ), Kemerovo, (977) Panacea Clinic, LLC, Moscow, (978) Nizhny Novgorod Regional Clinical Hospital N.A.Semashko, Nizhny Novgorod, (979) Moscow Hospital #15 O.M.Filatov, Moscow, (980) Budgetary Healthcare Institution of Voronezh Region, Voronezh City Clinical Hospital of Emergency Medical Care #1, Voronezh, (982) Autonomous Healthcare Institution, Voronezh Regional Clinical Consultative and Diagnostic Center, Voronezh, (983) Yaroslavl Regional Clinical Hospital, Yaroslavl, (987) Medical Union New Hospital, LLC, Ekaterinburg, (988) Hospital of Veterans Wars, Kemerovo, (989) State Budget Healthcare Institution of Sverdlovsk Region, Sverdlovsk Regional Clinical Hospital #1, Ekaterinburg, (990) Siberian State Medical University, Tomsk, (991) State Budget Healthcare Institution, Scientific and Research Institute, Regional Clinical Hospital #1 N.A., Krasnodar, (993) Volgograd State Medical University, Department of Therapy and Endocrinology, Volgograd

South Africa N=414 (416) Paarl Research Centre, Paarl, (417) TREAD Research cc, Cape Town, (418) Durbanville Medi-Clinic, Durbanville, (419) Unitas Hospital, Pretoria, (420) Somerset West Clinical Trial Unit, Somerset West, (421) Tiervlei Trial Centre, Bellville, (422) Langeberg Clinical Trials, Cape Town, (423) Synexus Helderberg, Somerset West, (424) Helderberg Research Institute, Somerset West, (425) Vincent Pallotti Hospital, Cape Town, (426) Wits Clinical Research Bara, Soweto, (427) Cardiology Research, Bloemfontein, (430) Newkwa Medical Centre, Durban, (431) Corbod Research Pty Ltd, Panorma, (432) Worthwhile Clinical Trials, Johannesburg, (433) Dr HFM Nortje Clinical Trials, Cape Town, (435) Drs' Joynt Venter and Associates, Witbank, (437) Dr P J Sebastian, Durban, (439) Boanerges Clinical Research, Bloemenstein, Free State, (440) Clinical Projects Research Centre, Worcester, (441) University of Cape Town, Cape Town

Poland N=359 (602) Synexus Polska Sp. Z O.o., Katowice, (603) Synexus Sp. Z O.o., Warsaw, (604) Centrum Medyczne Ogrodowa, Skierniewice, (605) Centrum Medyczne Nzoz As-Medica

Sp.Z O.o., Zgierz, (606) ZSGL LeK, Mikołów, (607) Podlaski Ośrodek Kardiologiczny, Białystok, (608) Institute of Cardiology, Warsaw, (609) Specjalistyczny Gabinet Lekarski Internistyczno-Kardiologiczny Ewa Laskowska-Derlaga, Tarnów, (610) NZOZ SALVIA, Katowice, (612) Centrum Kardiologiczne Pro Corde Sp. Z O.o., Wrocław, (613) Osteo-Medic Sc, Białystok, (614) Synexus Sp. Z O.o., Wrocław, (616) Przychodnia Specjalistyczna PROSEN; Department of Experimental and Clinical Physiology, Laboratory of Center for Preclinical Research, Medical University of Warsaw, Warsaw, (617) Centrum Nowoczesnych Terapii, Dobry Lekarz, Krakow

India N=262 (501) G.Kuppuswamy Naidu Memorial Hospital, Coimbatore, Tamilnadu, (502) Medwin Hospitals, Hyderabad, Telangana, (503) JSS Medical College Hospital, Mysuru, Karnataka, (504) Mycure Hospital, Visakhapatnam, Andhra Pradesh, (505) Shatabdi Super Specialty Hospital, Suyojit City Center, Opp. Mahamarg Bus Stand, Nashik, Maharashtra, (506) SR Kalla Memorial Gastro and General Hospital, Jaipur, (507) St. John's Medical College Hospital, Koramangla, Karnataka, (509) KLE Dr. Prabhakar Kore Hospital, Nehru Nagar, (510) Fortis Escorts Heart Institute, New Delhi, (511) Gleneagle Global Hospitals, Hyderabad, Telangana, (513) Monilek Hospital and Research Center, Jaipur, (514) Cardiac Care & Counselling Center, Pune, Maharashtra, (515) Dharma Vira Heart Cente, Sir Ganga Ram Hospital, New Delhi, (516) Vikram Hospital Pvt. Ltd, Mysore, Karnataka, (517) Bhatia Hospital, Mumbai, Maharastra, (518) Endocrinology Diabetes Centre, Bangalore, Karnataka, (524) Caritas Hospital, Kottayam, Kerala, (525) Vikram Hospital, Bangalore, Karnataka, (526) Madras Diabetes Research Foundation, Chennai, Tamilnadu, (527) Krishna Institute of Medical Sciences, Secunderabad, Telanagana

Canada N=250 (172) Recherche Clinique London, Sherbrooke, Québec, (173) Clinique Des Maladies Lipidiques De Québec, Québec, (175) Ronald Collette, MD, Burnaby, (176) DCTM Clinical Trials Group, Strathroy, Ontario, (177) Centre de recherche clinique de Laval, Laval, Québec, (178) SKDS Research Inc., Newmarket, Ontario, (181) Moran Medical Centre, Collingwood, Ontario, (182) Corunna Clinical Research Centre, Corunna, Ontario, (188) London Road Diagnostic Clinic, Sarnia, Ontario, (200) Heathy Heart Program, Vancouver, (201) McGill University Health Centre, Royal Victoria Hospital, Montreal, Québec, (202) Vancouver General Hospital, Vancouver, British Columbia, (219) North Road Clinical Research, Coquitlam, British Columbia, (271) Brampton Research Associates, Brampton, Ontario, (361) Sarnia Institute of Clinical Research, Sarnia, Ontario, (395) Alta Clinical Research Inc, Edmonton, Alberta, (397) Montreal Heart Institute, Montreal, Québec, (659) Centre de Sante et de Services Sociaux de Lanaudière, St-Charles-Borromée, Québec, (660) Institut Universitaire De Cardiologie Et De Pneumologie Du Québec, Université Laval, Québec

Romania N=202 (801) Medical Center Medcalis SRL, Timisoara, (803) Universitary Emergency Hospital, Cardiology Ward I, Bucuresti, (804) Centrul Medical International Bucuresti Dacia, Bucuresti, (805) Emergency County Hospital, Sibiu, (806) Mediclass Sananova SRL, Bucharest, (808) Clinic County Emergency Hospital Cluj-Napoca, Cluj-Napoca, (809) Universitary Emergency Hospital Bucharest, Bucharest, (810) Ilro Medical Clinic, Bucharest, (811) CardioMed SRL, Craiova, (812) Spitalul Judetean De Urgenta Braila, Braila, (813)

University of Medicine and Pharmacy Grigore T. Popa, Rehabilitation Hospital, Department of Cardiovascular Rehabilitation, Lasi, (814) Spitalul Clinic Judetean De Urgenta, Tirgu Mures, (815) Spitalul Clinic Judetean De Urgenta, Sibiu, (816) Centrul Med Plus SRL Bucuresti, Bucuresti, (817) Centrul Medical Galenus, Tirgu Mures, (818) CMI Cardiologie, Baia Mare, (819) SC Clinica Angiomed, Bucharest, (820) Spitalul De Urgenta Arges, Pitesti, (821) CMI Cardiologie, Constanta

Australia N=189 (301) Holy Spirit Northside Hospital, Brisbane, QLD, (302) The Alfred Hospital Heart Centre, Melbourne, VIC, (303) Fremantle Hospital, Fremantle, WA, (304) Dr Heart Pty Ltd, Woolloongabba, QLD, (305) St. Vincents Hospital (Melb) Dept. of Medicine, Fitzroy, VIC, (306) Joondalup Cardiovascular Trials Foundation, Joondalup, WA, (307) Launceston General Hospital, Launceston, TAS, (308) Royal Prince Alfred Hospital, Sydney, NSW, (309) Sir Charles Gairdner Hospital, Nedlands, (310) Royal Perth Hospital, School of Medicine and Pharmacology, Medical Research Foundation, Perth, WA, (311) Lismore Base Hospital Cardiac Catheter Lab, Northern Rivers Cardiovascular Clinic, Lismore, NSW, (312) Barwon Health University Hospital Geelong, Geelong, VIC, (313) Fiona Stanley Hospital, Murdoch, WA, (314) Austin Health, Heidelberg Heights, VIC, (316) Flinders Medical Centre and Flinders University, Bedford Park, SA, (317) Cardiovascular Trials WA (South), Bateman, WA, (319) Core Research Group Pty Ltd, Brisbane, QLD

New Zealand N=134 (402) Lipid and Diabetes Research, Christchurch, (405) Waitemata District Health Board, Diabetes Service, Auckland, (406) Cardiology Department, Nelson Hospital, Nelson, (408) Hawke's Bay District Health Board, Hastings, (411) Waitemata District Health Board, Auckland, (414) Cardiology Clinical Trials Unit, Waikato District Health Board, Hamilton, (415) Southern District Health Board, Dunedin Hospital, Dunedin, (442) Taranaki Base Hospital, New Plymouth, (444) Northland District Health Board, Whangarei, (445) Bay of Plenty Clinical Trials Unit, Tauranga