Definitions:

1. **Rehospitalization for cardiac ischemic events (CIE):** Rehospitalization for symptoms of myocardial ischemia at rest with at least one of the following:
   - New ST-segment deviation ≥ 1 mm or
   - Performance of a coronary revascularization procedure (PCI or CABG) during the same hospital stay. Revascularization could include the vessel(s) dilated at the initial procedure and/or additional vessels.

   Planned rehospitalization for performance of staged PCI identified at the time of index hospitalization was not included under the definition of Rehospitalization for cardiac ischemic events.

2. **Urgent target vessel revascularization (UTVR):** PCI or CABG for recurrent ischemia that, in the investigator's opinion, could not be delayed for more than 24 hours and was defined by the investigator as a nonelective procedure. Revascularization, either with CABG or PCI, must have included the vessel(s) dilated at the initial procedure.

3. **All-cause death:** death due to cardiac or noncardiac cause.

4. **Definition of Definite, Probable, and Possible Stent Thrombosis (Clinical Study Report, page 110)**

   Definite or confirmed angiographic stent thrombosis:
   - TIMI flow grade 0 with occlusion originating in the stent or in the segment 5 mm proximal or distal to the stented region in the presence of a thrombus.*
     or
   - TIMI flow grade 1, 2, or 3 and the presence of thrombus* originating in the stent or in the segment 5 mm proximal or distal to the stented region
     and
   - At least one of the following criteria (within 48 hours):
     - New onset of ischemic symptoms at rest (typical pain > 20 min)
     - New ischemic ECG changes suggestive of acute ischemia
     - Typical rise and fall in cardiac biomarkers

   *The incidental angiographic documentation of silent stent occlusion in the absence of clinical signs or symptoms is not considered a confirmed stent thrombosis.

   Please note that the sponsor's definition of definite stent thrombosis does not include the ARC pathological confirmation of stent thrombosis which is defined as the evidence of recent thrombus within the stent determined at autopsy or via examination of tissue retrieved following thrombectomy.

   Probable stent thrombosis
   - Any unexplained death within the first 30 days, irrespective of the time after the index procedure; any myocardial infarction, which is related to documented acute ischemia in the territory of the implanted stent without angiographic confirmation of stent thrombosis and in the absence of any other obvious cause.

   Possible stent thrombosis
   - Any unexplained death from 30 days following intracoronary stenting until end of study follow-up

9.1.8.3 Other Efficacy Endpoints

Other efficacy endpoints included but were not limited to
- Any target vessel revascularization (TVR)
- Any coronary vessel revascularization
- Transient ischemic attack (TIA)

9.1.8.4 Economic Endpoints

- Total 1-year medical care costs
- Initial hospitalization costs
- Total 30-day costs
- Incremental cost-effectiveness in terms of cost per death, nonfatal MI, or nonfatal stroke averted, cost per life year gained, and cost per quality adjusted life year

9.1.8.5 Safety Endpoints

- **Non-CABG related TIMI major bleeding:** any intracranial hemorrhage (ICH) OR any clinically overt bleeding (including bleeding evident on imaging studies) associated with a fall in hemoglobin (Hgb) of ≥ 5 gm/dL from baseline (accounting for the effect of transfusions on change in Hgb, defined as one unit packed red blood cells = 1 gm/dL Hgb = 3% hematocrit [Hct]).

- **Non-CABG-related TIMI life-threatening bleeding:** any non-CABG-related TIMI major bleeding that is fatal, leads to hypotension that requires treatment with intravenous inotropic agents, **OR** requires surgical intervention for ongoing bleeding, **OR** necessitates the transfusion of 4 or more units of blood (whole blood or packed red blood cells [RBC]) over a 48-hour period, **OR** any symptomatic ICH.

- **Non-CABG-related fatal bleeding:**

- **Non-CABG-related TIMI minor bleeding:** any clinically overt bleeding (including bleeding evident on imaging studies) associated with a fall in Hgb of ≥ 3 gm/dL but < 5 gm/dL from baseline (accounting for the effect of transfusions on change in Hgb, defined as one unit packed red blood cells = 1 gm/dL Hgb = 3% Hct).

- **CABG related bleeding**

9.1.9 Clinical Events Committee (CEC)

The CEC adjudicated deaths as CV or non-CV related, and deaths of unknown cause were considered CV related. Cardiac ischemic events (CIEs) were adjudicated as MIs separate from the index event, rehospitalization for CIE, or other. Cerebrovascular events were adjudicated as stroke or transient ischemic attack. Additionally, the CEC adjudicated bleeding endpoints according to TIMI classification: Major, Life-Threatening, Minor, Minimal, or no bleed and adjudicated whether or not bleeding was CABG-related. The CEC clinically adjudicated stent thrombosis.

9.1.10 Statistical Considerations

9.1.10.1 Power and Sample Size

For UA/NSTEMI subjects, the study was to provide 90% power to establish superiority relative to the triple endpoint based on the following assumptions:

- 10.5% of subjects in the clopidogrel group reaching the triple endpoint within 1 year of the PCI procedure based on event rates of the Unstable angina to prevent Recurrent Events study (CURE) for subset of subjects with a TIMI Study Group (TIMI) risk score ≥ 3.
- Average hazard ratio of 0.80 for CS-747 versus clopidogrel relative to the primary endpoint, and
- The time-to-first event analysis based on a two-sided log-rank test used a two-sided significance level (alpha) of 0.05 to assess superiority relative to the triple endpoint.

Treatment by subgroup interaction p-values were considered statistically significant at the 0.10 level.

Except for stent thrombosis, for each of the prespecified secondary endpoints in UA/NSTEMI subjects, the proposed sample size was to provide ≥ 80% power at a two-sided 0.05 significance level to establish superiority of prasugrel under the assumption of at least a 20% reduction in hazard in UA/NSTEMI subjects and an event rate of at least 7.75% in the clopidogrel group.

The proposed sample size was 13,000 subjects, assuming that ≤ 5% of the subjects would not be evaluable for the primary endpoint and that STEMI subjects would comprise 20 to 30% of the total enrollment (with a cap of 3500 subjects).

The study was to continue until 875 unstable angina and non-ST-segment elevation myocardial infarction (UA/NSTEMI) subjects reached one of the events in the triple composite endpoint (CV death, nonfatal MI, or nonfatal stroke) and a median duration of therapy of 12 months and a minimum follow-up of 6 months.

The blinded event rate was to be evaluated when 650 UA/NSTEMI subjects had reached the primary endpoint. However, the Study Operations Committee conducted a blinded review of the aggregated event rate when 589 subjects with UA/NSTEMI reached the primary endpoint and determined there was a slightly lower than anticipated aggregated event rate. Therefore, the size of the UA/NSTEMI population was increased to 10,100 subjects to meet the target of 875 events.

9.1.10.2 Plan for Evaluating the Primary Endpoint

The Statistical Analysis Plan was finalized on September 18, 2007.

The primary outcome was the composite of cardiovascular (CV) death, nonfatal MI, or nonfatal stroke. Due to a potentially varying hazard ratio, the primary analysis was based on the time from randomization to the onset of the first primary outcome using the Gehan-Wilcoxon test. Primary analyses were carried out in a hierarchical manner. At the first step, time-to-primary outcome was carried out at a one-sided significance level of 0.025 (equivalent to a two-sided test at 0.05) in the UA/NSTEMI subject population. If superiority of prasugrel treatment in the UA/NSTEMI subject population was successfully established, then time-to-first primary outcome was carried out at a one-sided significance level of 0.025 in the All ACS subject population. In this analysis, ACS classification (UA/NSTEMI or STEMI) was used as a stratification factor.

Corresponding two-sided 95% confidence intervals for the hazard ratios under the proportional hazards assumption were provided.

9.1.10.3 Plan for Evaluating Secondary Endpoints

After establishing the superiority of prasugrel over clopidogrel relative to the primary endpoint, analyses for secondary efficacy endpoints were performed using the log-rank test.

The secondary endpoints were comprised of two groups: the first group (Group 1) were those endpoints that did not need to be adjusted for multiplicity, and the second group (Group 2) were those that needed to be predefined in a hierarchical manner.

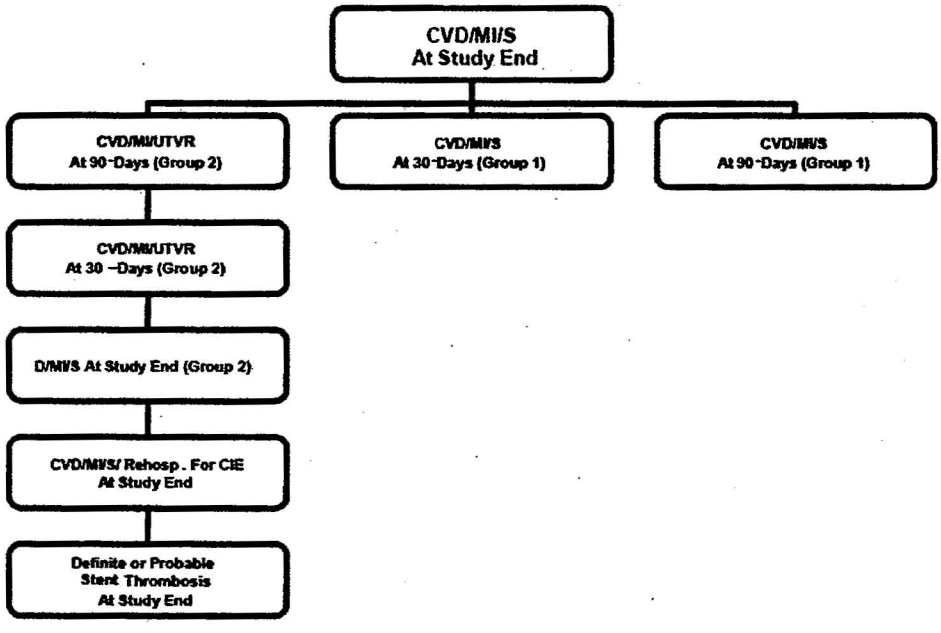
Group I was evaluated without adjusting for multiplicity, each at a one-sided 0.025 alpha level (equivalent to a two-sided 0.05 level):

- CV death, nonfatal MI, or nonfatal stroke at 90 days post randomization
- CV death, nonfatal MI, or nonfatal stroke at 30 days post randomization

The evaluations of subsequent endpoints relied on the superiority of prasugrel relative to the primary endpoint in the UA/NSTEMI subject population. To protect the overall type I error rate at a level of 0.05, the four remaining secondary endpoints included in Group 2 were evaluated hierarchically each at a one-sided 0.025 alpha level, as shown in Table 28.

- CV death, nonfatal MI, or UTVR at 90 days post randomization
- CV death, nonfatal MI, or UTVR at 30 days post randomization
- All-cause mortality, nonfatal MI, or nonfatal stroke at study end (after a median follow-up of at least 1 year post randomization)
- CV death, nonfatal MI, nonfatal stroke, or rehospitalization for cardiac ischemic event (CIE) at study end
- Definite or probable stent thrombosis per Academic Research Consortium definition

Figure 25. Evaluate the Superiority of Prasugrel Compared to Clopidogrel at a One-Sided Alpha Level of 0.025 in UA/NSTEMI Cohort Relative to



CIE: cardiac ischemic events; CVD: cardiovascular death; MI: myocardial infarction; Rehosp: Rehospitalization for CIE; S: stroke; UTVR: urgent target vessel revascularization

(Reproduced from Sponsor, Statistical Analysis Plan Amendment (b) dated September 18, 2007, page 9169)

9.1.10.4 Evaluation of Secondary Endpoints in the All ACS Subject Population

Each of the six secondary endpoints (Groups 1 and 2) were evaluated using the log-rank test in the All ACS subject population, each at a one-sided 0.025 significance level, provided that superiority of prasugrel was established relative to the primary endpoint in the All ACS (UA/NSTEMI/STEMI) subject population (and in the UA/NSTEMI subject population). UA/NSTEMI versus STEMI was used as the stratification factor in these analyses.

9.1.10.5 Evaluation of Endpoints in the STEMI Population

All primary and secondary study endpoints were evaluated in the STEMI population in an exploratory fashion.

9.1.10.6 Other Statistical Considerations

Since some subjects experienced particular adverse events more than once, the sponsor used a Poisson Regression model with the subject's duration of follow-up as an offset variable.

Safety endpoint analyses used the treated population consisting of subjects who received at least one dose of study drug (including the loading dose).

Three unblinded interim analyses were planned when 250, 450, and 650 UA/NSTEMI subjects reached the primary endpoint. However, the Data Monitoring Committee performed the three interim analyses when 161, 433, and 589 UA/NSTEMI subjects reached the primary endpoint, as shown in Table 41.

Table 41. Interim Analyses by the Data Monitoring Committee

			Number of Subjects Enrolled as of Data Cut-off Date		
Interim Analysis	Data Cut-off Date	Date of Report	UA/NSTEMI	STEMI	Number of UA/NSTEMI subjects confirmed to have reached the primary endpoint
1	12 April 2006	9 May 2006	5919	3527	161
2	02 August 2006	22 August 2006	7757	3539	433
3	11 October 2006	01 November 2006	8776	3532	589

Abbreviations: NSTEMI = non-ST-segment elevation myocardial infarction; STEMI = ST-segment elevation myocardial infarction; UA = unstable angina.

(Reproduced from Sponsor, Clinical Study Report, page 132)

9.1.10.7 Subgroup Analyses

There were numerous prespecified subgroup analyses for efficacy and safety. Definitions for some of the subgroups are described as follows:

- History of vascular disease was defined as meeting any of the following criteria:
  - Peripheral arterial disease (PAD)
  - Carotid/vertebral arterial disease
  - Prior > 50% stenosis of coronary artery
  - History of chronic stable angina
  - History of unstable angina (UA)
  - Prior MI
  - Prior stroke
  - Prior transient ischemic attack (TIA)

- Metabolic syndrome was defined as meeting any 3 of the following 5 criteria:
  - Waist circumference > 102 cm in men or > 88 cm in women
  - Fasting triglyceride ≥ 150 mg/dL
  - High-density lipoprotein cholesterol (HDL-C) < 40 mg/dL in men, < 50 mg/dL in women
  - Blood pressure ≥ 130/85 mm Hg
  - Fasting glucose ≥ 110 mg/dL

- The TIMI risk score for subjects with UA/NSTEMI (Antman et al. 2000) or STEMI (within 12 hours of symptom onset; Morrow et al. 2001) was calculated as the sum of points corresponding to the risk factors at baseline

Table 42. Calculation of TIMI RISK SCORE for Subjects with UA/NSTEMI or STEMI

Characteristics	Point
UA/NSTEMI	
Age ≥65	1
≥3 of following 5 CAD risk factors Family history of CAD Hypertension Hypercholesterolemia Diabetes Mellitus Current tobacco use	1
Prior Coronary Angiography that shows ≥50% Stenosis	1
ASA within 7 days prior to the onset of symptoms	1
Recent (≤24 hour) severe angina	1
Any pre-PCI biomarker >ULN[a]	1
ST segment deviation ≥0.5mm	1
Maximum number of points	**7**
STEMI ≤12 hours	
Age ≥75	3
65 – 74	2
Any of the following risk factors: Diabetes Mellitus Hypertension History of angina	1
Baseline SBP <100 mm Hg	3
Baseline Heart rate >100 bpm	2
Killip class II - IV	2
Weight <67 kg	1
Maximum number of points	**14**

Abbreviations: ASA = aspirin; CAD = coronary artery disease; HDL = high-density lipoprotein; LBBB = left bundle branch block; SBP = systolic blood pressure; ULN = upper limit of normal.

[a] biomarkers include: troponin and creatine kinase-myocardial bands.

Source: Antman et al. 2000; Morrow et al. 2006.

(Reproduced from Sponsor, Clinical Study Report, Table TAAL.9.4, page 130 of 27024)

- TIMI Risk Index = Heart Rate X $[(age/10)^2/Systolic\ BP]$

- Hepatic impairment at baseline
  - Concurrent elevations of alanine transaminases (ALT) results > 3 x ULN and total bilirubin results > 1.5 x ULN
  - Identified through a database search of pre-existing conditions

- Renal Impairment at baseline
  - Creatinine Clearance ≥ 2 mg/dL/min
  - Creatinine Clearance < 60 mL/min (Cockcroft-Gault Formula, 1976)

9.1.11 Results

9.1.11.1 Sites, Investigators, and Study Dates

The study was conducted from November 5, 2004 through July 22, 2007, with enrollment from November 5, 2004 to January 14, 2007. There were 725 study centers in 30 countries; however, 99 of these sites did not screen or enroll subjects. There were a total of 717 principal investigators, and 8 investigators had 2 study sites.

9.1.11.2 Good Practice, Monitoring, and Protocol Deviations

The study was conducted in accordance with Good Clinical Practices and the current Declaration of Helsinki. In 2005, blinded data suggested the rate of subacute stent thrombosis (SAT) in South African sites was higher than in other countries. On June 19, 2005, per Dr. Anthony Dalby, the South African Lead Investigator, study enrollment was stopped so that the clinical study material could be tested. It was subsequently determined that the higher incidence of SAT was related to the enrollment of high-risk subjects, statistical play of chance, and/or PCI technique with underdeployment of stents or use of a "crush" technique for bifurcation lesions. The randomization system for TRITON-TIMI 38 in South Africa was reactivated on July 11, 2005.

The protocol deviations that had the potential to influence efficacy or safety results are described in Table 43. These deviations occurred at similar rates between treatment groups, and were not thought to affect study outcome.

Table 43. Sponsor's Analysis: Summary of Protocol Violations Identified from the Clinical Database (TAAL)

	UA/NSTEMI		STEMI		All ACS	
Violation	**Prasugrel n**	**Clopidogrel n**	**Prasugrel n**	**Clopidogrel n**	**Prasugrel n**	**Clopidogrel n**
Inclusion/Exclusion Criteria (Fibrinolytic Therapy Outside of Specified Time Window Prior to Randomization (STEMI only))[a]	0	0	7	15	7	15
Study Drug (Late Administration of Loading Dose[b]	21	30	10	17	31	47
Excluded Medications (Concomitant Use of Open-Label Thienopyridine and Study Drug)[c]	213	222	74	77	287	299
Study Conduct (Randomization Based on Incorrect Strata (i.e. Subject presenting with UA/NSTEMI randomized in IVRS as STEMI or vice versa))	45	51	59	70	104	121
Study Conduct (Non-compliance for CK-MB Blood Samples)[c]	64	59	34	36	98	95

[a]Refers to subjects randomized within 24 hours after receiving fibrin-specific fibrinolytic therapy or randomized within 48 hours after receiving non-fibrin-specific fibrinolytic therapy.
[b]Defined as the administration of the loading dose > 1 hour after leaving the catheterization laboratory.
[c]Refers to subjects without at least one evaluable creatine kinase-myocardial band (CK-MB) measurement from the central laboratory prior to the end of percutaneous coronary intervention (one hour after leaving the catheterization laboratory) or not having at least 2 evaluable CK-MB measurements from the central laboratory taken after the end of PCI.
Reproduced from Sponsor, Clinical Study Report, Table TAAL.10.2, page 148 of 27024.

Site monitors performed 100% source data verification on at least the 1st, 3rd, and 5th subject and every 5th subject thereafter. As a result, at least 3785 subjects had source data verified. The significant protocol violations identified through this process are described in Table 44. None of these protocol violations were thought to significantly influence study outcome.

Table 44. Sponsor's Analysis: Number of Protocol Violations Identified by Site Monitoring (TAAL)

	UA/NSTEMI		STEMI		All ACS	
Violation	**Prasugrel n**	**Clopidogrel n**	**Prasugrel n**	**Clopidogrel n**	**Prasugrel n**	**Clopidogrel n**
Inclusion/Exclusion Criteria (High Risk of Bleeding, Hgb < 10 gm/dl)	1	7	0	3	1	10
Inclusion/Exclusion Criteria (Platelet Count < 100,000/mm^3)	0	2	1	1	1	3
Inclusion/Exclusion Criteria (Thienopyridine Use ≤ 5 Days Prior to Randomization)	6	16	6	5	12	21
Inclusion/Exclusion Criteria (International Normalized Ratio (INR) Known to be > 1.5 at the Time of Evaluation)	1	3	3	0	4	3
Study Drug (Administration of Wrong Kit)	11	15	8	4	19	19
Study Drug (Administration of Wrong Drug)	2	5	3	0	5	5
Study Drug (Administration of Expired Drug)	1	0	1	1	2	1

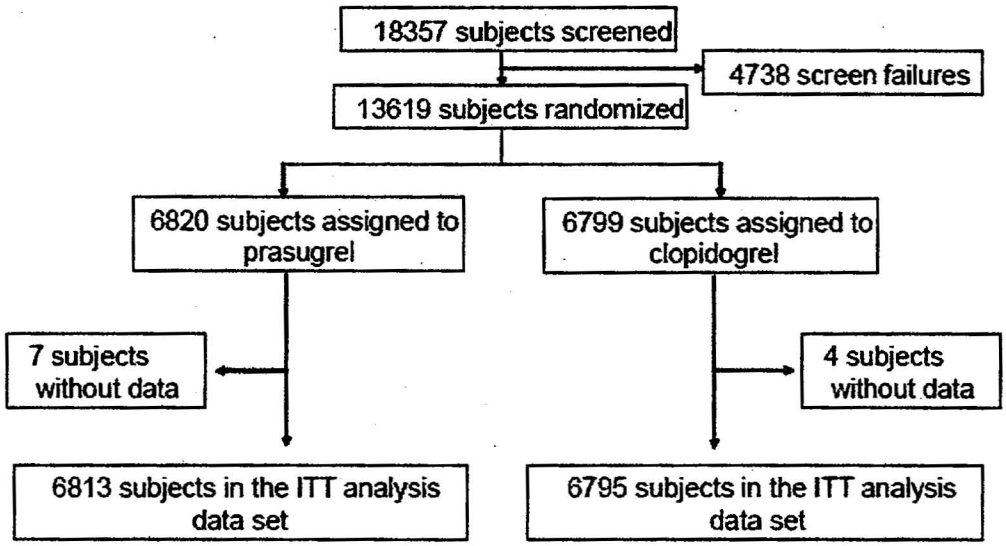
n=number of subjects with specified protocol violation.
Reproduced from Sponsor, Clinical Study Report, Table TAAL.10.3, page 150 of 27024.

9.1.11.3 Disposition of Subjects

A total of 13,619 subjects with ACS were randomized, including 6,799 subjects to clopidogrel (300 mg loading dose followed by once-daily 75 mg maintenance dose) and 6,820 subjects to prasugrel (60 mg loading dose followed by once-daily 10 mg maintenance dose). Subjects were treated until the subject's termination or 464 days from randomization, whichever was earlier. The maximum follow-up was 15 months.

Seven subjects randomly assigned to prasugrel and four subjects randomly assigned to clopidogrel were not included in the final analysis dataset due to an incomplete informed consent document. The remaining 13,608 subjects, including 6813 subjects in the prasugrel treatment group and 6795 subjects in the clopidogrel treatment group, comprised the intent-to-treat (ITT) analysis data set and were referred to as "All Randomized Subjects." Enrollment is summarized in Figure 26.

Figure 26. Enrollment of Subjects (TAAL)



(Reproduced from Sponsor, Figure TAAL. 10.1, page 138 of 27024)

Disposition of All Randomized Subjects is displayed in Table 45. In all populations, there were no significant differences between treatment groups.

Out of the 13,608 randomized patients, 13,457 subjects were treated, including 6741 in the prasugrel treatment group and 6716 subjects in the clopidogrel treatment group.

At the time of the index hospitalization, 6715 (98.56%) subjects underwent PCI in the prasugrel treatment group, including 5004 (99.21%) in the UA/NSTEMI population and 1711 (96.72%) in the STEMI population. In the clopidogrel treatment group, 6698 (98.57%) underwent PCI, including 4984 (99.09%) in the UA/NSTEMI population and 1714 (97.11%) in the STEMI population.

During the index hospitalization, 25 (0.37%) subjects in the prasugrel treatment group underwent CABG, including 16 (0.32%) in the UA/NSTEMI population and 9 (0.51%) in the STEMI population. In the clopidogrel treatment group, 23 (0.34%) subjects underwent CABG, including 12 (0.24%) in the UA/NSTEMI population and 11 (0.62%) in the STEMI population.

A total of 73 (1.07%) subjects in the prasugrel treatment group and 74 (1.09%) subjects in the clopidogrel treatment group were medically managed during the index hospitalization. In the UA/NSTEMI population, 24 (0.48%) and 34 (0.68%) subjects in the prasugrel and clopidogrel treatment groups, respectively, did not undergo revascularization. In the STEMI population, 49 (2.77%) and 40 (2.27%) in the prasugrel and clopidogrel treatment groups did not undergo revascularization.

From index hospitalization to study end, 213 subjects in the prasugrel treatment group underwent CABG, including 180 elective and 33 urgent surgeries. In the clopidogrel treatment group, 224 subjects underwent CABG, including 186 elective and 38 urgent surgeries.

Table 45. Sponsor's Analysis: Subject Disposition (All Randomized Subjects) (TAAL)

Subject Population	Disposition	Prasugrel n (%[a])	Clopidogrel n (%[a])	Total n (%[a])	OR (95% CI)[b]	p-value[b]
UA/NSTEMI	**Randomized**	**5044**	**5030**	**10074**		
	Protocol Completed	4766 (94.49)	4760 94.63)	9526 (94.56)	0.972 (0.819, 1.155)	0.750
	Protocol Completed Alive	4635 (91.89)	4639 (92.23)	9274 (92.06)	0.955 (0.827, 1.104)	0.534
	Died	131 (2.60)	121 (2.41)	252 (2.50)	1.082 (0.842, 1.389)	0.538
	Not Completed	278 (5.51)	270 (5.37)	548 (5.44)	1.028 (0.866, 1.222)	0.750
	Withdrawal of Consent	228 (4.52)	217 (4.31)	445 (4.42)	1.050 (0.868, 1.270)	0.615
	Less than Minimum Expected Follow-Up	7 (0.14)	6 (0.12)	13 (0.13)	1.164 (0.391, 3.465)	0.785
	Alive but Unable to Attend Study Termination Visit	37 (0.73)	35 (0.70)	72 (0.71)	1.055 (0.663, 1.677)	0.822
	Lost to Follow-Up	6 (0.12)	9 (0.18)	15 (0.15)	0.664 (0.236, 1.868)	0.435
	Other	0	3 (0.06)	3 (0.03)		NE
STEMI	**Randomized**	**1769**	**1765**	**3534**		
	Protocol Completed	1637 (92.54)	1641 (92.97)	3278 (92.76)	0.937 0.727, 1.209)	0.617
	Protocol Completed Alive	1579 (89.26)	1565 (88.67)	3144 (88.96)	1.062 (0.860, 1.311)	0.575
	Died	58 (3.28)	76 (4.31)	134 (3.79)	0.753 (0.532, 1.067)	0.110
	Not Completed	132 (7.46)	124 (7.03)	256 (7.24)	1.067 (0.827, 1.376)	0.617
	Withdrawal of Consent	114 (6.44)	106 (6.01)	220 (6.23)	1.078 (0.820, 1.417)	0.589
	Less than minimum Expected Follow-Up (< 166 days)	2 (0.11)	1 (0.06)	3 (0.08)		NE
	Alive but Unable to Attend Study Termination Visit	16 (0.90)	16 (0.91)	32 (0.91)	0.998 (0.497, 2.001)	0.995
	Lost to Follow-Up	0	1 (0.06)	1 (0.03)		NE
	Other	0	0	0		NE
All ACS	**Randomized**	**6813**	**6795**	**13,608**		
	Protocol Completed	6403 (93.98)	6401 (94.20)	12804 (94.09)	0.961 (0.833, 1.109)	0.587
	Protocol Completed Alive	6214 (91.21)	6204 (91.30)	12418 (91.26)	0.988 (0.877, 1.113)	0.845
	Died	189 (2.77)	197 (2.90)	386 (2.84)	0.956 (0.780. 1.170)	0.660
	Not Completed	410 (6.02)	394 (5.80)	804 (5.91)	1.040 (0.902, 1.200)	0.587
	Withdrawal of Consent	342 (5.02)	323 (4.75)	665 (4.89)	1.059 (0.906, 1.238)	0.471
	Less than minimum Expected Follow-Up (< 166 days)	9 (0.13)	7 (0.10)	16 (0.12)	1.283 (0.477, 3.446)	0.621
	Alive but Unable to Attend Study Termination Visit	53 (0.78)	51 (0.75)	104 (0.76)	1.037 (0.705, 1.525)	0.854
	Lost to Follow-Up	6 (0.09)	10 (0.15)	16 (0.12)	0.598 (0.217, 1.646)	0.314
	Other	0	3 (0.04)	3 (0.02)		NE

CI=confidence interval, n=number of subjects, OR=odds ratio, NE=not evaluated due to insufficient data.
[a]% is percent of randomized subjects
[b]Two-sided p-value based on Pearson chi-square test. The two-sided p-value and odds ratio for All ACS were adjusted for clinical presentation as a stratification factor using Cochran-Mantel-Haenszel method.
Reproduced from Sponsor, Clinical Study Report, Table TAAL 10.1, pages 141-143 of 27024.

Two subjects who were considered lost-to-follow-up in the analysis data set were located after the database lock on September 20, 2007. One subject, randomly assigned to prasugrel, had experienced an adjudicated MI prior to being considered lost-to-follow-up. The other subject had been randomly assigned to clopidogrel. Therefore, final clinical status was obtained for 13594 subjects (99.9%) and not 13592 subjects (99.9%).