XIENCE PRIME Everolimus Eluting Coronary Stent System (EECSS) China

Post-Approval, Single-Arm Study

Statistical Analysis Plan

Medical Research & Biometrics Center

National Center for Cardiovascular Diseases

26 May 2014

Statistical Analysis Plan

Protocol Number:	12-396
Name of Test Device:	XIENCE PRIME EECSS
Phase:	Post-Marketing
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SIGNATURE PAGE

Protocol Title: XIENCE PRIME Everolimus Eluting Coronary Stent System (EECSS) China:Post-Approval, Single-Arm Study

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1. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
ACC	American College of Cardiology
AE	Adverse Event
AHA	American Heart Association
ARC	Academic Research Consortium
AV	Abbott Vascular
CABG	Coronary Artery Bypass Graft
CAD	Coronary Artery Disease
CFDA	China Food and Drug Administration
CHD	Coronary Heart Disease
CK	Creatine Kinase
CK-MB	Creatine Kinase Myocardial-Band Isoenzyme
CSS	Coronary Stent System
CVD	Cardiovascular Disease
DES	Drug-eluting Stent
DS	Diameter Stenosis
EC	Ethics Committee
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
EECSS	Everolimus Eluting Coronary Stent System
FFR	Function Flow Reserve
GUSTO	Global Use of Strategies to Open Occluded Coronary Arteries
HbA_{1c}	Hemoglobin A_{1c}(glycated hemoglobin)
ICF	Informed Consent Form
ID	Ischemia-Driven
LAD	Left Anterior Descending Artery
LCX	Left Circumflex Artery
MI	Myocardial Infarction
PAS	Post-Approval Study
PCI	Percutaneous Coronary Intervention
RCA	Right Coronary Artery
SAE	Serious Adverse Event
SAS	Single-arm Study
SC	Study Completion
ST	Stent Thrombosis
TIMI	Thrombosis in Myocardial Infarction Flow
TLF	Target Lesion Failure
TLR	Target Lesion Revascularization
TVF	Target Vessel Failure
TVR	Target Vessel Revascularization

2. INTRODUCTION

Abbott Vascular (AV) obtained marketing approval for the XIENCE PRIME Everolimus Eluting Coronary Stent System (XIENCE PRIME EECSS) in China from the China Food and Drug Administration (CFDA) on August 10th, 2011.

This prospective, observational, open-label, multi-center, single-arm, post-approval study is designed to: Evaluate the continued safety and effectiveness of the XIENCE PRIME EECSS in a cohort of real-world patients receiving the XIENCE PRIME EECSS during commercial use in real-world settings in China

3. STUDY OBJECTIVES

The study will evaluate the continued safety and effectiveness of the XIENCE PRIME EECSS in a cohort of real-world patients receiving the XIENCE PRIME EECSS during commercial use in real-world settings in China

4. STUDY DESIGN

4.1. Study Design

XIENCE PRIME China is a prospective, observational, open-label, multi-center, single-arm, post-approval study (PAS).

4.2. Number of Patients to Be Registered

Approximately 2000 patients at approximately 45 sites across China will be consecutively enrolled in this study. Only patients who agree to participate by signing the informed consent form (ICF) and who will have or have received only XIENCE PRIME stents during the index procedure are eligible to be registered.

4.3. Patient Treatment

4.3.1. Baseline

1) Baseline Laboratory Assessments

Baseline laboratory data may be collected up to 4 weeks prior to the index procedure as appropriate. If multiple assessments are performed within 4 weeks prior to the index procedure, the most recent assessment value, or clinical significant findings should be included with the baseline information. In the event that the laboratory data (excluding cardiac biomarkers and electrocardiogram) is not available within the baseline window, it is strongly suggested that it be collected after the index procedure or before hospital discharge, but no later than 7 days post procedure.

The following baseline laboratory assessments will be collected:
- Lipid profile (low-density lipoprotein, high-density lipoprotein, triglycerides, and total cholesterol)
- Serum insulin, serum creatinine, serum fasting glucose, and glycated hemoglobin (HbA1c)
- For female subjects of childbearing potential, a urine pregnancy test will be performed according to hospital standard of care.

2) Patient History

The following medical history data will be collected at baseline (including, but no limited to):
- Demographics, including age and gender
- Cardiac history including Canadian Cardiovascular Society and Braunwald classifications of angina, Acute Coronary Syndrome, prior MI, and previous CABG and PCI
- Physical measurements, including weight, height, and current left ventricular ejection fraction
- Other risk factors, including stroke, diabetes mellitus, hypertension, dyslipidemia, renal insufficiency, anemia, tobacco use, and family history of premature coronary artery disease (CAD)

Any baseline medical history data that is not collected within 4 weeks prior to the index procedure may be obtained up to 7 days post procedure and will still be considered baseline data.

4.3.2. Pre-procedure

The following pre-procedural assessments will be collected within 72 hours prior to the procedure:
- Creatine kinase (CK), creatine kinase myocardial-band isoenzyme (CK-MB), and/or troponin I/T (the most recent assessment)
- Electrocardiogram (ECG)

4.3.3. Index Procedure

The following data will be collected (including, but no limited to):

1) Procedural Information:
- Stent use attributes (eg, size, diameter, overlapping, and number of stents)
- Lesion characteristics (ACC/AHA Classification Scheme of Coronary Lesions)
- All reportable adverse events (AEs)

2) Bailout Stenting or Alternative Procedures:
- If bailout stenting is needed during the index procedure and the patient wants to continue to be registered in the study, the bail-out stent(s) must be XIENCE PRIME stents.
- If planned staged procedure patients receive stents other than XIENCE PRIME stent during their follow-up procedure(s), they will still remain in the study.

4.3.4. Post-procedure

1) Post-procedural Information:
- All reportable AEs

2) Post-procedural Laboratory Assessment:

The following post-procedure cardiac biomarkers and ECG will be collected between 12 hours post procedure and the time of hospital discharge. For those patients with prolonged hospital stays, it is recommended that the assessment be conducted no later than 72 hours post procedure.
- CK, CK-MB, and/or troponin I/T
- Electrocardiogram (ECG)

4.3.5. Schedule of Events

Refer to Appendix IV Schedule of Events in the study protocol.

4.4. Patient Follow-up

Clinical follow-ups will occur as either hospital/office visits (preferable) or telephone contacts at 1, 2, 3, 4, and 5 years. The time window is ±42 days.

Data involving the following events will be collected at the specified time points and at any additional event-driven visits:
- All reportable AEs
- Dual antiplatelet therapy (aspirin, thienopyridine)

5. STUDY VARIABLES AND ENDPOINTS

5.1. Demographic and Baseline Characteristics

Demographic and baseline data may be collected up to 4 weeks prior to the index procedure. If multiple assessments are performed within 4 weeks prior to the index procedure, the most recent assessment value should be included with the baseline information. Any baseline medical history data (excluding cardiac biomarkers) that is not collected within 4 weeks prior to the index procedure may be obtained up to 7 days post procedure and will still be considered baseline data.

Demographic variables:

- Age (in years) to be derived as: (Date of the index procedure – Date of birth)/365.25
- Gender at birth (male, female)
- Height (cm)
- Weight (kg)
- BMI (kg/m^2) to be derived as: (Weight in kg)/(Height in meter)^2

Risk factors and medical history:

- Dyslipidemia
- Hypertension
- Family history of premature Coronary Artery Disease (CAD)
- Tobacco use
- Diabetes mellitus
- Chronic Obstructive Pulmonary Disease (COPD)
- Prior/current Peripheral Artery Diseases (PAD)
- Heart failure
- Renal Insufficiency
- Anemia
- Stroke
- Non-coronary heart disease
- Cancer
- History of recreational drug use/abuse
- History of alcohol abuse
- Previous Myocardial Infarction (prior MI)
- History of coronary intervention
- Current evidence of ischemia
- Acute myocardial infarction (AMI)
- Braunwald unstable angina classification (Class I - III)
- Canadian Cardiovascular Society angina classification (Class I - IV)
- Acute Coronary Syndrome (ACS)
- Left Ventricular Ejection Fraction (LVEF)

Cardiac Enzymes Assessments

- CK Measurement Obtained
- Abnormal CK value (yes or no) , yes=value > normal upper limit
- CK-MB Measurement Obtained
- Abnoraml CK-MB value (yes or no) , yes=value > normal upper limit
- Troponin I or T Measurement Obtained
- Abnoraml Troponin value (yes or no)

5.2. Procedure Records

Index Procedure Records

- Time of Index Procedure Used (index procedure end date and time - index procedure start date and time)
- Total Number of Lesions Treated (Does not include lesion to be treated during Staged Procedure)
- Subject Received any GP IIb/IIIa Inhibitor
- Only XIENCE PRIME EECS Stent(s) Inserted Beyond the Guide Catheter
- Access Site Location (femoral, brachial, radial, or other)
- Access Site Side (left, right)
- Staged Procedure Planned

Loading Doses for Anti-Platelet Medications (pre or during procedure)

- Subject Received Loading Dose of Aspirin per Site Standard or under chronic treatment
- Aspirin Dose (mg)
- Subject Received Loading Dose of Clopidogrel per Site Standard or under chronic treatment
- Clopidogrel Dose (mg)
- Subject Received Ticlopidine per Site Standard
- Ticlopidine dose (mg)
- Subject Received Loading Dose of Other Anti-Platelet Medication per Site Standard or under chronic treatment
- Other Anti-Platelet Medication dose (mg)

Antiplatelet Medications

- Antiplatelet Medication (Aspirin, Clopidogrel, Ticlopidine and Other)
- Medication Start Date
- Medication Stopped/Ongoing
- Medication Stope Date

Target Lesion Information

- Procedure type (index procedure or staged procedure)
- Quantitative Vessel Measurement Done
- Lesion location within CASS segment
- Lesion length (mm)
- Reference Vessel Diameter (mm)
- Diameter Stenosis Prior to Any Treatment (%)
- TIMI Flow Prior to Wire Crossing
- Thrombus
- Tortuosity
- Calcification
- Contour
- AHA/ACC Classification (A, B1, B2, C)
- Bend (Angle) (None, Moderate, Severe)
- Bifurcation
- Lesion Pre-dilatation Done
- Final Diameter stenosis (%)
- Total Number of Device Implanted
- Name of Device Implanted
- Device Diameter (mm)
- Device Length (mm)
- Maximum device balloon pressure during device implate (atm)
- Post-device Dilatation Done

5.3. Patient with DAPT Usage

The DAPT usage is assessed at 1, 2, 3, 4 and 5 years. The DAPT usage will include but will not limited to:

- the number of patients on DAPT at a certain visit

5.4. Key Endpoints

The following key site reported endpoints are assessed at 1, 2, 3, 4, and 5 years:

- Composite rate of cardiac death and all myocardial infarction (MI) (Q-wave and non–Q-wave)
- Composite rate of all death and any myocardial infarction (MI) (Q-wave and non–Q-wave)
- Target lesion failure (TLF): the composite rate of cardiac death, target vessel MI (TV-MI), and ischemia-driven target lesion revascularization (ID-TLR)
- Target vessel failure (TVF): the composite rate of cardiac death, all MI, and ischemia-driven target vessel revascularization (ID-TVR)
- Stent thrombosis (definite and probable, per Academic Reasarch Consortium [ARC] definition)
- Death (cardiac, vascular, and non-cardiovascular)
- Any MI (including Q-wave and non–Q-wave)
- Revascularization (target lesion, target vessel, and non-target vessel) (PCI and Coronary Artery Bypass Graft [CABG])

The clinical endpoints described above are direct measurement of safety and effectiveness of coronary stent implantation.

5.5. Adverse Events

The variables related to reportable AEs include:

- AE term
- SAE or not
- Days to event (AE start date - index procedure date)
- Outcome of Adverse Event
- Related to Study Device (not related, possible, unknown)
- Action and/or Treatment

6. PATIENT POPULATION

6.1. Disposition of Patients

A total of approximately 2000 patients will be consecutively registered at up to 45 sites in China.

6.1.1. Patient Screening

Patients admitted for PCI, and who will have or have had the XIENCE PRIME EECSS implanted should be invited to participate in the study. Once informed consent is obtained, patient's data is to be entered into the electronic Case Report Form (eCRF) screening log.

6.1.2. Eligibility Criteria

6.1.2.1. Inclusion Criteria

- The patient must be at least 18 years of age at the time of signing the informed consent.
- The patient or his/her legally-authorized representative signs the EC-approved ICF.
- Only XIENCE PRIME stent(s) is (are) implanted during the index procedure.

6.1.2.2. Exclusion Criteria

No other exclusion criteria are specified for this study.

6.1.3. Point of Registration

The enrollment service must be called after both of the following conditions have been met:

- A patient or patient's legally-authorized representative has provided an EC approved, signed and dated ICF.
- Only XIENCE PRIME stent(s) is/are implanted in the coronary vasculature during the index procedure.

6.1.4. Patient Deregistration

This study will consecutively register all consenting patients who have met these eligibility criteria. If a patient received a stent other than the XIENCE PRIME stent (including any bail-out stents) during the index procedure and is thus not eligible to be registered into the study, this patient is to be de-registered.

A de-registered patient will not undergo the protocol follow-up regimen or follow-up by the study team. De-registered patients may be replaced until the total number of required patients for the study is reached.

6.1.5. Patient Discontinuation

Each registered patient should remain in the clinical trial until the required follow-up periods are complete. The patient has the right to withdraw from the study at any time without penalty or loss of benefit. Possible reasons for patient discontinuation may include, but are not limited to:

- Patient death
- Patient voluntary withdrawal
- Patient withdrawn by Investigator
- Patient lost to follow-up
- Study is terminated

6.2. Per Protocol Set

The Per Protocol Set (PPS) will be used for the primary analysis. The PPS consist of all patients registered in the study who received only XIENCE PRIME stents during the index procedure. All of the descriptive analysis will be based on the PPS. A flow chart is followed to make the determination of PPS clear.

If a patient misses one of the follow-ups but returns for the next, the previous visit will be considered a missed visit.

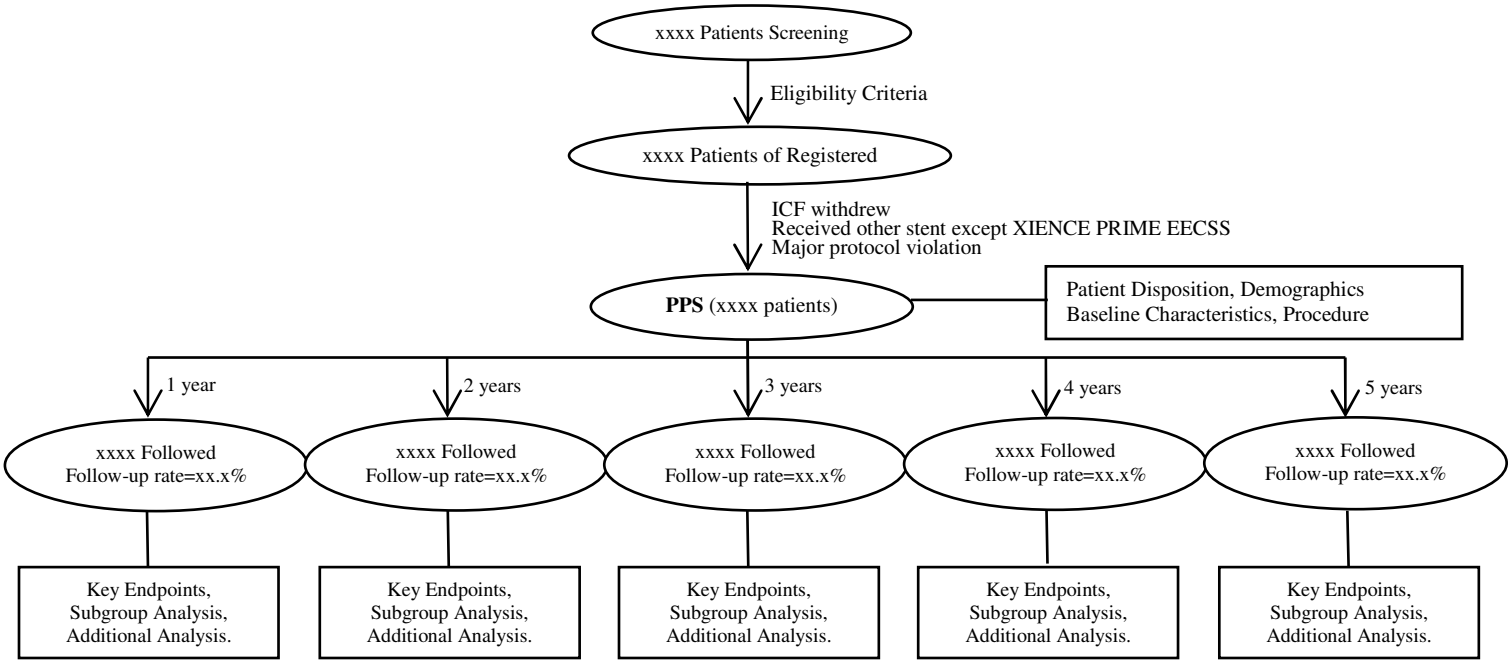
If a patient misses 2 consecutive follow-ups and attempts to contact the patient are unsuccessful, the patient will be considered lost to follow-up.

If a patient considered lost to follow-up subsequently returns for a visit or contacts the research personnel to provide an update, this patient should no longer be considered lost to follow-up and should be returned to the study.

The number of patients followed at each year will be used as the denominator for event rate calculation, respectively. This number will equal to the size of PPS minus the number of patients who lost to follow-up at a certain visit. It should notice that if the patient experienced some major key endpoint such as all death, all MI, all revascularization, or stent thrombosis event in the previous visit, he/she will not be excluded from the denominator even if he/she was lost to follow-up at the current visit.

Patients who have officially withdrawn or been withdrawn by the Investigator from the study are not considered lost to follow-up

Above information about dropout and withdraw will be recorded in the Study Completion (SC) Case Report Form.



7. STATISTICAL METHODS

7.1. Sample Size Calculations and Assumptions

Approximately 2000 patients will be consecutively registered into the study from the general Chinese interventional cardiology population. The sample size of 2000 is based on CFDA's requirements for post approval studies, but not based on statistical hypothesis testing.

No pre-specified hypothesis tests are planned for this study.

7.2. General Considerations

7.2.1. General Methods

All analyses will be performed using SAS statistical software (Version 9.3 or higher), unless otherwise noted. In case that any parameters need to be derived, an independent programmer will verify that calculated variables (e.g., age, height or weight conversions) are correct. The program review also will include a check whether analyses conform to specifications of the Statistical Analysis Plan. All output will be incorporated into Word files, and formatted as to the appropriate page sizes.

For categorical variables such as ST, Death and MI, results will be summarized with patient counts, percentages, and exact 95% Clopper-Pearson confidence internal for the percentages. For continuous variables such as age, results will be summarized with the numbers of observations (N), means, standard deviations (SD), median, the 25th percentile (Q1), the 75th percentile (Q3), the minimum and the maximum, and 95% confidence internal for the means. These calculations will be done under the assumption that the data are approximately normal in distribution. For time-to-event variables, such as time to TLF, survival curves may be constructed using Kaplan-Meier estimates, and log rank test results for subgroup analysis will be displayed for descriptive purposes only.

7.2.2. Procedures for Accounting for Missing, Unused or Spurious Data

All analyses will be based on available data with missing data excluded. Any unused or spurious data will ve noted as appropriate in report.

7.3. Patient Disposition, Demographics and Baseline Characteristics

Patient disposition in each site will be presented including number of enrollment, early termination as well as study completion, and size of PPS in excel document attached.

The summary of demographics and baseline characteristic previously described in section 5.1 will be performed based on PPS. Baseline characteristic variables include risk factors baseline laboratory assessments, medical history, cardiac history and status and baseline lesion characteristics.

7.4. Procedure Records

The summary of procedure records previously described in section 5.2 will be performed based on PPS. Procedure records include index procedure records, loading doses for anti-platelet medications (pre or during procedure), treated lesion information and stent implant details.

7.5. Post-Procedural Assessments

The summary of post-procedural assessments previously described in section 5.3 will be performed based on PPS. Variables related to post-procedural assessments are about post-procedural cardiac biomarkers. .

7.6. Antiplatelet Medications

The summary of antiplatelet medication status in 5 years previously described in section 5.4 will be performed based on PPS. Information of antiplatelet medications use includes antiplatelet medication dosage for index procedure and post-procedure, dual antiplatelet therapy interruption.

7.7. Key Endpoints Analysis

Rate and confidence intervals will be summarized descriptively for key endpoints previously described in section 5.5 based on PPS. Key endpoints will be assessed at 1, 2, 3, 4, and 5 years respectively.

7.8. Adverse Events

The summary of adverse events will be performed based on PPS. Adverse Events will be presented including subject number, age, gender, event term, SAE or not, days to event, outcome, relationship to study device (not related, possible, unknown), action and/or treatment, etc.

8. STATISTICAL TABLES AND LISTINGS TO BE GENERATED

Table 1: Baseline Demographics - Per Subject Analysis
(Based on Data Extracted on xx/xx/xxxx)
(Per-Protocol Set)

	XIENCE PRIME (N=xxxx)
Age	
Mean±SD(N)	xx.xx±xx.xx(xxx)
Median	xx.xx
Q1 : Q3	xx.xx : xx.xx
Min : Max	xx.xx : xx.xx
[95% Confidence Interval][1]	[xx.x, xx.x]
Age Group	
– <65 years	xx.x% (xx/xxxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
– ≥65 years	xx.x% (xx/xxxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
Sex	
– Male	xx.x% (xx/xxxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
– Female	xx.x% (xx/xxxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]

[1] By normal approximation.
[2] By Clopper-Pearson exact confidence interval.
Note: Q1: the 25th percentile Q3: the 75th percentile

Table 2: Physical measurements - Per Subject Analysis

(Based on Data Extracted on xx/xx/xxxx)
(Per-Protocol Set)

	XIENCE PRIME (N=xxxx)
Height (cm)	
Mean±SD(N)	xx.xx±xx.xx(XXX)
Median	xx.xx
Q1 : Q3	xx.xx : xx.xx
Min : Max	xx.xx : xx.xx
[95% Confidence Interval][1]	[xx.x, xx.x]
Weight (kg)	
Mean±SD(N)	xx.xx±xx.xx(xxx)
Median	xx.xx
Q1 : Q3	xx.xx : xx.xx
Min : Max	xx.xx : xx.xx
[95% Confidence Interval][1]	[xx.x, xx.x]
BMI (kg/m^2)	
Mean±SD(N)	xx.xx±xx.xx(xxx)
Median	xx.xx
Q1 : Q3	xx.xx : xx.xx
Min : Max	xx.xx : xx.xx
[95% Confidence Interval][1]	[xx.x, xx.x]
BMI Group	
– <18.5	xx.x% (xx/xxxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
– ≥18.5 - <24	xx.x% (xx/xxxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
– ≥24 - <28	xx.x% (xx/xxxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
– ≥28	xx.x% (xx/xxxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]

[1] By normal approximation.
[2] By Clopper-Pearson exact confidence interval.
Note: Q1: the 25th percentile Q3: the 75th percentile

Table 3: Baseline Risk Factors and Medical History - Per Subject Analysis

(Based on Data Extracted on xx/xx/xxxx)
(Per-Protocol Set)

	XIENCE PRIME (N=xxxx)
Dyslipidemia	
– No lipid disorder	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
– Lipid disorder requiring medication	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
– Lipid disorder not requiring medication	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Hypertension	
– No Hypertension	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
– Hypertension Requiring Medication	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
– Hypertension not Requiring Medication	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Family history of Premature Coronary Artery Disease (CAD)	
– No family history of premature CAD	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
– Family history of premature CAD	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
– Family history not available	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Tobacco Use	
– Never used tobacco	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Former tobacco user, quit over 1 month ago	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Current tobacco user or former tobacco user, quit within the past month	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]

	XIENCE PRIME (N=xxxx)
Diabetes Mellitus	
– No Diabetes Mellitus	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Unkown	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Diabetes Mellitus	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Type I diabetes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Type II diabetes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
Chronic Obstructive Pulmonary Disease (COPD)	
– Yes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
Prior/Current Peripheral Artery Disease (PAD)	
– Yes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
Heart Failure	
– Yes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
Renal Insufficiency	
– Yes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]

	XIENCE PRIME (N=xxxx)
Anemia	
– Yes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
Stroke	
– Yes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
Non-coronary heart disease	
– Yes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
Cancer	
– Yes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
History of Recreational Drug Use/Abuse	
– Yes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
History of Alcohol Abuse	
– Yes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]

	XIENCE PRIME (N=xxxx)
Small Vessel[2]	
– Yes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
Long Lesion[3]	
– Yes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]

[1] By Clopper-Pearson exact confidence interval.
[2] Small vessel: reference vessel diameter ≤2.5 mm
[3] Long lesion: length>28mm

Table 4: Cardiac History - Per-Subject Analysis

(Based on Data Extracted on xx/xx/xxxx)
(Per-Protocol Set)

	XIENCE PRIME (N=xxxx)
History of Previous MI	
– Yes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
History of Coronary Interventions	
– Yes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Brachytherapy	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– CABG	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– PTCA with metallic stent	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– PTCA alone	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– PTCA with unknown stent type	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– PTCA with adjunctive device other than stent	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– PTCA with drug eluting stent	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
Coronary interventions performed on the target vessel(s)	
– Yes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]

	XIENCE PRIME (N=xxxx)
Current Evidence of Ischemia	
– AMI	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Unstable angina	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Stable angina	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Silent ischemia	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Abnormal Fractional Flow Reserve(FFR)	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No current evidence of ischemia	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
Acute Myocardial Infarction (AMI)	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– ST-elevation MI (STEMI)	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Non-ST-elevation MI (NSTEMI)	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Not applicable	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
Unstable Angina	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
Braunwald Classification	
– Class I	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Class II	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Class III	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
Stable Angina	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
Canadian Cardiovascular Society Angina Classification	
– Class I	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Class II	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Class III	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Class IV	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
No Current Evidence of Ischemia	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Angiographic stenosis	xx.x% (xx/xxxx)
[95% Confidence Interval]1	[xx.x, xx.x]
– Other indications	xx.x% (xx/xxxx)
[95% Confidence Interval]1	[xx.x, xx.x]

	XIENCE PRIME (N=xxxx)
Acute Coronary Syndrome (ACS)	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Yes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
Left Ventricular Ejection Fraction (LVEF)	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– Yes	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– No	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
Left Ventricular Ejection Fraction(LVEF)	
Mean±SD(N)	xx.xx±xx.xx(xxx)
Median	xx.xx
Q1 : Q3	xx.xx : xx.xx
Min : Max	xx.xx : xx.xx
[95% Confidence Interval][2]	[xx.x, xx.x]
LVEF (%) Group	
– <30	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– ≥30 - < 40	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]
– ≥40	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x, xx.x]

[1] By Clopper-Pearson exact confidence interval.
[2] By normal approximation.

Table 5: Procedure Information- Per Procedure Analysis

(Based on Data Extracted on xx/xx/xxxx)
(Per-Protocol Set)

	XIENCE PRIME Index Procedure (N=xxxx) (P=xxxx)
Procedure Duration (min)	
Mean ± SD (n)	xx.x ± xx.x (xx)
Median	xx.x
(Q1, Q3)	(xx.x, xx.x)
Range (min, max)	(xx.x, xx.x)
[95% Confidence Interval][1]	[xx.x, xx.x]
Only XIENCE PRIME Stent(s) Inserted	xx.x% (xx/xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
Total Number of Target Lesion(s) Treated	
Mean ± SD (n)	xx.x ± x.x (xxx)
Median	xx.x
(Q1, Q3)	(xx.x, xx.x)
Range (min, max)	(xx, xx)
[95% Confidence Interval][1]	[xx.x, xx.x]
1 Target Lesion	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
2 Target Lesions	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
3 or more Target Lesions	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
Access Site Location	
– Femoral	xx.x% (xx/xxx)
[95% Confidence Interval][2]	xx.x% (xx/xxx)
– Radial	xx.x% (xx/xxx)
[95% Confidence Interval][2]	xx.x% (xx/xxx)
– Brachial	xx.x% (xx/xxx)
[95% Confidence Interval][2]	xx.x% (xx/xxx)
– Other	xx.x% (xx/xxx)
[95% Confidence Interval][2]	xx.x% (xx/xxx)
Access Site Side	
– Right	xx.x% (xx/xxx)
[95% Confidence Interval][2]	xx.x% (xx/xxx)
– Left	xx.x% (xx/xxx)
[95% Confidence Interval][2]	xx.x% (xx/xxx)
Hospitalization Duration (days)	
Mean ± SD (n)	xx.x ± xx.x (xx)
Median	xx.x
(Q1, Q3)	(xx.x, xx.x)
Range (min, max)	(xx.x, xx.x)
[95% Confidence Interval][1]	[xx.x, xx.x]
Staged Procedure Planned	xx.x% (xx/xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]

[1] By normal approximation.
[2] By Clopper-Pearson exact confidence interval.

Table 6: Drug Administered During the Index Procedure - Per Procedure Analysis

(Based on Data Extracted on xx/xx/xxxx)
(Per-Protocol Set)

	XIENCE PRIME Index Procedure (N=xxxx) (P=xxx)
Antiplatelet/Anticoagulant/Anti-thrombotic Administered During Procedure	
Yes	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
No	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
GP IIb/IIIa Inhibitor	
Yes	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
No	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Bivalirudin	
Yes	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
No	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Low Molecular Weight Heparin	
Yes	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
No	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Unfractionated Heparin	
Yes	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
No	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Other	
Yes	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
No	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]

[1] By normal approximation.
Note : N is the number of subjects; P is the total number of procedures.

Table 7: Baseline Lesion Characteristics - Per Lesion Analysis

(Based on Data Extracted on xx/xx/xxxx)
(Per-Protocol Set)

Baseline Lesion Charateristics	XIENCE PRIME Index Procedure (N=xxxx) (L=xxx)
Treated Lesion Type	
De novo	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Restenosis	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Restenosis with Prior Treatment	
– Drug Eluting Stent	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
– Metallic Stent	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
– Other	xx.x% (xx/xxxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Target Vessel	
RCA	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
LAD	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
LCX	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
LMCA	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Graft	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Ostial Lesion	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
TIMI Flow Prior to Any Treatment	
TIMI 0	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
TIMI 1	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
TIMI 2	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
TIMI 3	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Thrombus	
Present	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Absent	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Tortuosity	
None	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Moderate	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Severe	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]

Baseline Lesion Charateristics	**XIENCE PRIME Index Procedure (N=xxxx) (L=xxx)**
Calcification	
No Calcification	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Mild	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Moderate	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Severe	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Contour	
Smooth	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Irregular	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
AHA/ACC Classification	
A	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
B1	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
B2	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
C	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Bend (Angle)	
None (<45 degrees)	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Moderate (45 -89 degrees)	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Severe (≥90 degrees)	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
Bifurcation Lesion	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]

[1] By Clopper-Pearson exact confidence interval.
Note: N is the total number of subjects; L is the total number of lesions.

Table 8: Lesion Measurement by Physician Visual Estimation - Per Lesion Analysis

(Based on Data Extracted on xx/xx/xxxx)
(Per-Protocol Set)

Lesion Measurement by Physician Visual Estimation	XIENCE PRIME Index Procedure (N=xxxx) (L=xxx)
Lesion Length (mm)	
Mean ± SD (L)	xx.x ± x.x (xxx)
Median	xx.x
(Q1, Q3)	(xx.x, xx.x)
Range (min, max)	(xx.x, xx.x)
[95% Confidence Interval][1]	[xx.x, xx.x]
< 10 mm	xx.x% (xx/xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
10 – 20 mm	xx.x% (xx/xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
> 20 mm	xx.x% (xx/xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
Reference Vessel Diameter (mm)	
Mean ± SD (L)	xx.x ± x.x (xxx)
Median	xx.x
(Q1, Q3)	(xx.x, xx.x)
Range (min, max)	(xx.x, xx.x)
[95% Confidence Interval][1]	[xx.x, xx.x]
Diameter Stenosis, Prior to Any Treatment (%)	
Mean ± SD (L)	xx.x ± x.x (xxx)
Median	xx.x
(Q1, Q3)	(xx.x, xx.x)
Range (min, max)	(xx.x, xx.x)
[95% Confidence Interval][1]	[xx.x, xx.x]
Final Diameter Stenosis (%)	
Mean ± SD (L)	xx.x ± x.x (xxx)
Median	xx.x
(Q1, Q3)	(xx.x, xx.x)
Range (min, max)	(xx.x, xx.x)
[95% Confidence Interval][1]	[xx.x, xx.x]

[1] By normal approximation.
[2] By Clopper-Pearson exact confidence interval.
Note: N is the total number of patients; L is the total number of lesions.

Table 9: Target Lesion Characteristics - Per Subject Analysis

(Based on Data Extracted on xx/xx/xxxx)
(Per-Protocol Set)

	XIENCE PRIME Index Procedure (N=xxxx) (L=xxx)
Number of Target Lesion per Subject	
Mean±SD	xx.xx±xx.xx
Median	xx.xx
Q1 : Q3	xx.xx : xx.xx
Min : Max	xx.xx : xx.xx
[95% Confidence Interval][2]	[xx.x%, xx.x%]
1 Lesion	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
2 Lesions	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]
3 Lesions or more	xx.x% (xx/xxx)
[95% Confidence Interval][1]	[xx.x%, xx.x%]

[1] By Clopper-Pearson exact confidence interval.
[2] By normal approximation.
Note: N is the total number of patients; L is the total number of lesions.

Table 10: Study Stent Usage - Per Subject Analysis

(Based on Data Extracted on xx/xx/xxxx)
(Per-Protocol Set)

	XIENCE PRIME Index Procedure (N=xxxx)
Number of Implanted Study Stents per Subject	
Mean ± SD (n)	xx.x ± x.x (xxx)
Median	xx.x
(Q1, Q3)	(xx.x, xx.x)
Range (min, max)	(xx, xx)
[95% Confidence Interval][1]	[xx.x, xx.x]
One Study Stent	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
Two Study Stents	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
Three Study Stents or more	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
Length of Total Implanted Study Stents	
Mean ± SD (n)	xx.x ± x.x (xxx)
Median	xx.x
(Q1, Q3)	(xx.x, xx.x)
Range (min, max)	(xx, xx)
[95% Confidence Interval][1]	[xx.x, xx.x]

[1] By normal approximation.
[2] By Clopper-Pearson exact confidence interval.
Note: N is the total number of patients
Note: There are xx misplaced study stents.
Note: This table includes all implanted study stents during index procedure.

Table 11: Total Study Stent Usage - Per-Stent Analysis

(Based on Data Extracted on xx/xx/xxxx)
(Per-Protocol Set)

	XIENCE PRIME Index Procedure (N=xxxx) (S=xxx)
Study Stent Size Used per Stent Diameter[1]	
2.25	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
2.5 mm	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
2.75 mm	xx.x%(xx/xx)
[95% Confidence Interval][2]	xx.x%(xx/xx)
3.0 mm	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
3.5 mm	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
4.0 mm	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
Length[1]	
8 mm	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
12 mm	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
15 mm	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
18 mm	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
23 mm	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
28 mm	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
33 mm	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]
38 mm	xx.x% (xx / xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]

[1] Denominators are based on the total number of study stents implanted.
[2] By Clopper-Pearson exact confidence interval.
Note: There are xx misplaced study stents.
Note: This table includes all implanted study stents during index procedure.
Note: N is the total number of subjects; S is the total number of stents.

Table 12: Post-procedure Antiplatelet Medication - Per Subject Analysis

(Based on Data Extracted on xx/xx/xxxx)
(Per-Protocol Set)

	Aspirin (N=xxxx)	Clopidogrel (N=xxxx)	Ticlopidine (N=xxxx)	Other (N=xxxx)	DAPT[#]
Duration (days)					
Mean ± SD (n)	xx.x ± xx.x (xx)	xx.x ± xx.x (xx)	xx.x ± xx.x (xx)	xx.x ± xx.x (xx)	xx.x ± xx.x (xx)
Median	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
(Q1, Q3)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Range (min, max)	[xx.x%, xx.x%]	[xx.x%, xx.x%]	[xx.x%, xx.x%]	[xx.x%, xx.x%]	[xx.x%, xx.x%]
[95% Confidence Interval][1]					
<407days	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)
≥407 - <772days	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)
≥772 - <1137days	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)
≥1137 - <1502days	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)
≥1502 - <1867days	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)
≥1867days	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)
On medication at hospital discharge[*]	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]	[xx.x%, xx.x%]	[xx.x%, xx.x%]	[xx.x%, xx.x%]	[xx.x%, xx.x%]

[1] By normal approximation.
[2] By Clopper-Pearson exact confidence interval.
[*] Note: Denominator is the number of patients discharged.
[#] Note: DAPT is Aspirin & Clopidogrel/Ticlopidine/Other.

Table 13: Antiplatelet Loading Dose Received for Index Procedure - Per Subject Analysis

(Based on Data Extracted on xx/xx/xxxx)
(Per-Protocol Set)

	Aspirin (N=xxxx)	**Clopidogrel (N=xxxx)**	**Ticlopidine (N=xxxx)**	**Other (N=xxxx)**
Loading dose received	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)	xx.x% (xx/xxx)
[95% Confidence Interval][2]	[xx.x%, xx.x%]	[xx.x%, xx.x%]	[xx.x%, xx.x%]	[xx.x%, xx.x%]
Dose (mg)				
Mean ± SD (n)	xx.x ± xx.x (xx)	xx.x ± xx.x (xx)	xx.x ± xx.x (xx)	xx.x ± xx.x (xx)
Median	xx.x	xx.x	xx.x	xx.x
(Q1, Q3)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Range (min, max)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
[95% Confidence Interval][1]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]	[xx.x, xx.x]

[1] By normal approximation.
[2] By Clopper-Pearson exact confidence interval.

Table 14: Hierarchical Subject Counts of Endpoint Events through xxx Days

(Based on Data Extracted on xx/xx/xxxx)
(Per-Protocol Set)

	XIENCE PRIME (N=xxxx)
In Hospital	
Composite rate of Cardiac death and any MI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Cardiac death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Q-wave MI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Non Q-wave MI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Composite rate of All Death, any MI	
– Cardiac Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Vascular Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Non-Cardiovascular Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– QMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– NQMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Target lesion failure (TLF)	
Composite rate of Cardiac Death, Target Vessel MI, ID-TLR	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Cardiac Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– TV QMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– TV NQMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– ID-TLR CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– ID-TLR PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Target vessel failure (TVF)	
Composite rate of Cardiac Death, all MI, ID-TVR	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Cardiac Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– QMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– NQMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– ID-TLR CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– ID-TLR PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– ID-TVR CABG, non-target lesion	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– ID-TVR PCI, non-target lesion	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]

	XIENCE PRIME (N=xxxx)
Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Cardiac Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Vascular Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Non-Cardiovascular Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Any MI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– QMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– NQMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Revascularization	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– All TLR CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– All TLR PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– All TVR CABG, non-target lesion	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– All TVR PCI, non-target lesion	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– All Non TVR CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– All Non TVR PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
0 through XXX Days	
Composite rate of Cardiac death and any MI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Cardiac death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Q-wave MI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Non Q-wave MI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Composite rate of All Death, any MI	
– Cardiac Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Vascular Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Non-Cardiovascular Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– QMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– NQMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]

	XIENCE PRIME (N=xxxx)
Target lesion failure (TLF)	
Composite rate of Cardiac Death, Target Vessel MI, ID-TLR	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Cardiac Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– TV QMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– TV NQMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– ID-TLR CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– ID-TLR PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Target vessel failure (TVF)	
Composite rate of Cardiac Death, all MI, ID-TVR	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Cardiac Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– QMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– NQMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– ID-TLR CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– ID-TLR PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– ID-TVR CABG, non-target lesion	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– ID-TVR PCI, non-target lesion	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]

	XIENCE PRIME (N=xxxx)
Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Cardiac Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Vascular Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– Non-Cardiovascular Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Any MI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– QMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– NQMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Revascularization	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– All TLR CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– All TLR PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– All TVR CABG, non-target lesion	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– All TVR PCI, non-target lesion	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– All Non TVR CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
– All Non TVR PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]

[1] By Clopper-Pearson exact confidence interval.
Note: In-hospital is defined as hospitalization less than or equal to 7 days post index procedure.
Note: Subjects are only counted once for each type of event in each time period.
Note: All death and MI in this table are per ARC classification.
Note: The hierarchical order is applied to each endpoint independently. Subjects are only counted once in the hierarchical order of cardiac death, vascular death, non-cardiovasulcar eath, QMI, NQMI, TLR CABG, TLR PCI, TVR-CABG non target lesion, TVR-PCI non target lesion, and Non-TVR.
Note: This table includes revascularizations on any vessel(s) / lesion(s) for subjects with multiple target vessels / lesions treated.
Note: Denominator exclude subjects who are truly lost-to-follow-up, defined as subjects who are lost to follow-up through given timepoint without any key event (all death, all MI, all revascularization) or stent thrombosis event.

Table 15: Non-Hierarchical Subject Counts of Endpoint Events through xxx Days

(Based on Data Extracted on xx/xx/xxxx)
(Per-Protocol Set)

	XIENCE PRIME (N=xxxx)
In-Hospital	
All Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Cardiac Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Vascular Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Non-Cardiovascular Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
All ARC MI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
QMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
NQMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Target Vessel ARC MI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Target Vessel QMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Target Vessel NQMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
All Revascularization	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
All TLR	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]

	XIENCE PRIME (N=xxxx)
All TVR, non-target lesion	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
All TVR (TLR and TVR, non-target lesion)	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
ID- Revascularization	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
ID-TLR	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
ID-TVR, non-target lesion	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
ID-TVR (TLR and TVR, non-target lesion)	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Non TVR[2]	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]

	XIENCE PRIME (N=xxxx)
0 throuth XXX Days	
All Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Cardiac Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Vascular Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Non-Cardiovascular Death	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
All ARC MI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
QMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
NQMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Target Vessel ARC MI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Target Vessel QMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Target Vessel NQMI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
All Revascularization	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
All TLR	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
All TVR, non-target lesion	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]

	XIENCE PRIME (N=xxxx)
All TVR (TLR and TVR, non-target lesion)	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
ID- Revascularization	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
ID-TLR	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
ID-TVR, non-target lesion	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
ID-TVR (TLR and TVR, non-target lesion)	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Non TVR[2]	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
CABG	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
PCI	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]

[1] By Clopper-Pearson exact confidence interval.
[2] Non TVR includes revascularizations that are not in the target vessel.
Note: Subjects are only counted once for each type of event in each time period.
Note: In-hospital is defined as hospitalization less than or equal to 7 days post index procedure.
Note: Denominator exclude subjects who are truly lost-to-follow-up, defined as subjects who are lost to follow-up through given timepoint without any key event (all death, all MI, all revascularization) or stent thrombosis event.
Note: TVR includes TLR and TVR, non-target lesion.
Note: Revascularization includes TLR, TVR, non-target lesion, and non TVR.

Table 16: Stent Thrombosis per ARC classification through xxx Days - Per-Subject Analysis

(Based on Data Extracted on xx/xx/xxxx)
(Per-Protocol Set)

	XIENCE PRIME (N=xxxx)
Early Stent Thrombosis (0 – 30 days)	
Definite	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Probable	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Definite/Probable	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Late Stent Thrombosis (31 – 365 days)	
Definite	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Probable	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Definite/Probable	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Overall Stent Thrombosis (0-xxxx days)	
Definite	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Probable	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Definite/Probable	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Overall Stent Thrombosis (0-365 days)	
Definite	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Probable	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Definite/Probable	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Overall Stent Thrombosis (365-730 days)	
Definite	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Probable	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Definite/Probable	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Overall Stent Thrombosis (730-1095 days)	
Definite	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Probable	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Definite/Probable	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Overall Stent Thrombosis (1095-1460 days)	
Definite	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Probable	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Definite/Probable	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]

Overall Stent Thrombosis (1460-1825 days)	
Definite	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Probable	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Definite/Probable	xx.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]

[1] By Clopper-Pearson exact confidence interval.

Note: All counts presented in this table are subject counts.

Note: Denominator exclude subjects who are truly lost-to-follow-up, defined as subjects who are lost to follow-up through given timepoint without any key event (all death, all MI, all revascularization) or stent thrombosis event.

Table 17: Baseline Laboratory Assessments - Per-Subject Analysis
(Per-Protocol Set)

	XIENCE PRIME (N= xxxx)
Abnormal CK	x.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Abnormal CK-MB	x.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]
Abnormal Troponin I/T	x.xx% (xx/xxx)
[95% Confidence Interval][1]	[xx.xx%, xx.xx%]

[1] By Clopper-Pearson exact confidence interval.

Table 18: The Cardiac Enzymes Change from Baseline-Normal to Post-Procedure-Abnormal – Per-Subject Analysis (Per-Protocol Set)

	XIENCE PRIME (N= xxxx)
CK (Normal to Abnormal) [95% Confidence Interval][1]	x.xx% (xx/xxx) [xx.xx%, xx.xx%]
CK-MB (Normal to Abnormal) [95% Confidence Interval][1]	x.xx% (xx/xxx) [xx.xx%, xx.xx%]
Troponin I/T (Normal to Abnormal) [95% Confidence Interval][1]	x.xx% (xx/xxx) [xx.xx%, xx.xx%]

[1] By Clopper-Pearson exact confidence interval.

Table 19 Description of Site Reported Adverse Events

Subject No.	Age	Gender	Event Term	SAE or not	Days to Event	Outcome	Relationship to Study Device	Action and/or Treatment
xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
…								
…								