Edwards Lifesciences

STATISTICAL ANALYSIS PLAN

Protocol Title:	**Edwards EVOQUE Tricuspid valve Replacement: Investigation of Safety and Clinical Efficacy after replacemeNt of tricuspid valve with transcatheter Device**
Protocol Number:	2019-06[redacted] (US)
SAP Version:	[redacted]
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SAP Author:	[redacted]

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TABLE OF CONTENTS

Glossary of Terms

ABBREVIATION	DEFINITION OR DESCRIPTION
6MWT	6 Minute Walk Test
ADL	Activities of Daily Living
AE	Adverse Event
AKI	Acute Kidney Injury
AT	As-Treated (Population)
BMI	Body mass index
BNP	B-type Natriuretic Peptide
CABG	Coronary Artery Bypass Grafting
CBC	Complete Blood Count
CEC	Clinical Events Committee
CMP	Comprehensive Metabolic Panel
CI	Confidence Interval
CIP	Clinical Investigation Plan
CSHA	Canadian Study of Health and Aging
CSR	Clinical study report
DSMB	Data Safety Monitoring Board
EDC	Electronic Data Capture
Echo	Echocardiogram
eGFR	Estimated Glomerular Filtration Rate
GGT	Gamma-Glutamyl Transferase
GHER	Global Health Economics and Reimbursement
HF	Heart Failure
INR	International Normalized Ratio
KCCQ	Kansas City Cardiomyopathy Questionnaire
KM	Kaplan-Meier
LDH	Lactic Acid Dehydrogenase
MAE	Major Adverse Event
MI	Myocardial Infarction
MVARC	Mitral Valve Academic Research Consortium
NT-proBNP	N-terminal pro B-type Natriuretic Peptide
NYHA	New York Heart Association
OR	Operating Room
PCI	Percutaneous Coronary Intervention
PP	Per-Protocol (Population)

ABBREVIATION	DEFINITION OR DESCRIPTION
PT	Prothrombin Time
PTT	Partial Thromboplastin Time
PVL	Paravalvular Leak
QoL	Quality of Life
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System (software)
SD	Standard Deviation
SF-12	12-Item Short Form Health Survey
SF-36	36-Item Short Form Health Survey
STS	Society of Thoracic Surgery
TEE	Transesophageal echocardiogram/echocardiography
TMF	Trial Master File
TMTT	Transcatheter Mitral and Tricuspid Therapies
TR	Tricuspid Regurgitation
TTE	Transthoracic echocardiogram/echocardiography
TTV	Transcatheter Tricuspid Valve
TV	Tricuspid Valve
UADE	Unanticipated Adverse Device Effect
VKA	Vitamin K Antagonists

1. INTRODUCTION

This statistical analysis plan (SAP) specifies the statistical methods to be implemented for the analysis of data collected within the scope of Edwards Lifesciences's Protocol #2019-06 (Edwards EVOQUE Tricuspid valve Replacement: Investigation of Safety and Clinical Efficacy after replacemeNt of tricuspid valve with transcatheter Device (TRISCEND Study)) [redacted] (US) and provides detailed instructions as to how each analysis will be performed.

[redacted]

2. STUDY DESIGN

2.1 Study Objectives

The objectives of this feasibility study are to:

- Evaluate the safety and performance of the EVOQUE system
- Provide guidance for future clinical study designs utilizing the EVOQUE system
- Provide guidance for future EVOQUE system development efforts

2.2 Overall Study Design and Plan

This is a prospective, single-arm, multi-center study to evaluate the safety and performance of the EVOQUE system in the treatment of patients with at least moderate TR and signs of, symptoms from, or prior heart failure hospitalizations for TR.

Up to 200 patients (upon FDA approval) will be enrolled in this study at up to 30 investigational sites (upon FDA approval). Subjects out of US will also be included in the analyses.

Enrolled study patients will be assessed at the following intervals: Screening/baseline, Procedure, Discharge, 30 days, 6 months, 1 year, 2 years, 3 years, 4 years, and 5 years post-procedure.

2.3 Sample Size Consideration

This is a multi-center, prospective, single-arm study. Up to 200 patients (upon FDA approval) will be enrolled in this study at up to 30 investigational sites (upon FDA approval). This sample size was established based on typical sample sizes for feasibility studies, and no statistical justification was utilized. This sample size is considered adequate to evaluate the safety and performance of the EVOQUE System.

3. STUDY ENDPOINTS

3.1 Safety Endpoints

Safety will be analyzed as a composite endpoint of Major Adverse Events (MAEs) at 30 days post-enrollment which includes:

- Cardiovascular mortality

- Myocardial infarction (MI)
- Stroke
- Renal complications requiring unplanned dialysis or renal replacement therapy
- Severe bleeding (includes fatal, life-threatening, extensive, or major bleeding, as defined by MVARC[1])
- Non-elective tricuspid valve re-intervention, percutaneous or surgical
- Major access site and vascular complications
- Major cardiac structural complications
- Device-related pulmonary embolism

3.2 Performance Endpoints

Device Success

- Device success is achieved if the study device is deployed as intended and the delivery system is successfully retrieved as intended at the time of the patient's exit from the OR/cardiac catheterization laboratory. This endpoint will have a per device analysis performed.

Procedural Success

- Procedural success is "device success" without clinically significant paravalvular leak (PVL)[2-4] on a transthoracic echocardiogram (TTE, assessed by the echo core lab) at time of discharge. This endpoint will have a per patient analysis performed.

Clinical Success

- Clinical success is "procedural success" without any MAEs at 30 days. This endpoint will have a per patient analysis performed.

3.3 Echocardiographic Endpoints and Parameters

3.3.1 Echocardiographic Endpoint

- The echocardiographic endpoint is reduction in TR grade, measured by comparing the screening/baseline TTE to the discharge TTE. This endpoint will be assessed by the echo core lab using a 5-grade classification system.[5]

3.3.2 Echocardiographic Parameters

- TTE parameters will be assessed at screening/baseline, discharge, 30 days, 6 months, 1 year, and annually until 5 years post-procedure (assessed by the echo core lab)
  1. TR grade
  2. Paravalvular leak severity
  3. Regurgitant volume
  4. TV inflow gradient
  5. Cardiac output

6. Right atrium volume
7. Left ventricular ejection fraction
8. Inferior vena cava dimensions/respiratory variations
9. Hepatic vein flow reversal
10. Pulmonary artery pressure (mean)
11. Right ventricular function

3.4 Clinical and Functional Endpoints and Parameters

3.4.1 Clinical and Functional Endpoints

- The following endpoints will be assessed at 12 months and annually until 5 years post-procedure:
  A. All-cause mortality
  B. Heart failure hospitalizations
  C. Non-elective tricuspid valve re-intervention, percutaneous or surgical
- The following endpoints will be assessed at baseline, 30 days, 6 months, 12 months, and annually until 5 years post-procedure:

A. Volume overload assessed by serial measurements of:
   1. Body weight
   2. Edema assessment (1+ to 4+)
   3. Ankle circumference measurement
   4. Patient edema questionnaire

B. Functional class, functional status, and quality of life assessed by:
   1. New York Heart Association (NYHA) Classification
   2. 6-Minute Walk Test (6MWT)
   3. Kansas City Cardiomyopathy Questionnaire (KCCQ)
   4. Short Form Health Survey (SF-36v2)

3.4.2 Clinical and Functional Parameters

- The following parameters will be assessed at baseline:

  A. Canadian Study of Health and Aging (CSHA) Clinical Frailty Scale
  B. Katz Index of Independence in Activities of Daily Living (Katz ADL)
  C. Patient Preference Survey

- The following general clinical and laboratory parameters will be assessed at discharge, 30 days, 6 months, 12 months, and annually until 5 years post-procedure:

  A. Complete Blood Count (CBC)
  B. Comprehensive Metabolic Panel (CMP)
  C. Coagulation Panel (PT or PTT; INR for patients on vitamin K antagonist [VKA])
  D. BNP(B-type natriuretic peptide) or NT-proBNP
  E. GGT
  F. Uric acid and eGFR

3.4.3 Additional Safety Listings

A listing of all AEs and SAEs for the entire study population (i.e., enrolled population) will be provided.

3.5 Exploratory Computed Tomography (CT) Parameters

The following parameters will be assessed at 30 days and 12 months (where data is available):

A. Cardiac remodeling (e.g., RV dimensions and volume)
B. EVOQUE valve frame dimensions
C. EVOQUE valve leaflet assessment
D. EVOQUE valve positioning

3.6 Electronic Diary and Activity Monitoring Sub-study

A sub-study of up to 10 sites and up to 45 patients with data through 12 months will be conducted as follows:

Electronic Diary (eDiary): To measure quality of life improvement in greater detail, electronic patient reported outcomes will be collected via a handheld device. The following assessments will be used to measure quality of life throughout the sub-study period:

A. KCCQ
B. EQ-5D-5L
C. SF-12
D. Mood questionnaire
E. Symptom burden

A daily assessment will be administered from baseline (for a minimum of 14 days before the index procedure) and then from post discharge through the 12-month follow-up visit.

Activity Monitoring: To measure the improvement in functional status, an activity monitor (wristwatch) will be worn by patients. The monitor is worn from baseline (for a minimum of 14 days before index procedure), paused at time of admission for index procedure, and resumed post discharge and worn through the 12-month follow-up visit.

For patients participating in the sub-study, a separate data analysis plan will be developed to analyze the actigraphy data collected from the activity monitor and electronic patient reported outcome data collected from the eDiary.

3.7 Additional Patient-Centered Exploratory Endpoints

The following exploratory endpoints (based on MVARC) will be assessed for As-Treated (AT) Population.

3.7.1 Exploratory Technical Success

- Absence of procedural mortality
- Successful access, delivery, and retrieval of the delivery system

- Successful deployment and correct positioning (including repositioning/recapture if needed) of the first intended device
- Freedom from additional unplanned or emergency surgery or re-intervention related to the device or access procedure

3.7.2 Exploratory Device Success

Device success will be assessed at 30 days, 6 and 12 months, and annually until 5 years post-implant procedure. All of the following must be present:

- Absence of procedural mortality or stroke
- Proper placement and positioning of the device
- Freedom from unplanned surgical or interventional procedures related to the device or access procedure
- Intended safety and performance of the device including:
    - No evidence of structural failure (e.g., major fracture, malpositioning, frozen prosthetic leaflet) or functional failure (e.g., for hemodynamic performance, the device maintains insufficiency relief without producing TV stenosis)
    - No specific device-related technical failure issues and complications (e.g., para-device complications, device-related pulmonary embolism)
    - TR reduction of at least 1 grade from baseline

Structural and functional failure will be assessed by the echo core lab. Intended safety and performance of the implanted device will be assessed at each visit. If previously identified safety or performance issues resulting in device failures at earlier visits are no longer present via TTE at a later visit (e.g., a previously identified paravalvular leak or frozen prosthetic leaflet is no longer present), a patient may be considered to have device success at the later visit.

3.7.3 Exploratory Procedural Success

Procedural success will be assessed at 30 days post-implant procedure. All of the following must be present:

- Device success
- Absence of major device or procedure related serious adverse events (SAEs): Life threatening bleed; major vascular or cardiac structural complications requiring unplanned reintervention or surgery; Stage 2 or 3 AKI (includes new dialysis); MI or need for PCI/CABG; stroke; severe HF or hypotension requiring IV inotrope, ultrafiltration or mechanical circulatory support; prolonged intubation > 48 hours; any valve-related dysfunction, migration, thrombosis, or other complication requiring surgery or repeat intervention

3.7.4 Exploratory Individual Patient Success

Individual patient success will be assessed at 12 months post-device implant. All of the following must be present:

- Device success
- Patient returned to pre-procedural setting (i.e., return to prior living arrangement or equivalent)

- No-rehospitalizations or re-interventions for the underlying condition (TR, HF)
- Improvement from baseline in symptoms (NYHA class improvement ≥ 1 class)
- Improvement from baseline in functional status (6MWD improvement ≥ 30 meters)
- Improvement from baseline in QOL (KCCQ improvement ≥ 10 points)

4. ANALYSIS POPULATIONS

Analysis will be performed for the Enrolled, As-Treated (AT), and Per-Protocol (PP) populations defined below:

- **Enrolled Population**: All patients enrolled in the study, defined as patients who sign informed consent and have had the study procedure attempted (attempted defined as skin incision for study device). Enrolled population will be used for the safety analyses.
- **As-Treated Population**: A subset of the enrolled population who have had the study device implanted at the exit of procedure room. The AT population will be the analysis population for performance and functional endpoint analysis.
- **Per-Protocol Population**: A subset of the AT population who had no protocol deviations relating to inclusion and exclusion criteria for the trial.

5. DEFINITIONS

5.1 Analysis Dates and Days

- Reference Start Date and Day 0

  The reference start date is defined to be the date of the index procedure. The index procedure is defined as the time the first skin incision for the study device is established. If a patient has multiple procedure forms, information will be presented on the procedure with the first date when the site has indicated that the interventional skin incision for study device is performed. If no form has this indicated, then the procedure information corresponding to the date of the first procedure will be used.

  The reference start date is considered to be day 0.

- Last Participation Date

  The Last Participation Date is defined as the last date the patient was seen (refer to the programming convention for complete details).

- Last Participation Day

  Last Participation Day = Last Participation Date – Reference Start Date

  Note: Last Participation Day is used as censor day for Kaplan-Meier analysis.

- Study Day

  Study Day = Date – Reference Start Date

5.2 Analysis Windows

An assessment is considered scheduled if the assessment is identified by a nominal visit name (e.g., "Discharge," "30 day," and "1 year") regardless of if the actual visit date is within the protocol-defined visit window. An assessment is considered unscheduled if no nominal visit name is identified. Unless specified, any functional endpoints collected from unscheduled assessments should be excluded from analyses.

6. DATA AND ANALYSIS CONVENTIONS

6.1 General Conventions

For continuous variables, results will be summarized with the number of observations, mean, standard deviation, median, minimum, maximum, and 90% confidence interval (CI) by normal approximation. For categorical variables, results will be summarized with patient count, percentage, and 90% CI by normal approximation, where appropriate.

Survival analysis techniques will be used to analyze time-to-event variables. Patients without events will be censored at their last participation date in the study. For patients who did not have an event but remain in the study, they will be censored at the database extract date. Time to first event curves will be constructed using Kaplan-Meier estimates. Descriptive statistics will be presented at each assessment, including change from baseline to subsequent time point for selected endpoints. For the determination of event rates, the number of patients in the patient population who have had the events or have been followed up to the upper bound of the follow-up visit window will be used as the denominator. Unless otherwise noted, patients with missing data will be excluded from the denominator.

When the sample size is small (e.g., <10 patients), analysis may be performed in the form of listings only.

Quality of life questionnaires will be scored according to algorithms provided by the vendor. The various summary scores produced by the algorithms will be analyzed as continuous variables.

Unless otherwise specified, confidence limits will be two sided, using alpha = 0.05.

Unless otherwise specified, the precise form of each algorithm will be the default of SAS, using the latest release installed at Edwards Lifesciences (Edwards) at the time of analysis.

6.2 Handling of Missing Data

For AEs with partial onset dates, if the year is not missing, imputation will be performed by finding the earliest possible date on or after the index procedure. If the year is missing, no imputation will be performed.

For endpoint-related AEs (such as MAEs) with partial dates, in addition to applying the imputation method above, the sponsor will review the events and related records on a case-by-case basis, and manually verify the imputed dates. All imputations will be documented and filed in the Trial Master File (TMF).

For missing data due to patient withdrawal or lost to follow-up in the analyses of time-dependent endpoints, the patients will be censored on the last participation date as stated above.

Unless otherwise specified, all statistical analyses will be performed using only those patients with available data required for endpoint analysis, and no other missing value imputation will be performed.

7. SUMMARY OF BASELINE INFORMATION

7.1 Patient Enrollment and Accountability

The number of enrolled patients will be summarized overall and by investigational site. The table will be sorted by enrollment going from the highest enrollment site to the lowest enrollment site. The number of enrolled patients in each analysis population will be summarized as well.

The summary of subject disposition will include numbers of enrolled patients, eligible for visit, and non-eligible for visit by follow-up visit.

7.2 Demographics and Baseline Characteristics

Descriptive summary statistics of demographics and baseline characteristics will be presented for all three analysis populations. All demographics and baseline data will be listed as well.

- Age (years)
- Gender
- Body Mass Index (BMI)
- STS Mortality Score for MV Replacement Only (%)
- EuroSCORE II (%)
- TR grade (assessed by TTE)
- NYHA classification
- Clinical Frailty
- Katz ADL

7.3 Medical History and Prior Intervention

Medical history and prior interventions grouped by event types (cardiovascular, cardiovascular intervention and surgeries, and non-cardiovascular) will be summarized by counts and percentages for all three analysis populations.

7.4 Procedural Information

Procedural information will be summarized including but not limited to procedure duration and total length of stay for the index hospitalization for all three analysis populations.

8. STATISTICAL ANALYSIS OF STUDY ENDPOINTS

For statistical analyses of the study endpoints, Enrolled and AT populations will be used, unless otherwise stated.

8.1 Safety Endpoint

The safety endpoint of MAEs at 30 days shall be analyzed via the Kaplan-Meier method for the Enrolled and AT populations. In addition, the event rates of individual component of MAEs will also be calculated at 30 days, 6 months, and annually until 5 years post-procedure by the Kaplan-Meier method:

- Cardiovascular mortality
- Myocardial infarction (MI)
- Stroke
- Renal complications requiring unplanned dialysis or renal replacement therapy
- Severe bleeding (includes fatal, life-threatening, extensive, or major bleeding, as defined by MVARC)
- Non-elective tricuspid valve re-intervention, percutaneous or surgical
- Major access site and vascular complications
- Major cardiac structural complications
- Device-related pulmonary embolism

The number and percentage of patients with at least one MAE at 30 days will be summarized. The number of MAE at 30 days, 6 months, and annually will be reported as well. Additional analyses of safety endpoints using the PP population will be performed if there is/are a clinically meaningful difference(s) from the enrolled and AT populations.

8.2 Performance Endpoints

Device success, procedural success, and clinical success will be summarized by counts and percentages. For device success, the percentage will be based on the number of attempted device (per device analysis) in the Enrolled population. Procedural success will be analyzed based on the number of patients (per patient analysis) in the AT population, and device success per patient will be defined as at least one device success. Clinical success will be analyzed based on the number of patients (per patient analysis) in the AT population.

Additional analyses of performance endpoints using the PP population will be performed if there is/are a clinically meaningful difference(s) from the enrolled and AT populations.

8.3 Echocardiographic Endpoints and Parameters

The TR grade, collected by TTE and assessed by the echo core lab, at screening/baseline, discharge, 30 days, 6 months, 1 year, and annually until 5 years post-procedure will be summarized and plotted using count and percentage of patients who are in each classification category in the AT population. Paired analysis of the following visit compared with the screening/baseline visit will be performed using Wilcoxon signed-rank test if the paired data are more than 15 patients. The number and percentage of patients with moderate or less TR grading at screening/baseline, discharge, 30 days, 6 months, and 1 year will be summarized. The number and percentage of patients with at least one, two, three, four and five TR grade reductions at discharge will be reported. Transthoracic Echocardiogram (TTE) parameters assessed at baseline, discharge, 30 days, 6 months, 12 months, and annually until 5 years post procedure will be summarized using mean, SD, median, minimum, and maximum as well as change from baseline for each variable in the AT population.

Patients that undergo any type of repair or replacement procedure for the tricuspid valve will be excluded from the echocardiographic analysis at the time of the reintervention and summarized in a table.

8.4 Clinical and Functional Endpoints and Parameters

The clinical and functional endpoints and parameters will be presented in the AT population.

All-cause mortality rates, heart failure hospitalization rates, and non-elective tricuspid valve re-intervention (percutaneous or surgical) rates at 12 months and annually thereafter and the corresponding 95% confidence intervals will be computed using Kaplan-Meier estimates with the standard errors being computed using Greenwood's formula.

Volume overload assessed by serial measurements will be summarized at each timepoint using descriptive statistics.

NYHA class will be assessed at baseline, 1 month, 6 months and annually up to 5 years. The distribution (numbers of patients and percentages) in the various NYHA classes will be tabulated and plotted for each timepoint.

Change from baseline in NYHA class, body weight, ankle circumference measurement, and edema assessment will be presented as shift from baseline for each of the pre-specified follow-up periods. Paired t-test (for continuous data) or Wilcoxon signed-rank test (for categorical data) will be performed comparing the following timepoint with the screening/baseline data. Patients who are missing a baseline or follow-up value will be excluded from the paired analysis.

Quality of life (KCCQ, SF-36v2) and functionality (6MWT) measurements will be summarized at each visit using descriptive statistics. Change from baseline at corresponding follow-up visits will be summarized by mean and standard deviation. Patients who are missing a baseline or follow up values will be excluded from the analysis. For the analyses of 6MWT, patients unable to perform the walk due to a medical reason will be considered to have walked an actual distance of zero.

Patient Preference Survey at baseline will be performed and reported by Edwards Global Health Economics and Reimbursement (GHER) separately.

The number and percentage of patients who had clinically significant abnormal laboratory parameters (out of normal range) collected per protocol will be summarized at each visit.

8.5 Electronic Diary and Activity Monitoring Sub-Study Endpoints

For patients participating in the sub-study, the electronic patient reported outcome data and actigraphy data collected from the activity monitor will be obtained by Edwards GHER department outside of the electronic data capture (EDC) RAVE system. These data will be analyzed by summary statistics for the AT population, and more in-depth analyses will be performed and reported by GHER separately.

8.6 Exploratory Computed Tomography (CT) Endpoints

The following data will be assessed and summarized descriptively at 30 days and 12 months (when the data are available).

- Cardiac remodeling (e.g., RV dimensions and volume)
- EVOQUE frame dimensions
- EVOQUE leaflet assessment
- EVOQUE positioning

8.7 Patient-centered Exploratory Endpoints

The patient-centered exploratory endpoints (as described in Section 3.7) will be analyzed as categorical variables and counts and percentages in the AT population.

- Exploratory Device Success (30 days and all post-procedural intervals)
- Exploratory Procedural Success (30 days)
- Exploratory Technical Success (at exit from OR/Cath lab)
- Exploratory Individual Patient Success (1 year)

The patient-centered exploratory endpoints (as described in Section 3.7) will be analyzed as categorical variables and counts and percentages in the AT population.

9. ANALYSIS OF SAFETY

9.1 Deaths

The primary cause of death will be summarized descriptively by counts and percentages at 30 days and 1 year and annually thereafter.

9.2 Adverse Events

All Clinical Events Committee (CEC)-adjudicated and site-reported AEs with onset on or after the procedure date (Day 0) after implant will be summarized by early events (≤ 30 days) and late events (> 30 days) for the Enrolled Population. Summaries of incidence rates (counts and percentages) will be reported. SAEs will be summarized by early events (≤ 30 days) and late events (> 30 days) as well.

AEs with onset prior to procedure will not be collected. Listings for all AEs and SAEs that occur post-procedure in the Enrolled Population will be provided.

9.3 Cardiac Monitoring

The counts and percentages of patients who experience newly identified ECG changes, as identified by ambulatory cardiac monitoring, resulting in PPM, ICD, or CRT device implantation will be reported. Two-sided 90% confidence intervals will be constructed around the percentages of patients who experience newly identified ECG changes resulting in PPM, ICD, or CRT device implantation. These analyses will only include patients who undergo ambulatory cardiac monitoring. The reported confidence intervals will be compared to the ranges reported in the literature data.

The count and percentage of patients who have a change in therapy (either new pacemaker for bradycardia or new ICD/new pharmacotherapy for tachycardias) as a result of ECG changes identified by ambulatory cardiac monitoring will be reported. This analysis will only include patients who undergo ambulatory monitoring.

10. CHANGES FROM PROTOCOL SPECIFIED ANALYSES

The patient-centered exploratory endpoints are not specified in the study protocol and only described in Section 3.7 of this SAP.

11. REFERENCES

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4. Konoske R, Whitener G, Nicoara A. Intraoperative Evaluation of Paravalvular Regurgitation by Transesophageal Echocardiography. *Anesth Analg.* 2015;121(2):329-336.
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12. APPENDIX

None

13. PEER REVIEW REQUEST, PER SAP INSTRUCTION [redacted]

Yes	Name of Reviewer:	No	Reason Peer Review not Needed:

☑	[redacted]	☐	