	UA/NSTEMI			STEMI			All ACS		
Randomized Subjects	**Prasugrel (N=5044)**	**Clopidogrel (N=5030)**	**p-value[a]**	**Prasugrel (N=1769)**	**Clopidogrel (N=1765)**	**p-value[a]**	**Prasugrel (N=6813)**	**Clopidogrel (N=6795)**	**p-value[a]**
History of Heart Failure (n, %[b])									
Num Subjects	5044	5030	0.789[1]	1769	1765	0.189[1]	6813	6795	0.435[2]
Heart Failure	217 (4.30)	211 (4.19)		48 (2.71)	36 (2.04)		265 (3.89)	247 (3.64)	
Atrial Fibrillation (n, %[b])									
Num Subjects	5044	5030	0.892[1]	1769	1765	0.919[1]	6813	6795	0.938[2]
Heart Failure	170 (3.37)	172 (3.42)		41 (2.32)	40 (2.27)		211 (3.10)	212 (3.12)	
History of Peripheral Artery Disease (PAD) (n, %[b])									
Num Subjects	5044	5030	0.612[1]	1769	1765	0.783[1]	6813	6795	0.565[2]
PAD	282 (5.59)	293 (5.83)		67 (3.79)	70 (3.97)		349 (5.12)	363 (5.34)	
History of Carotid/Vertebral Artery Disease (CVD) (n, %[b])									
Num Subjects	5044	5030	0.636[1]	1769	1765	0.805[1]	6813	6795	0.738[2]
CVD	161 (3.19)	169 (3.36)		32 (1.81)	30 (1.70)		193 (2.83)	199 (2.93)	
Metabolic Syndrome (n, %[b])									
Num Subjects	5044	5030	0.948[1]	1769	1765	0.420[1]	6813	6795	0.727[2]
CVD	2257 (44.75)	2254 (44.81)		709 (40.08)	684 (38.75)		2966 (43.53)	2938 (43.24)	
Prior PCI (n, %[b])									
Num Subjects	5044	5030	0.600[1]	1769	1765	0.721[1]	6813	6795	0.536[2]
Prior PCI	790 (15.66)	807 (16.04)		114 (6.44)	119 (6.74)		904 (13.27)	926 (13.63)	
Prior CABG (n, %[b])									
Num Subjects	5044	5030	0.157[1]	1769	1765	0.919[1]	6813	6795	0.166[2]
Prior CABG	500 (9.91)	457 (9.09)		41 (2.32)	40 (2.27)		541 (7.94)	497 (7.31)	
Prior Coronary Angiography with ≥ 50% Stenosis of Major Epicardial Vessel (n, %[b])									
Num Subjects	5044	5030	0.426[1]	1769	1765	0.879[1]	6813	6795	0.427[2]
Stenosis ≥ 50%	1191 (23.61)	1154 (22.94)		165 (9.33)	162 (9.18)		1356 (19.90)	1316 (19.37)	

	UA/NSTEMI			STEMI			All ACS		
Randomized Subjects	**Prasugrel (N=5044)**	**Clopidogrel (N=5030)**	**p-value[a]**	**Prasugrel (N=1769)**	**Clopidogrel (N=1765)**	**p-value[a]**	**Prasugrel (N=6813)**	**Clopidogrel (N=6795)**	**p-value[a]**
Hepatic Impairment Based on Hy's Rule at Baseline (n, %[b])									
Num Subjects	5044	5030	NE	1769	1765	NE	6813	6795	NE
Yes	2 (0.04)	0		0	0		2 (0.03)	0	
Hepatic Impairment Based on Pre-Existing Conditions (n, %[b])									
Num Subjects	5044	5030	0.330[1]	1769	1765	0.996[1]	6813	6795	0.3292[2]
Yes	23 (0.46)	30 (0.60)		8 (0.45)	8 (0.45)		31 (0.46)	38 (0.56)	
Peptic Ulcer Disease (n, %[b])									
Num Subjects	5044	5030	0.296[1]	1769	1765	0.538[1]	6813	6795	0.561[2]
Yes	288 (5.71)	312 (6.20)		112 (6.33)	103 (5.84)		400 (5.87)	415 (6.11)	
Tobacco Use (n, %[b])									
Num Subjects	5044	5030	0.598[1]	1769	1765	0.052[1]	6813	6795	0.481[2]
Any Use	3255 (64.53)	3292 (65.45)		1207 (68.23)	1198 (67.88)		4462 (65.49)	4490 (66.08)	
Current Use	1778 (35.25)	1811 (36.00)		834 (47.15)	772 (43.74)		2612 (38.34)	2583 (38.01)	
Prior Use	1477 (29.28)	1481 (29.44)		373 (21.09)	426 (24.14)		1850 (27.15)	1907 (28.06)	
Never Used	1789 (35.47)	1738 (34.55)		562 (31.77)	567 (32.12)		2351 (34.51)	2305 (33.92)	
Time from Onset of Qualifying symptoms to Randomization (hours) (n, %[b])									
Num Subjects	4956	4922	0.404[1]	1733	1729	0.704[1]	6689	6651	0.579[2]
≤ 24 hours	1978 (39.91)	1924 (39.09)		1259 (72.65)	1266 (73.22)		3237 (48.39)	3190 (47.96)	
> 24 hours	2978 (60.09)	2998 (60.91)		474 (27.35)	463 (26.78)		3452 (51.61)	3461 (52.04)	

	UA/NSTEMI			STEMI			All ACS		
Randomized Subjects	**Prasugrel (N=5044)**	**Clopidogrel (N=5030)**	**p-value[a]**	**Prasugrel (N=1769)**	**Clopidogrel (N=1765)**	**p-value[a]**	**Prasugrel (N=6813)**	**Clopidogrel (N=6795)**	**p-value[a]**
Time from Onset of Qualifying Symptoms to Randomization (h)									
Num Subjects	4956	4922	0.484[4]	1733	1729	0.546[4]	6689	6651	0.404[5]
Mean	38.236	36.853		26.379	25.426		35.164	33.882	
SD	132.989	40.349		45.940	47.005		116.942	42.474	
Minimum	0.00	0.35		0.02	0.00		0.00	0.00	
Lower Quartile	16.63	16.68		2.93	2.83		10.08	9.30	
Median	28.92	29.04		6.42	5.62		24.85	25.20	
Upper Quartile	48.62	49.02		27.82	26.90		46.48	46.68	
Maximum	8830.25[†]	841.03		332.13	334.83		8830.25	841.03	
GPIIb/IIIa Use Through 3 Days After Randomization (n, %[b])									
Num Subjects	5044	5030	0.317[1]	1769	1765	0.433[1]	6813	6795	0.208[2]
Yes	2570 (50.95)	2613 (51.95)		1100 (62.18)	1120 (63.46)		3670 (53.87)	3733 (54.94)	
Statin Use (n, %[b])									
Num Subjects	5044	5030	0.945[1]	1769	1765		6813	6795	0.932[2]
Any Statin	4029 (79.88)	4008 (79.68)		1343 (75.92)	1332 (75.47)		5372 (78.85)	5340 (78.59)	
Atorvastatin									
Any Dose	2024 (40.13)	2003 (39.82)		683 (38.61)	690 (39.09)	0.845[1]	2707 (39.73)	2693 (39.63)	0.932[2]
≥ 80	426 (8.45)	428 (8.51)		170 (9.61)	176 (9.97)		596 (8.75)	604 (8.89)	
< 80	1252 (24.82)	1248 (24.81)		398 (22.50)	400 (22.66)		1650 (24.22)	1648 (24.25)	
Other Statin	2005 (39.75)	2005 (39.86)		660 (37.31)	642 (36.37)		2665 (39.12)	2647 (38.96)	
No Statin	1015 (20.12)	1022 (20.32)		426 (24.08)	433 (24.53)		1441 (21.15)	1455 (21.41)	
ACE Inhibitor (n, %[b])									
Num Subjects	5044	5030	0.002[1]	1769	1765	0.518[1]	6813	6795	0.003[2]
Yes	2714 (53.81)	2550 (50.70)		827 (46.75)	806 (45.67)		3541 (51.97)	3356 (49.39)	
Beta Blocker (n, %[b])									
Num Subjects	5044	5030	0.616[1]	1769	1765	0.581[1]	6813	6795	0.912[2]
Yes	3892 (77.16)	3860 (76.74)		1150 (65.01)	1163 (65.89)		5042 (74.01)	5023 (73.92)	

	UA/NSTEMI			STEMI			All ACS		
Randomized Subjects	**Prasugrel (N=5044)**	**Clopidogrel (N=5030)**	**p-value[a]**	**Prasugrel (N=1769)**	**Clopidogrel (N=1765)**	**p-value[a]**	**Prasugrel (N=6813)**	**Clopidogrel (N=6795)**	**p-value[a]**
Calcium Channel Blocker (n, %[b])									
Num Subjects	5044	5030	0.184[1]	1769	1765	0.451[1]	6813	6795	0.361[2]
Yes	866 (17.17)	814 (16.18)		140 (7.91)	152 (8.61)		1006 (14.77)	966 (14.22)	
Received Aspirin within 7 Days Prior to Symptom Onset (n, %[b])									
Num Subjects	5044	5030	0.899[1]	1769	1765	0.363[1]	6813	6795	0.804[2]
Yes	2060 (40.84)	2048 (40.72)		266 (15.04)	285 (16.15)		2326 (34.14)	2333 (34.33)	

Num Subjects=number of subjects with non-missing values for category, n=number of subjects in sub-category, NE=not evaluated due to insufficient data.

†Sponsor was queried about this time from onset of qualifying symptoms to randomization. The sponsor believes the investigator incorrectly entered the date for symptom onset. A Data Clarification form had been sent to the study site.

[a]Two-sided p-values: [1]Pearson chi-square, [2]CMH general association, [3]CMH row mean with rank scores, [4]t-test, [5]ANOVA with clinical presentation as a blocking factor.

[b]% is percent of Num Subjects

[c]p-value is based on North America, South America, Western Europe, Eastern Europe, Rest of World.

[d]p-value is based on None vs. Any.

[e]p-value is based on Yes vs. No.

[f]p-value is based on Current, Prior, and Never.

[g]p-value is based on Atorvastatin, Other Statins, and No Statins

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Table 48. Index Procedure (All Randomized Subjects) (TAAL)

	UA/NSTEMI			STEMI			All ACS		
Randomized Subjects	**Prasugrel (N=5044)**	**Clopidogrel (N=5030)**	**p-value[a]**	**Prasugrel (N=1769)**	**Clopidogrel (N=1765)**	**p-value[a]**	**Prasugrel (N=6813)**	**Clopidogrel (N=6795)**	**p-value[a]**
Index Procedure n (%[b])[c]									
Num Subjects	5044	5030	0.508[1]	1769	1765	0.503[1]	6813	6795	0.956[2]
PCI	5004 (99.21)	4984 (99.09)		1711 (96.72)	1714 (97.11)		6715 (98.56)	6698 (98.57)	
No PCI	40(0.79)	46 (0.91)		58 (3.28)	51 (2.89)		98 (1.44)	97 (1.43)	
CABG	16(0.32)	12 (0.24)		9 (0.51)	11 (0.62)		25 (0.37)	23 (0.34)	
Medically Treated	24(0.48)	34 (0.68)		49 (2.77)	40 (2.77)		73 (1.07)	74 (1.09)	
Culprit Lesion(s)									
Number of Intervened Culprit Lesions per Subject n (%[b]):									
Num Subjects	4897	4854	0.886[1]	1677	1670	0.320[1]	6574	6524	0.735[2]
1 Culprit Lesion	4679 (95.55)	4635 (95.49)		1611 (96.06)	1615 (96.71)		6290 (95.68)	6250 (95.80)	
≥ 2 Culprit Lesions	218 (4.45)	219 (4.51)		66 (3.94)	55 (3.29)		284 (4.32)	274 (4.20)	
Subjects with Single Culprit Lesion									
Type of intervention in Culprit Lesion n (%[b])[d]									
Num Subjects	4679	4635	0.356[1]	1611	1615	0.551[1]	6290	6250	0.272[2]
Any Stent	4487 (95.90)	4462 (96.27)		1531 (95.03)	1542 (95.48)		6018 (95.68)	6004 (96.06)	
Drug Eluting	2345 (50.12)	2345 (50.59)		515 (31.97)	527 (32.63)		2860 (45.47)	2872 (45.95)	
Cypher	1027 (21.95)	1013 (21.86)		228 (14.15)	256 (15.85)		1255 (19.95)	1269 (20.30)	
Taxus	1160 (24.79)	1156 (24.94)		262 (16.26)	251 (15.54)		1422 (22.61)	1407 (22.51)	
Other	164 (3.51)	181 (3.91)		28 (1.74)	26 (1.61)		192 (3.05)	207 (3.31)	
Bare Metal	2163 (46.23)	2159 (46.58)		1027 (63.75)	1026 (63.53)		3190 (50.72)	3185 (50.96)	
No Stent	192 (4.10)	173 (3.73)		80 (4.97)	73 (4.52)		272 (4.32)	246 (3.94)	
PTCA Only	182 (3.89)	165 (3.56)		78 (4.84)	70 (4.33)		260 (4.13)	235 (3.76)	
Other PCI Procedure	10 (0.21)	8 (0.17)		2 (0.12)	3 (0.19)		12 (0.19)	11 (0.18)	

	UA/NSTEMI			STEMI			All ACS		
Randomized Subjects	**Prasugrel (N=5044)**	**Clopidogrel (N=5030)**	**p-value[a]**	**Prasugrel (N=1769)**	**Clopidogrel (N=1765)**	**p-value[a]**	**Prasugrel (N=6813)**	**Clopidogrel (N=6795)**	**p-value[a]**
Total Stent Length (mm) in Culprit Lesion n (%[b])									
Num Subjects	4487	4462	0.628[3]	1531	1542	0.830[3]	6018	6004	0.666[3]
≤ 20	2844 (63.38)	2824 (63.29)		903 (58.98)	918 (59.53)		3747 (62.26)	3742 (62.33)	
21-30	1080 (24.07)	1035 (23.20)		397 (25.93)	398 (25.81)		1477 (24.54)	1433 (23.87)	
31-40	397 (8.85)	400 (8.96)		150 (9.80)	121 (7.85)		547 (9.09)	521 (8.68)	
>40	166 (3.70)	203 (4.55)		81 (5.29)	105 (6.81)		247 (4.10)	308 (5.13)	
Number of Stents in Culprit Lesion n (%[b])									
Num Subjects	4487	4462	0.396[3]	1531	1542	NE	6018	6004	0.340[3]
1	4188 (93.34)	4145 (92.90)		1405 (91.77)	1406 (91.18)		5593 (92.94)	5551 (92.46)	
2	265 (5.91)	273 (6.12)		105 (6.86)	115 (7.46)		370 (6.15)	388 (6.46)	
3	29 (0.65)	29 (0.65)		21 (1.27)	17 (1.10)		60 (0.83)	46 (0.77)	
4	5 (0.11)	15 (0.34)		0	4 (0.26)		5 (0.08)	19 (0.32)	
Vessel of the Culprit Lesion n (%[b])									
Num Subjects	4679	4635	0.209[1]	1611	1614	NE	6290	6249	0.215[2]
Native Coronary Artery	4485 (95.85)	4433 (95.64)		1594 (98.94)	1594 (98.76)		6079 (96.65)	6027 (96.45)	
LM	44 (0.94)	40 (0.86)		2 (0.12)	7 (0.43)		46 (0.73)	47 (0.75)	
LAD	1680 (35.91)	1690 (36.46)		632 (39.23)	640 (39.65)		2312 (36.76)	2330 (37.29)	
RCA	1305 (27.89)	1368 (29.51)		703 (43.64)	699 (43.31)		2008 (31.92)	2067 (33.08)	
LCX	1371 (29.30)	1270 (27.40)		242 (15.02)	237 (14.68)		1613 (25.64)	1507 (24.12)	
RI	85 (1.82)	65 (1.40)		15 (0.93)	11 (0.68)		100 (1.59)	76 (1.22)	
Graft	194 (4.15)	202 (4.36)		17 (1.06)	20 (1.24)		211 (3.35)	222 (3.55)	
Venous	177 (3.78)	187 (4.03)		13 (0.81)	17 (1.05)		190 (3.02)	204 (3.26)	
Arterial	17 (0.36)	15 (0.32)		4 (0.25)	3 (0.19)		21 (0.33)	18 (0.29)	
Bifurcation Lesion in Culprit n (%[b])									
Num Subjects	**4679**	**4635**	**0.451[1]**	**1611**	**1615**	**0.788[1]**	**6290**	**6250**	**0.594[2]**
Yes	**242 (5.17)**	**256 (5.52)**		**75 (4.66)**	**72 (4.46)**		**317 (5.04)**	**328 (5.25)**	
No	**4437 (94.83)**	**4379 (94.48)**		**1536 (95.34)**	**1543 (95.54)**		**5973 (94.96)**	**5922 (94.75)**	

	UA/NSTEMI			STEMI			All ACS		
Randomized Subjects	**Prasugrel (N=5044)**	**Clopidogrel (N=5030)**	**p-value[a]**	**Prasugrel (N=1769)**	**Clopidogrel (N=1765)**	**p-value[a]**	**Prasugrel (N=6813)**	**Clopidogrel (N=6795)**	**p-value[a]**
Study Drug									
Timing of Loading Dose Relative to Index PCI (n, (%)[b]									
Num Subjects	4965	4923	0.623[1]	1691	1687	0.599[1]	6656	6610	0.637[2]
Pre-PCI	**1257 (25.32)**	**1205 (24.48)**		**455 (26.91)**	**453 (26.85)**		**1712 (25.72)**	**1658 (25.08)**	
≥ 6 Prior	118 (2.38)	93 (1.89)		14 (0.83)	6 (0.36)		132 (1.98)	99 (1.50)	
< 6 Prior	1139 (22.94)	1112 (22.59)		441 (26.08)	447 (26.50)		1580 (23.74)	1559 (23.59)	
During PCI	**3660 (73.72)**	**3671 (74.57)**		**1221 (72.21)**	**1213 (71.90)**		**4881 (73.33)**	**4884 (73.89)**	
First Wire in to Last Wire Out	958 (19.30)	932 (18.93)		254 (15.02)	236 (13.99)		1212 (18.21)	1168 (17.67)	
Last Wire Out to Leaving Cath Lab	1473 (29.67)	1435 (29.15)		459 (27.14)	466 (27.62)		1932 (29.03)	1901 (28.76)	
Leaving Cath Lab to 1h later	1229 (24.75)	1304 (26.49)		508 (30.04)	511 (30.29)		1737 (26.10)	1815 (27.46)	
Post PCI	**48 (0.97)**	**47 (0.95)**		**15 (0.89)**	**21 (1.24)**		**63 (0.95)**	**68 (1.03)**	

Num Subjects = number of subjects with nonmissing values for category, n = number of subjects in sub-category, NE = not evaluated due to insufficient data.
[a]Two-sided p-values: [1]Pearson chi-square, [2]CMH general association, [3]CMH row mean with rank scores.
[b]% is percent of Num Subjects.
[c]p-value is based on PCI vs. No PCI. [d]p-value is based on Any Stent vs. No stent.
[e]p-value is based on single vessel categories: LM, LAD, RCA, LCX, RI, Venous Graft and Arterial Graft.
[f]p-value is based on Single Vessel vs. Multiple Vessels. [g]p-value is based on Monotherapy vs. Multiple Therapies.
[h]p-value is based on Pre-PCI, During PCI, and Post-PCI.
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9.1.11.5 Duration of Follow-Up (All Randomized Subjects)

The mean duration of follow-up was similar in the UA/NSTEMI population by treatment group. Patients in the STEMI population had a longer mean follow-up because enrollment was capped and completed earlier than the UA/NSTEMI population. The duration of follow-up is displayed in Table 49.

Table 49. Duration of Follow-Up (All Randomized Subjects) (TAAL)

	UA/NSTEMI			STEMI			All ACS		
	Prasugrel	Clopidogrel	p-value[a]	Prasugrel	Clopidogrel	p-value[a]	Prasugrel	Clopidogrel	p-value[a]
Randomized	5044	5030	0.335[1]	1769	1765	0.680[1]	6813	6795	0.520[2]
Mean (days)	363.7	366.0		423.1	421.5		379.1	380.4	
SD	120.0	120.4		111.0	113.7		120.5	121.2	
Minimum	1	1		1	1		1	1	
Lower Quartile	274	275		450	450		322	337	
Median	438	441		458	458		450	450	
Upper Quartile	458	459		464	464		462	462	
Maximum	464	464		464	464		464	464	

[a]Two-sided p-values: [1]t test, [2]ANOVA with clinical presentation as a blocking factor.
Reproduced from Sponsor, Clinical Study Report, Table TAAL.11.4, page 200.

9.1.11.6 Primary Efficacy Endpoint

In all treatment groups, prasugrel significantly reduced the CEC Adjudicated composite endpoint of CV death, nonfatal MI, and nonfatal stroke, as displayed in Table 50.

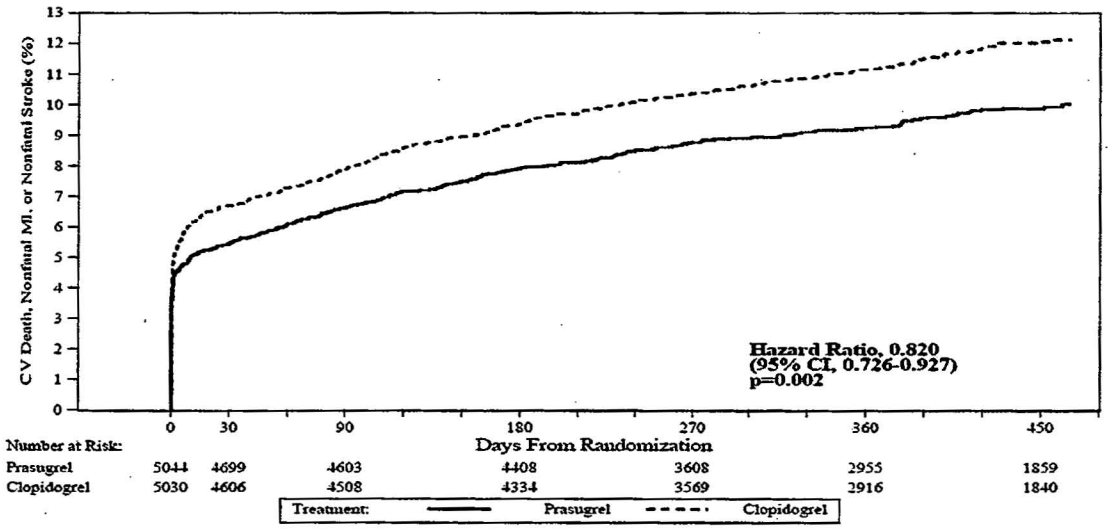
Table 50. Number and Percentage of Subjects Reaching the Composite Endpoint of CV Death, Nonfatal MI, or Nonfatal Stroke--CEC Adjudicated (All Randomized Subjects) (TAAL)

Subject Population	Prasugrel			Clopidogrel			Total			Cox Proportional HR (95% CI)[b]	Gehan-Wilcoxon p-value[c]
	N	n	(%[a])	N	n	(%[a])	N	n	(%[a])		
UA/NSTEMI	5044	469	(9.30)	5030	565	(11.23)	10074	1034	(10.26)	**0.820 (0.726, 0.927)**	0.002
STEMI	1769	174	(9.84)	1765	216	(12.24)	3534	390	(11.04)	0.793 (0.649, 0.968)	0.019
All ACS	6813	643	(9.44)	6795	781	(11.49)	13608	1424	(10.46)	0.812 (0.732, 0.902)	< 0.001

CI: confidence interval; HR: hazard ratio; N=number randomized; n=number of subjects reaching the endpoint; NE=not evaluated due to insufficient data.
[a]% is percentage of randomized subjects reaching the primary endpoint.
[b]Hazard ratio and a 95% confidence interval used as an estimate of overall relative risk, Prasugrel versus Clopidogrel over the course of the study.
[c]Two-sided p-values are based on Gehan-Wilcoxon test comparing event free survival distributions of Prasugrel and Clopidogrel. Clinical presentation, UA/NSTEMI vs. STEMI, was used as a stratification factor in analysis involving all ACS subjects.
Reproduced from Sponsor, Clinical Study Report, Table TAAL.11.5, page 202 of 27024)
Analysis verified by Ququan Liu, M.D., M.S.

The Kaplan-Meier estimates of the incidence of the primary composite endpoint in the UA/NSTEMI population is displayed in Figure 27. It appears that most of the treatment effect was realized within the first several days of study drug administration.

Figure 27. Hazard Ratio and 95% Confidence Interval for the Composite Endpoint of CV Death, Nonfatal MI, or Nonfatal Stroke--CEC Adjudicated (All Randomized UA/NSTEMI Subjects) (TAAL)



(Reproduced from Sponsor, Clinical Study Report, Figure TAAL.11.2a, page 204 of 27024)

Please see the Integrated Summary of Efficacy and the Integrated Summary of Safety for all other results.

9.1.11.7 Results of FDA Subgroup Analyses

Numerous subgroup analyses are displayed in Table 51.