English translation for reference only

Statistical Analysis Plan

Device Name:	XIENCE PRIME SV Everolimus-eluting Stent (12-303) XIENCE Xpedition 2.25 mm Everolimus-eluting Stent (14-306)
Surveillance Type:	Post Marketing Surveillance
Version:	2.0
Date:	June 23, 2015.

Abbott Vascular Inc.

date : / /

by :

Sherry Cao,
Associate Director, Clinical Research, Biometrics

EPS Corp.

date : / /

by :

Kitagaito Satoshi,
Manager, Clinical Information Division, Data Science Center, Statistics Analysis Department 2

Version History

Version	Revision Period	Date Created/Revised	Author/Reviser	Reason
1.0		2014/6/2	N. Tsukamoto	Initial creation
2.0		2015/6/23	N. Tsukamoto	Added descriptions relating to XIENCE Xpedition 2.25 mm.

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1. Surveillance Overview

1.1. Objectives

This is a post-marketing use result survey (hereinafter referred to as "Survey") conducted per the standards required by the Minster of Health, Labor and Welfare provided in the standards for post-marketing surveillances and studies [except for those defined in the Ministerial Ordinance on Good Clinical Practice for Medical Devices (MHLW Ordinance No. 36, 2005)] based on Paragraph 4, Article 14-4 and Paragraph 4, Article 14-6 (including application mutatis mutandis per Article 19-4) of the Pharmaceutical Affairs Law (Law No. 145, 1960, hereinafter referred to as "PAL") by the Marketing Authorization Holder or accredited foreign manufacturer of a medical device defined in Paragraph 1, Article 14 of the PAL. The purpose of the Survey is to know the frequency and status of adverse device effects and adverse events in order to assure the safety of the new medical device, and to collect efficacy and safety information to be evaluated for repeat review by PMDA. The Survey is conducted per the Ministerial Ordinance on Good Post-marketing Surveillance Practice (MHLW Ordinance No. 38, 2005, hereinafter referred to as "GPSP Ordinance").

1.2. Patients of the Surveillance

[XIENCE PRIME SV Everolimus-eluting Stent]

Based on the GPSP Ordinance, the Survey enrolls patients with ischemic heart disease potentially indicated for treatment with the XIENCE PRIME Everolimus-eluting Stent (Approval No. 22400BZX00145000, April 6, 2012, hereinafter referred to as "Surveillance Device") without any predefined specific inclusion or exclusion criteria. As a general rule, enrolled patients must be treated with XIENCE PRIME as part of treatment given in each survey site in the real-world setting and must be available for angiographic follow-up at 8 months and clinical follow-up at 1 year.

In addition to the patients who will first be enrolled in this Surveillance, patients who have been participating in a pre-market clinical trial of the XIENCE PRIME SV stent (the AVJ-09-385 trial: A Clinical Evaluation of the AVJ-09-385 Coronary Stent System in Japanese Population) are included in the subject. The patients enrolled in the AVJ-09-385 trial were to be followed for five years, and the patient follow-up had been performed as part of a pre-market study until the marketing approval date. Upon consultation with the PMDA, it was agreed that the trial be continued as a Post Marketing Surveillance after marketing approval, and the trial (follow-up) completion date be the marketing approval date. Based on the agreement, the AVJ-09-385 trial was continued as the Post Marketing Surveillance upon marketing approval.

[XIENCE Xpedition 2.25 mm Everolimus-eluting Stent]

Based on the GPSP Ordinance, the Survey enrolls patients with ischemic heart disease potentially indicated for treatment with the XIENCE Xpedition 2.25 mm Everolimus-eluting Stent (Approval No. 22500BZX00309000, May 20, 2014, hereinafter referred to as "Surveillance Device") without any predefined specific inclusion or exclusion criteria. As a general rule, enrolled patients must be treated with XIENCE PRIME as part of treatment given in each survey site in the real-world setting and must be available for angiographic follow-up at 8 months and clinical follow-up at 1 year.

1.3. Planned Sample Size

[XIENCE PRIME SV Everolimus-eluting Stent]

The target sample size of the Surveillance is approximately 300 patients from approximately 30 sites, including 62 patients continuing from the AVJ-09-385 trial.

MACE (composite of cardiac death, myocardial infarction and ischemia-driven target lesion revascularization) rate of this surveillance is expected to be 15%, based on past trials. For 300 patients, half of 95% confidence interval of MACE rate of 15% is 4.2%. This is 28% of expected MACE rate of 15%. This range will be enough to evaluate safety and efficacy of XIENCE PRIME SV in real world practice in Japanese hospitals.

[XIENCE Xpedition 2.25 mm Everolimus-eluting Stent]

The target sample size of the Surveillance is approximately 100 patients from at least 5 sites.

The stent component of the device is identical to the XIENCE PRIME SV Everolimus-eluting Stent (EES) which is currently under use result surveillance (Marketing Approval No. 22500BZX00070000). Provided that the in-stent LL of both the XIENCE PRIME SV EES and the Surveillance Device is 0.2mm with standard deviation of 0.5 mm, the QCA follow-up rate of 300 subjects in the XIENCE PRIME SV EES use result surveillance is 75% (225 lesions), $\alpha = 0.05$ (one-sided), power = 90%, and non-inferiority margin = 0.195 mm, 75 patients is required to demonstrate the non-inferiority to the XIENCE V PRIME SV EES. Considering drop-put, approximately 100 subjects can be a target sample size to guarantee efficacy of the device.

1.4. Treatment of Patients

[XIENCE PRIME SV Everolimus-eluting Stent]

The treatment strategy will be determined by the physician according to the healthcare facility's standard of care for interventional cardiology.

It is recommended that each enrolling physician review the most recently updated IFU and assess the

contraindications, warnings, and precaution sections for treating potential patients.
Although antiplatelet medication is ultimately determined by physicians, enrolled patients will be encouraged to receive adjunctive antiplatelet therapy consisting of an indefinite duration of aspirin, along with required a minimum of 6 months of thienopyridine (clopidogrel, ticlopidine, etc.). And in the Xience Prime IFU, enrolled patients will receive antiplatelet therapy required a minimum of 12 months of thienopyridine. It is recommended that physicians review the requirements of the most recent thienopyridine IFU before treating patients. Required lab assessments and clinical observations to evaluate thienopyridine side effects must be conducted per its approved IFU.

[XIENCE Xpedition 2.25 mm Everolimus-eluting Stent]
The treatment strategy will be determined by the physician according to the healthcare facility's standard of care for interventional cardiology.
It is recommended that each enrolling physician review the most recently updated IFU and assess the contraindications, warnings, and precaution sections for treating potential patients.
Although antiplatelet medication is ultimately determined by physicians, enrolled patients of low bleeding risk will be encouraged to receive adjunctive antiplatelet therapy consisting of an indefinite duration of aspirin in addition to a required minimum of 12 months of thienopyridine (clopidogrel, ticlopidine, etc.) per product IFU. It is recommended that physicians review the requirements of the most recent thienopyridine IFU before treating patients. Laboratory tests and clinical observations required for evaluating adverse reactions to thienopyridine medication should be performed in accordance with the IFU.

2. Definitions of Analysis Populations and Acronyms

2.1. Definitions of Analysis Populations

No	Term	Definition
1	Surveillance Period	[XIENCE PRIME SV EES] From March 7, 2013 to December 31, 2019 [XIENCE Xpedition 2.25 mm EES] From July 1 to March 31, 2021
2	Data Lock Date	Data will be locked at the following dates for periodical reporting: 1st Data Lock Date：Sep/05/2013 2nd Data Lock Date：Sep/05/2014 3rd Data Lock Date：Sep/05/2015 4th Data Lock Date：Sep/05/2016 5th Data Lock Date：Sep/05/2017 6th Data Lock Date：Sep/05/2018 7th Data Lock Date：Sep/05/2019 Each analysis will include the cases of which case cards have been frozen before the data are locked.
3	Case with Case Card collected	A case of which case card data has been fixed.
4	XP_SV Arm	The group of patients with Case Card collected who were treated with the XIENCE PRIME SV EES.
5	XX_SV Arm	The group of patients with Case Card collected who were treated with the XIENCE Xpedition 2.25 mm EES.

Analysis will be performed for the XP_SV Arm and the XX_SV Arm each and for all enrolled patients.

2.2. Definition of Term

No	Term	Definition
1	Dual Antiplatelet Therapy	Combined use of aspirin and thienopiridine (e.g. clopidogrel, ticlopidine).

2.3. Acronyms

No	Acronym	Description
1	CABG	Coronary Artery Bypass Grafting
2	CTO	Chronic Total Occlusion
3	eGFR	Estimated Glomerular Filtration Rate
4	LAD	Left Anterior Descending Artery

No	Acronym	Description
5	LCX	Left Circumflex Artery
6	LMT	Left Main Trunk
7	LVEF	Left Ventricular Ejection Fraction
8	PCI	Percutaneous Coronary Intervention
9	POBA	Plain Old Balloon Angioplasty
10	Q1	First Quartile
11	Q3	Third Quartile
12	RCA	Right Coronary Artery
13	SVG	Saphenous Vein Graft
14	TLR	Target Lesion Revascularization
15	TVR	Target Vessel Revascularization

3. Analysis Methods

3.1. Statistical Analysis Environment

Statistical analysis software: SAS Windows Edition, Version 9.2 or higher, SAS Institute Inc.

3.2. Calculation Methods

Data Item	Calculation Method etc.
Summary Statistic (continuous variable)	Mean value, SD, number of sample, median, Q1, Q3, minimum value, maximum value, and 95% CI of mean value will be calculated. Number of sample: To be represented in integer. Mean, SD, median, Q1, Q3: To be represented to one decimal below the data for calculation. Minimum, maximum: To be represented in the same decimal as the data for calculation.
CI of Mean Values	CI based on t distribution will be calculated: $$CI = \bar{x} \pm t_{(1-\alpha/2;n-1)} \frac{S}{\sqrt{n}}$$
Summary Statistic (incidence)	Incidence (%), count of events (numerator), analysis population (denominator) and 95% CI of mean value will be calculated.
CI of Occurrences	Exact CI based on Clopper-Pearson method will be calculated: $$\pi_L = \frac{\nu_2}{\nu_2 + \nu_1 F_{\alpha/2}[\nu_1, \nu_2]} \quad \nu_1 = 2(n - x + 1), \nu_2 = 2x$$ $$\pi_U = \frac{\nu_1 F_{\alpha/2}[\nu_1, \nu_2]}{\nu_2 + \nu_1 F_{\alpha/2}[\nu_1, \nu_2]} \quad \nu_1 = 2(x + 1), \nu_2 = 2(n - x)$$
Age (in years)	Actual age at procedure (enrollment) date will be calculated from year/month of birth (day will be deemed as 1st day of the month).
Body Mass Index	BMI will be calculated from weight (kg) and height (cm): Body Mass Index = Weight (kg) / (Height [cm]/100) ^{2}
Follow-up Time Window	8-month Follow-up: 8 months post procedure ± 30 days 1-year Follow-up: 1 year post procedure ± 30 days 2-year Follow-up: 2 years post procedure ± 30 days 3-year Follow-up: 3 years post procedure ± 30 days 4-year Follow-up: 4 years post procedure ± 30 days 51-year Follow-up: 5 years post procedure ± 30 days Data collected outside time window can be used as data collected at respective follow-up time point if the quality of the data is confirmed as qualified.

4. Statistical Analysis Details

4.1. Surveillance Overview and Case Composition

- Data to be aggregated: Cases with Case Card collected

4.1.1. Number of Cases by Site

Number of cases with Case Card collected by site will be aggregated by treatment group.

Table 1: Number of Cases by Site

4.1.2. Case Card Collected

Case card collected per binder will be aggregated by treatment group.

Table 2: Follow-up Rate

4.1.3. Status at Surveillance Completion

Status at surveillance completion will be aggregated by treatment group.

Table 3: Status at Surveillance Completion

4.1.4. Ischemic Findings at Enrollment

The percentage in cases and the CI of each ischemic finding at enrollment defined as below will be calculated by treatment group.

Table 4: Ischemic Findings at Enrollment

Breakdown of the data item will be provided in brackets [ ].

No	Data Item
1	Acute Myocardial Infarction [STEMI, NSTEMI]
2	Unstable Angina [Braunwald Classification: Class I to Class III]
3	Stable Angina [CCS Angina Classification: Class I to Class IV]
4	Silent Ischemia
5	Old Myocardial Infarction (with no ischemic findings)
6	Coronary Stenosis (with no ischemic findings)

4.1.5. Basic Demography

The summary statistics or percentage in cases and the CI of the basic demography defined as below will be calculated by treatment group.

Table 5: Basic Demography

Summary statistics will be calculated for the items with asterisk *.

No	Data Item
1*	Age (in years)
2	Age ≥ 75 years
3	Gender at Birth (Male/Female)
4*	Height (cm)
5*	Weight (kg)

No	Data Item
6*	Body Mass Index (kg/ m^2)
7	Body Mass Index < 18.5 kg/m^2 Body Mass Index ≥ 18.5 kg/m^2, < 25 kg/m^2 Body Mass Index ≥ 25 kg/m^2, < 30 kg/m^2 Body Mass Index ≥ 30 kg/m^2, < 35 kg/m^2 Body Mass Index ≥ 35 kg/m^2, < 40 kg/m^2 Body Mass Index ≥ 40 kg/m^2

4.1.6. Risk Factors and History

The percentage in cases and the CI of the risk factors and history defined as below will be calculated by treatment group.

Table 6: Risk Factors and History

Breakdown of the data item will be provided in brackets [ ].

No	Data Item
1	LVEF < 30%
2	History of MI
3	Previous CABG
4	Previous PCI
5	Family history of premature coronary disease
6	Current smoker or quitted smoking within the past 1 month
7	Hypertension [Requiring medication, Not requiring medication]
8	Dyslipidemia [Requiring medication, Not requiring medication]
9	History of renal failure (renal disorder) [On dialysis, Terminal renal failure (eGFR < 30 mL/min/1.73m^2), Chronic renal disorder (eGFR < 60 mL/min/1.73m^2)]
10	History of stroke
11	History of severe bleeding
12	History of unstable arrhythmia
13	Anticoagulation therapy

4.1.7. Diabetic Status

The percentage in cases and the CI of the diabetic status defined as below will be calculated by treatment group.

Table 7: Diabetic Status

Breakdown of the data item will be provided in brackets [ ].

No	Data Item
1	History of diabetes [Type 1 diabetes, Type 2 diabetes]
2	History of diabetes requiring medication [Requiring insulin, Requiring oral diabetic medication]

4.2. Lesion and Treatment

4.2.1. Treated Lesions

The summary statistics or percentage in cases and the CI of the treated lesions defined as below will be

calculated by treatment group.

Table 8-1: Treated Lesions (Main branch for bifurcate lesions)

Summary statistics will be calculated for the items with asterisk *.

No	Data Item
1*	Number of target lesions per patient
2	Number of target lesions per patient: 1 lesion
3	Number of target lesions per patient: 2 lesions
4	Number of target lesions per patient: 3 lesions
5	Number of target lesions per patient: ≥ 4 lesions
6	Lesion Type: *De novo* lesion
7	Lesion Type: Stent restenosis
8	Lesion Type: Restenosis other than stent implanted
9	Lesion Type: Other

Table 8-2: Target Lesion Locations (Main branch for bifurcate lesions)

Breakdown of the data item will be provided in brackets [ ].

No	Data Item
1	Native coronary artery [LMT [Protected, unprotected], RCA, LAD, LCX]
2	SVG
3	Artery graft

Table 8-3: Target Lesion Locations in AHA Segments (Main branch for bifurcate lesions)

Item

No	Data Item
1	AHA-1 - AHA-15

Table 8-4: Complex Lesion Status

Item

No	Data Item
1	Complex Lesion: Bifurcation
2	Complex Lesion: Culprit for STEMI
3	Complex Lesion: CTO
4	Complex Lesion: Ostial (located at aortic ostium or within 3 mm from the origin of LAD/LCX bifurcation)
5	Complex Lesion: Heavy calcification
6	Complex Lesion: Thrombus in the target vessel
7	Complex Lesion: > 90° angulation of or proximal to the lesion
8	Complex Lesion: Excess tortuousity of or proximal to the lesion
9	Complex Lesion: Other

4.2.2. Treated Lesion Stenosis Assessment (all lesions, assessed by site)

The summary statistics of pre-procedure lesion length (mm) will be calculated by treatment group.

Also, the summary statistics of lesion diameter (mm) and %DS will be calculated by treatment group.

Table 9: Treated Lesion Stenosis Assessment (all lesions, assessed by site)

4.2.3. General Procedure Information

The summary statistics or percentage in cases and the CI of the procedure information defined as below will be calculated by treatment group.

Table 10: General Procedure Information

Summary statistics will be calculated for the items with asterisk *.

No	Data Item
1	Access Site: Femoral
2	Access Site: Radial
3	Access Site: Brachial
4	Access Site: Other
5*	Number of treated lesions per patient
6*	Number of target lesions per patient
7*	Number of lesions treated with XP_SV/XX_SV only Only mean, SD and number of samples will be calculated.
8*	Number of lesions treated with stent other than XP_SV/XX_SV Only mean, SD and number of samples will be calculated.
9*	Number of non-target lesions Only mean, SD and number of samples will be calculated.
10*	Total number of stents implanted per patient
11*	Total stent length (mm) implanted per patient
12*	Procedure time (min)

4.2.4. Treatment for Treated Lesions

The summary statistics or percentage in cases and the CI of treatment for treated lesions defined as below will be calculated by treatment group.

Table 11-1: Treatment for Treated Lesions

Summary statistics will be calculated for the items with asterisk *.

No	Data Item
1	Thrombectomy
2	Direct stent only
3	Direct stent + post-dilatation
4	Pre-treatment + stent
5	Pre-treatment + stent + post-dilatation
6	Pre-treatment for lesion: Direct stent (with no pre-treatment)
7	Pre-treatment for lesion: Pre-dilatation by POBA
8	Pre-treatment for lesion: Rotablator
9	Pre-treatment for lesion: Pre-dilatation by cutting balloon
10	Pre-treatment for lesion: Pre-dilatation by scoring balloon
11	Pre-treatment for lesion: Other
12	Post-dilatation
13*	Maximum balloon diameter (mm)
14*	Maximum balloon pressure (atm)

Table 11-2: Number of Stents Implanted in Target Lesion

Summary statistics will be calculated for the items with asterisk *.

No	Data Item
1*	Number of stents implanted in target lesion (per lesion)
2*	Number of XP_SV/XX_SV stents implanted Only mean, SD and number of samples will be calculated.
3	Number of XP_SV/XX_SV stents implanted: 1 stent
4	Number of XP_SV/XX_SV stents implanted: 2 stents
5	Number of XP_SV/XX_SV stents implanted: 3 stents
6*	Number of other stents implanted Only mean, SD and number of samples will be calculated.
7	Number of other stent implanted: 0 stent
8	Number of other stent implanted: 1 stent
9	Number of other stent implanted: 2 stent
10	Bailout stent
11*	Total stent length implanted (mm, per lesion)

4.2.5. Bifurcation Lesion Information

The percentage in cases and the CI of the bifurcation lesion information defined as below will be calculated by treatment group.

Table 12: Bifurcation Lesion Information

Item

No	Data Item
1	Bifurcation Type: True
2	Bifurcation Type: False
3	Bifurcation Type: Unknown
4	Other information to be defined

4.2.6. Treatment for Bifurcation Lesions

The percentage in cases and the CI of treatment for bifurcation lesions will be calculated by bifurcation type and treatment group.

Table 13-1: Treatment for Bifurcation Lesions (Bifurcation Type: True)

Table 13-2: Treatment for Bifurcation Lesions (Bifurcation Type: False)

Table 13-3: Treatment for Bifurcation Lesions (Bifurcation Type: All Types)

Item

No	Data Item
1	Provisional Stent [Stent implanted only in main branch, Provisional T, Provisional Culottes]
2	Elective Stent [Classic T, Modified T, Crush, Culottes, Kissing Stent]
3	Kissing Balloon

4.2.7. Stent Used

The XP_SV/XX_SV stents used will be aggregated by diameter and length.

Table 14: Number of Stents Used by Size

Item

No	Data Item
1	Stent Diameter: 2.25mm
2	Stent Length 8mm、12mm、15mm、18mm、23mm、28mm、33mm、38mm

4.2.8. Success Rate

The success rates and the CIs of stent implantation by device (XP_SV or XX_SV only), procedure by lesion, and XP_SV/XX_SV implantation by patient will be calculated by treatment group.

Table 15: Success Rate

4.2.9. Hospitalization Information

The summary statistics of post-procedure hospitalization period (days) will be calculated by treatment group. Also, the percentage in cases and the CI of prolonged hospitalization due to SAE will be calculated by treatment group.

Table 16: Hospitalization Information

4.3. Antiplatelet Medications

4.3.1. Antiplatelet Medications

The percentage in cases and the CI of antiplatelet medications at each follow-up time point will be calculated by treatment group.

No	Follow-up Time Point
1	Pre-procedure
2	Procedure date to discharge date
3	1day + discharge date to 8MFU date
4	1day + 8MFU to 1YFU
5	1day + 1YFU to 2YFU
6	1day + 2YFU to 3YFU
7	1day + 3YFU to 4YFU
8	1day + 4YFU to 5YFU

Table 17: Antiplatelet Medications (at each follow-up time point)

Item

No	Data Item
1	Dual Antiplatelet Therapy [Aspirin + clopidogrel, Aspirin + ticlopidine]
2	Aspirin, clopidogrel, ticlopidine, cilostazol, other

4.4. Adverse Events

4.4.1. Adverse Events (Composite Endpoint)

The occurrence rates of adverse events (composite endpoint) at each occurrence time and follow-up time point will be calculated.

Item

No	Timing of Onset
1	Procedure date to procedure date ± 3 days
2	4 days + procedure date to discharge date
3	1 day + discharge date to 8MFU
4	1day + 8MFU to 1YFU
5	1day + 1YFU to 2YFU
6	1day + 2YFU to 3YFU
7	1day + 3YFU to 4YFU
8	1day + 4YFU to 5YFU

Table 18: Adverse Events (Composite endpoint, at each follow-up time point)

Breakdown of the data item will be provided in brackets [ ].

No	Data Item
1	Target lesion failure [Cardiac death, Target vessel MI, Ischemia-driven TLR]
2	Death + MI + Revascularization [Death, MI, Revascularization]
3	Target vessel failure [Cardiac death, MI, Ischemia-driven TLR, Ischemia-driven TVR (non-TLR)]
4	Major adverse cardiac event (Cardiac death, All MI, Ischemia-driven TLR)
5	Death or MI
6	Cardiac death or MI
7	Cardiac death or target vessel MI

Adjudication of MI is based on the definition by WHO (SPIRIT III)

4.4.2. Adverse Events (by event)

The occurrence rates of adverse events (by event) at each follow-up time point will be calculated by treatment group.

Table 19: Adverse Events (by event, at each follow-up time point)

Breakdown of the data item will be provided in brackets [ ].

No	Data Item
1	Death [Cardiac death, Non-coronary vascular death, Non-cardiovascular death]
2	Myocardial Infarction [STEMI, NSTEMI, QMI, NQMI]
3	TLR [Ischemia-driven TLR [CABG, PCI], Non-ischemia-driven TLR [CABG, PCI]]
4	TVR (non-TLR) [Ischemia-driven TVR (non-TLR) [CABG, PCI], Non-ischemia-driven TVR (non-TLR) [CABG, PCI]]
5	TVR (TLR or TVR, non-TLR) [ischemia-driven TVR (TLR or TVR, non-TLR) [CABG, PCI], non-ischemia-driven TVR (TLR or TVR, non-TLR) [CABG,

No	Data Item
	PCI]
6	Non-TVR [CABG, PCI]
7	All revascularization [Ischemia-driven revascularization [CABG, PCI], Non-ischemia-driven revascularization [CABG, PCI]]
8	Bleeding

Adjudication of MI is based on the definition by WHO (SPIRIT III)

4.5. Attachment Forms

4.5.1. List of Adverse Device Effects and Infections Occurred (Attachment Form 3)

List of Adverse Device Effects and Infections Occurred will be created.

List of Adverse Device Effects and Infections Occurred (attachment Form 3)

Line

No	Data Item	Definition
1	Number of Sites	Each site will be counted by its name.
2	Number of Cases	Number of cases will be aggregated.
3	Number of ADE Cases	Two or more ADEs occurred in a single case will be counted as one case.
4	Number of ADEs Occurred	Number of ADEs occurred will be aggregated.
5	Occurrence Rate	= Number of ADEs Occurred / Number of Cases x 100
6	Event Name	Calculation will be done based on MedDRA coding

4.5.2. List of Serious Adverse Events Occurred (Attachment Form 3-2)

List of Serious Adverse Events Occurred will be created.

List of Serious Adverse Events Occurred (Attachment Form 3-2)

Line

No	Data Item	Definition
1	Number of Sites	Each site will be counted by its name.
2	Number of Cases	Number of cases will be aggregated.
3	Number of Cases in which SAE Occurred	Two or more SAEs occurred in a single case will be counted as one case.
4	Number of SAEs Occurred	Number of SAEs occurred will be aggregated.
5	Occurrence Rate	= Number of SAEs Occurred / Number of Cases x 100
6	Event Name	Calculation will be done based on MedDRA coding