

Statistical Analysis Plan (SAP)

The PulseSmart study
Safety and Effectiveness Evaluation of the THERMOCOOL SMARTTOUCH™ SF Catheter with the TRUPULSE™ Generator for treatment of drug refractory symptomatic Paroxysmal Atrial Fibrillation (PAF) (BWI202308)

Protocol Version: 1.0

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SAP Revision: 1.0
SAP Revision Date: 26/JAN/2024

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Revision History

Revision Number	Revision Date (DD/MM/YYYY)	Reasons for Revision
1.0	26/JAN/2024	Original document: SAP template version 5.0 implemented.

List of Acronyms and Abbreviations

AAD	Anti-arrhythmic Drug
AE Fistula	Atrial-esophageal Fistula
AF	Atrial Fibrillation
AFEQT	Atrial Fibrillation Effect on QualiTy-of-life
AFL	Atrial Flutter
AT	Atrial Tachycardia
BMI	Body Mass Index
CEC	Clinical Events Committee
CIP	Clinical Investigation Plan
CT	Computed Tomography
CV	Cardioversion
DCCV	Direct Current Cardioversion
DMC	Data Monitoring Committee
ECG	ElectroCardioGram
FDA	Food and Drug Administration
FPI	First Pass Isolation
FWER	Familywise Error Rate
HRQoL	Health Related Quality of Life
LA	Left Atrium
LOCF	Last Observation Carry Forward
LVEF	Left Ventricle Ejection Fraction
Max	Maximum
Min	Minimum
mITT	Modified Intent-To-Treat
MMSE	Mini Mental State Examination

MRA	Magnetic Resonance Angiogram
MRI	Magnetic Resonance Imaging
mRS	Modified Rankin Scale
NIHSS	National Institutes of Health Stroke Scale
NIS	Nationwide Inpatient Sample
NSD	Non-study Device
OSA	Obstructive Sleep Apnea
PAE	Primary Adverse Event
PAF	Paroxysmal Atrial Fibrillation
PEE	Primary Effectiveness Endpoint
PF	Pulsed Field
PFA	Pulsed Field Ablation
PG	Performance Goal
PP	Per-Protocol
PV	Pulmonary Vein
PVI	Pulmonary Vein Isolation
PVS	Pulmonary Vein Stenosis
QoL	Quality of Life
Q1	First Quartile
Q3	Third Quartile
RF	Radiofrequency
SADE	Serious Adverse Device Effects
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SP	Safety Population
STSF	THERMOCOOL SMARTTOUCH™ SF

TTM	Transtelephonic Monitor
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect

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1 Study Design

This clinical investigation is a prospective, interventional, single-arm, multi-center, and pre-market clinical evaluation of the Biosense Webster Pulsed Field (PF)/Radiofrequency (RF) Ablation System (THERMOCOOL SMARTTOUCH™ SF (STSF) Catheter and TRUPULSE™ Generator, and the CARTO™ 3 System V7.9 workstation). The primary objective of this trial is to evaluate the safety and effectiveness of the ablation system for the treatment of Paroxysmal Atrial Fibrillation (PAF).

The study will enroll 135 subjects with drug refractory PAF who are candidates for atrial fibrillation ablation CCI in Canada and Australia. To ensure the generalizability of study results and minimize the influence of any single site, C [redacted] in the study will be allowed at a single site. All subjects will be followed for 12 months and scheduled for evaluation at 7 days, 1-, 3-, 6- and 12 months following the index ablation procedure.

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2 Treatment Assignment

All subjects will be treated with the Biosense Webster Ablation System, which includes the TRUPULSE™ Generator (D-1417-01-IC), the THERMOCOOL SMARTTOUCH™ SF Bi-directional Navigation Catheter (D-1348-05-SI-10) (also referred to as THERMOCOOL SMARTTOUCH™ SF (STSF) Catheter), the CARTO™ 3 System V7.9 workstation with PFA THERMOCOOL SMARTTOUCH™ SF Support (CARTO® 3 V7.9.1, CARTO® 3 V7.9 Phase 1) and related components and accessories needed for the ablation procedure will be used in conjunction with the investigational devices.

3 Randomization and Blinding Procedures

This is a non-randomized single-arm trial with all subjects undergoing ablation procedure with the PF/RF ablation system. Therefore, masking of treatment assignments for operators and subjects will not be performed.

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4 Interval Windows

Each subject who undergoes initial ablation procedure per protocol will be required to complete follow-up visits through 12 months post initial ablation procedure. Follow-up visits should be scheduled according to the following timeframes: 7 day +3 days (7-10; phone call or clinic visit), 1 month ±7 days (1M Day 23-37), 3 month ±14 days (3M, Day 76-104), 6 month ±30 days (6M, Day 150-210), and 12 month ±30 days (12M, Day 335-395). CCI

5 Levels of Significance

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6 Analysis Sets

For the analysis of study endpoints, the analysis sets defined in the following sections will be used:

- **Safety Population Analysis Set (SP):** CCI

- **Modified Intent-To-Treat (mITT) Analysis Set**: CCI

- **Per Protocol Analysis Set (PP)**: CCI

7 Sample Size Justification

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[redacted]

[redacted]

8 Statistical Analysis Methods

8.1 General Conventions

Descriptive summaries for continuous variables include the number of observations (n), mean, standard deviation (SD), median, 25th percentile (Q1), 75th percentile (Q3), minimum (Min), and maximum (Max). For categorical data, frequency tables will be provided to show the count (n) and percentage (%) within a particular category. Percentages will be based on the number of observations with available data. Unless specified otherwise, all confidence intervals will be at a 95% confidence level.

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8.2 Disposition of Study Subjects

Subject disposition and accountability of the study subjects will be summarized descriptively for all enrolled subjects. The definition of disposition categories can be found in section 13.1.4 of the study protocol.

8.3 Demographic and Baseline Characteristics

Subject demographics and baseline characteristics such as medical history, AAD use history, concomitant AAD after enrollment, and atrial fibrillation history will be summarized descriptively for the enrolled subjects as well as the subjects in the CCI [redacted]

8.4 Endpoints and Associated Hypotheses

8.4.1 Primary Endpoints

8.4.1.1. Primary Safety Endpoint

The primary safety endpoint for a subject is defined as having Primary Adverse Events (PAEs) (within 7 days of an index ablation procedure (including the initial and repeat procedures) which use the investigational STSF catheter and TRUPULSE™ generator per clinical investigation plan). The definition of PAE can be found in section 17.1.3 of the study protocol.

To evaluate the primary objective of the study, the PAE rate will be compared against a performance goal (PG) of 12%. The formal hypotheses to test the primary safety endpoint are given as follows:

$$H_0: P_S \geq 0.12$$

$$H_a: P_S < 0.12$$

where P_S represents the primary adverse event rate.

8.4.1.2. Primary Effectiveness Endpoint

The primary effectiveness endpoint (PEE) for a subject is defined as freedom from documented (symptomatic and asymptomatic) atrial tachyarrhythmia (AF, AT or AFL of unknown origin+) episodes based on electrocardiographic data (12-lead ECG or ≥30 seconds on ECG or sponsor provided Holter device) during the effectiveness evaluation period (Day 91-Day 365) and freedom from the following failure modes:

- **Acute procedural failure**, including:
  - Failure to achieve entrance block in all pulmonary veins using the investigational device (except those that are silent and/or cannot be cannulated post-procedure) by the end of the procedure

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CCI [redacted]

- **Repeat ablation failure**, including:
  - More than 1 repeat ablation procedures for AF/AT/ AFL (of unknown origin+) during the 3-Month Blanking Period (Day 0-90 post index procedure).
  - Any repeat ablation procedure for AF/AT/ AFL (of unknown origin+) during the evaluation period.

- **Non-study device failure**, including:
  - Use of a non-study device to treat PV targets to achieve isolation of clinically relevant PVs (all PVs except those that are silent and/or cannot be cannulated) during index or repeat procedure in the blanking period.
  - Use of a non-study device for ablation in the left atrium during either index or repeat procedure within the blanking period.

- **AAD failure**:
  - Taking a new AAD (Class I & III) for atrial tachyarrhythmia (AF, AT or AFL of unknown origin+) or taking a previously failed Class I/III AAD after the 3-month follow-up visit window (i.e., any time beyond Day 104 to 365 post index procedure).
  - Oral amiodarone is prescribed/taken post index ablation procedure.

- **Continuous AF/AT/AFL of unknown origin+** on a standard 12-lead ECG during the effectiveness evaluation period.

- **Any DC cardioversion procedure** during the evaluation period for documented atrial tachyarrhythmia (AF, AT or AFL of unknown origin+) recurrences ascertained through protocol specified arrhythmia monitoring methods (12-lead ECG, Holter).

C [redacted]
C [redacted]

To evaluate the primary objective of the study, the 12-month effectiveness success rate will be compared against a PG of 50%. The formal hypotheses to test the primary effectiveness endpoint are given as follows:

$$H_0: P_E \leq 0.5$$

$$H_a: P_E > 0.5$$

where P_E represents the 12-month effectiveness success rate.

8.4.2 **Secondary Endpoint**

The secondary endpoint for a subject is defined as the change in total Atrial Fibrillation Effect on Quality-of-Life (AFEQT) score at 12M post procedure compared to the baseline score. The definition of a secondary endpoint can be found in section 11.2 of the study protocol.

The AFEQT™ questionnaire includes 20 questions on a 7-point Likert scale. Questions 1-18 evaluate Health Related Quality of Life (HRQoL) and questions 19-20 relate to patients' satisfaction with treatment. CCI [redacted]

- [redacted]
- [redacted]
- [redacted]

CCI [redacted]

Overall and subscale scores range from 0 to 100. A score of 0 corresponds to complete disability, while a score of 100 corresponds to no disability.

To evaluate the secondary objective of the study, the change in quality of life (QoL) at 12 months after the ablation procedure assessed by the AFEQT score will be formally tested using the following set of hypotheses:

$$H_0: \mu_d \leq 0$$

$$H_A: \mu_d > 0$$

where μ_d is the mean change of overall AFEQT scores between baseline AFEQT score and 12-month AFEQT score (i.e., $AFEQT_{12M} - AFEQT_{baseline}$).

8.4.3 **Additional Endpoints**

No statistical hypothesis testing will be formulated for additional endpoints.

8.4.3.1. **Additional Safety Endpoint**

- Occurrence of Serious Adverse Device Effects (SADEs)
- Occurrence of Unanticipated (Serious) Adverse Device Effects (UADEs and USADEs)
- Occurrence of non-serious adverse events (non-SAEs)
- Occurrence of device and/or procedure related Serious Adverse Events (SAEs) within 7 days (early-onset), 8-30 days (peri-procedural), and >30 days (late onset) of initial ablation procedure

The definition of SAEs can be found in section 17.1.2 of the study protocol.

8.4.3.2. **Additional Effectiveness Endpoint**

- Acute procedural success: the achievement of electrical isolation for all PVs which is evidenced by the confirmation of entrance block at the end of the procedure. Use of solely RF mode for PV isolation, resulting from study device malfunction leading to a failure in PF energy delivery is also deemed a failure.
- Acute reconnection: the restoration of electrical conduction in the targeted veins, which is identified by adenosine/isoproterenol challenge.
- First pass isolation: the achievement of entrance block in targeted veins after the first encirclement, which is evaluated prior to the adenosine challenge.
- Ablation by a non-study device for PVI (Touch-up): Use of non-study device for touch-up ablation to achieve PV isolation in all clinically relevant targeted PVs.
- Repeat ablation procedures for left atrial arrhythmia (AF, AT or AFL of unknown origin*) within the 12-month FU period will be assessed. The evaluation will include the timing of repeat ablation (blanking period or after blanking), any reconnections of targeted PVs from the index procedure, and the type of arrhythmia treated during the repeat ablation, along with their corresponding targets.
- 12 Month Single Procedure Treatment Success: freedom from documented symptomatic atrial tachyarrhythmia (AF, AT or AFL of unknown origin+) episodes based on electrocardiographic data (12-lead ECG or ≥30 seconds on ECG or sponsor provided Holter device) during the effectiveness evaluation period (Day 91-Day 365) following a single index ablation procedure, and freedom from the following failure modes:
    - Acute procedural failure: Failure to achieve entrance block in all pulmonary veins using the investigational device (except those that are silent and/or cannot be cannulated post-procedure) by the end of the procedure
    - Non-study device failure: use of a non-study device to treat pulmonary vein targets to achieve isolation of clinically relevant PVs (all PVs except those that are silent and/or cannot be cannulated) during the index procedure.
    - Any repeat ablation procedure for AF/AT/AFL (of unknown origin+) post the index procedure

- 12-Month freedom from symptomatic recurrence: freedom from documented symptomatic atrial tachyarrhythmia (AF, AT or AFL of unknown origin+) episodes based on electrocardiographic data (12-lead

ECG or ≥30 seconds on ECG or sponsor-provided Holter device) during the effectiveness evaluation period (Day 91-Day 365).

- Hospitalization for cardiovascular events: the impact of ablation procedure on CV hospitalization 12M after the index procedure, in comparison to the hospitalization history prior to enrollment
- DC Cardioversion: the impact of ablation procedure on the number of receiving DCCV 12M after the index procedure, in comparison to the history of DCCV prior to enrollment.
- AAD Utilization: the impact of ablation procedure on the utilization of antiarrhythmic drugs during the follow-up, in comparison to the baseline AAD use

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8.4.3.3. Additional Procedural Data

Including but not limited to:

- Total procedure time (from first femoral puncture to last catheter out)
- PVI time
- PF/RF application time
- Mapping time
- Number of PFA/RF applications by left and right PV
- Total fluoroscopy time
- Fluid delivered from the study catheter
- Total study catheter left atrial dwell time
- Ablation parameters per application ((e.g., temperature, power, impedance, contact force (CF), PF or RF, RF power, PF/RF tag index per segments etc.)
- VISITAG SURPOINT™ values (Tag Index) per segment
- Power Range
- CF Range
- Use of paralytics and type of anesthesia
- Device Deficiency Information (if applicable)

8.5 Analysis of Primary Endpoints

The PAE rate will be formally compared against a performance goal of 12% and the PEE rate will be formally compared to a performance goal of 50%.

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8.5.1 Plans for Interim Analysis

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8.5.1.1. Interim Analysis of Primary Safety Endpoint

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8.5.1.2. Interim Analysis of Primary Effectiveness Endpoint

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8.5.1.3. Success Criteria for Interim Analysis

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8.5.2 Plans for Final Analysis

The final analyses as described below will be conducted based on the complete 12-month follow-up data only if the early success is not achieved.

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8.5.2.1. Final Analysis of Primary Safety Endpoint

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CCI [redacted]

8.5.2.2. Final Analysis of Primary Effectiveness Endpoint

CCI [redacted]

8.5.2.3. Success Criteria for Final Analysis

CCI [redacted]

8.6 Sensitivity Analyses

To investigate the robustness of the primary endpoint analyses, the following sensitivity analyses will be performed for both primary endpoints.

8.6.1 Interim Analysis

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8.6.1.1. Primary Safety Endpoint

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CCI [redacted]

[redacted]

[redacted]

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[redacted]

8.6.1.2. Primary Effectiveness Endpoint

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[redacted]

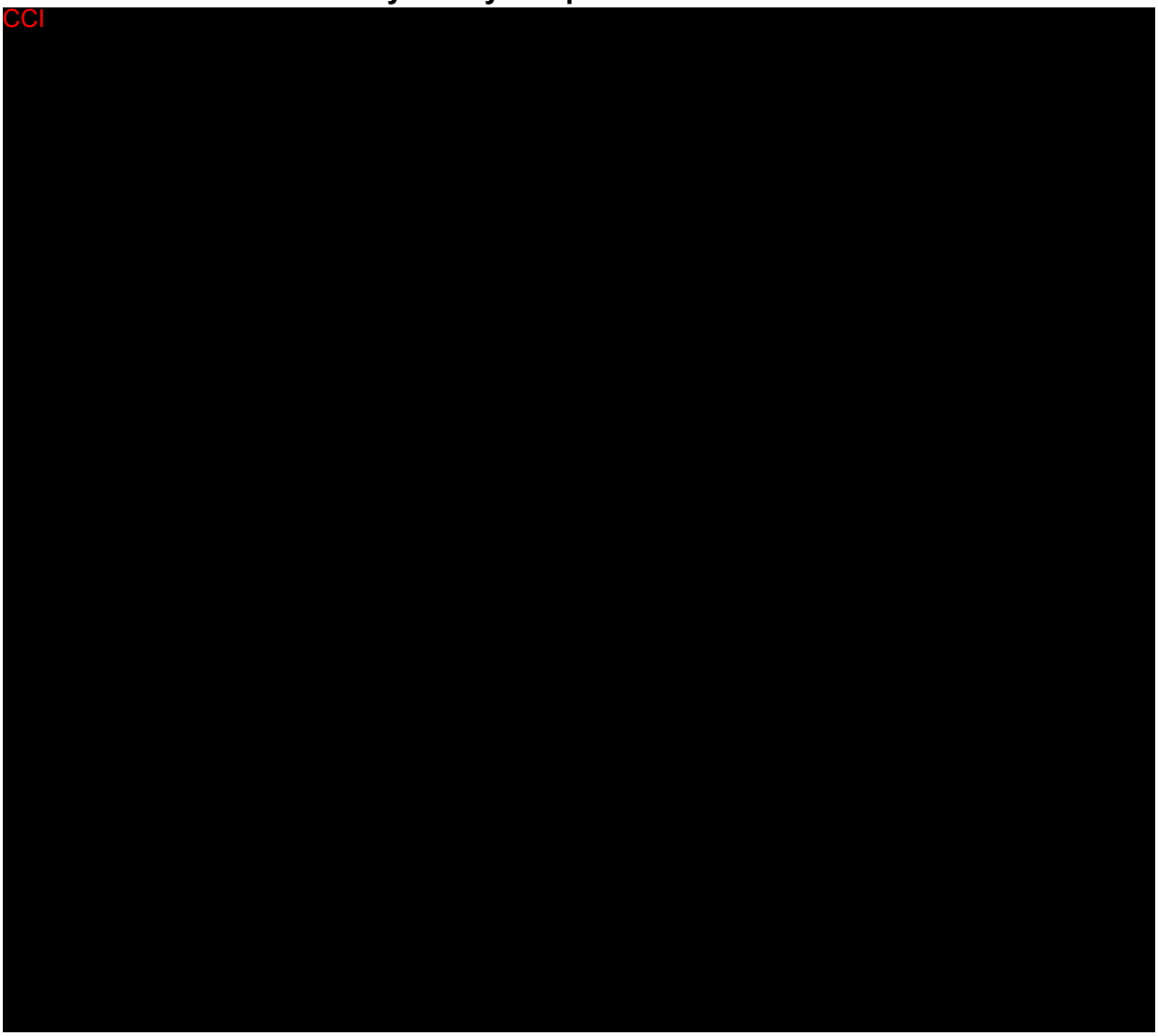
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8.6.2 Final Analysis

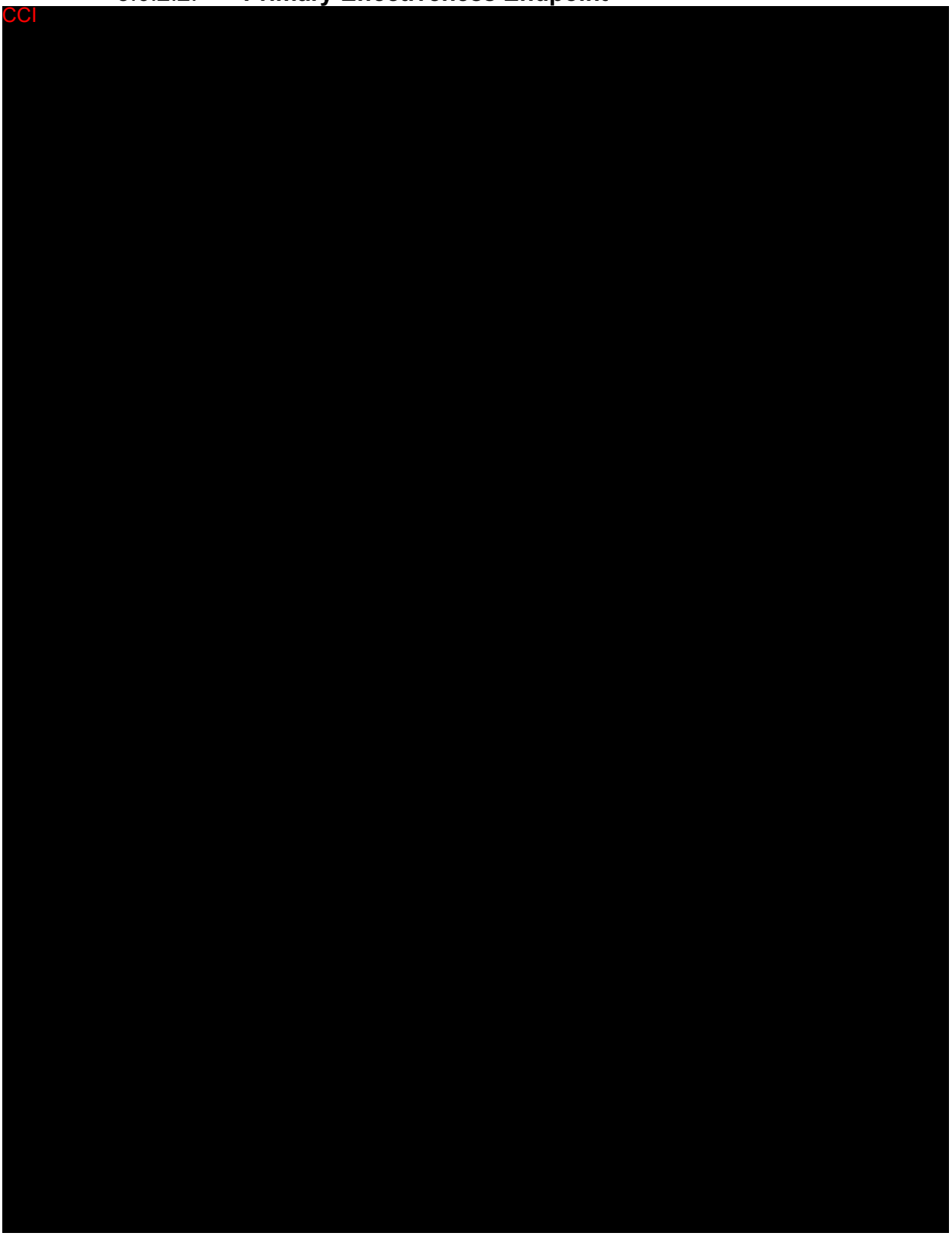
To investigate the robustness of the final analysis result, the following sensitivity analyses will be performed at the time of the final analysis with complete follow-up data:

8.6.2.1. Primary Safety Endpoint



8.6.2.2. **Primary Effectiveness Endpoint**

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8.7 Subgroup Analyses

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[redacted]

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8.8 Assessment of Site Homogeneity

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8.9 Exploratory Analyses

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8.10 Handling of Missing Data

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[redacted]

8.10.1 **Interim Analysis**

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8.10.2 **Final Analysis**

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CCI [redacted]

8.11 Adjustments for Multiplicity

CCI [redacted]

8.12 Analyses of Secondary Endpoint

Baseline AFEQT scores and changes from baseline at each follow-up timepoint the questionnaire is administered will be summarized descriptively for the following five scores. The overall AFEQT score and subscale scores across study visits will also be plotted.

- Overall AFEQT Score (18 questions)
- Symptom Subscale Score (4 questions)
- Daily Activities Subscale Score (8 questions)
- Treatment Concern Subscale Score (6 questions)
- Treatment Satisfaction Score (2 questions)

CCI [redacted]

8.13 Analyses of Additional Endpoint

No statistical hypothesis testing will be formulated for the additional endpoints. All additional endpoints will be summarized descriptively in the analysis sets specified below.

CCI [redacted]

8.13.1 Additional Safety Endpoints

The additional safety endpoints will be summarized descriptively as the total number of events, number of subjects with events, and percentage of subjects with events. CCI [redacted]

8.13.2 Additional Effectiveness Endpoints

CCI [redacted]

- **Acute procedural success**: defined as achievement of electrical isolation of all PVs which is evidenced by the confirmation of entrance block at the end of the procedure. Use of a non-study catheter to achieve PVI due to study device related reason is considered an acute procedural failure. Use of solely RF mode for PV isolation, resulting from study device malfunction leading to a failure in PF energy delivery is also deemed a failure.

  The rate of acute procedural success will be summarized descriptively. The number and percentage of subjects and PVs with acute procedural success will be presented. The following will also be summarized descriptively by both subject and by PV:

  - **Acute reconnection**: defined as the restoration of electrical conduction in the targeted veins, which is identified by adenosine/isoproterenol challenge. The number and percentage of targeted PVs and subjects where acute reconnection was identified by adenosine/isoproterenol challenge:

CCI [redacted]

- **First pass isolation (FPI)**: The number and percentage of targeted PVs and subjects with achievement of entrance block after first encirclement evaluated prior to the adenosine challenge:

CCI [redacted]

- **Touch-up by NSD**: The number and percentage of targeted PVs and subjects ablated by a NSD for PVI during index procedure:

CCI [redacted]

- **Repeat ablation procedure**:
  - **Incidence of repeat procedures**: Kaplan-Meier estimates and plots will be used to characterize the time to the first repeat ablation procedure for AF/AT/AFL of unknown origin within the 12-month follow-up period. The probability of freedom from repeat ablation for AF/AT/AFL of unknown origin at each monthly timepoint post index procedure will be presented. CCI [redacted]
  - **PV reconnection**: The number and percentage of targeted PVs and subjects at the repeat procedure where PV reconnection was observed:

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[redacted]

- **12 Month Single Procedure Treatment Success**: Kaplan-Meier estimates and plots will be used to characterize the time to first documented symptomatic atrial tachyarrhythmia (AF, AT or AFL of unknown origin+) episodes based on electrocardiographic data (12-lead ECG or ⩾30 seconds on ECG or sponsor provided Holter device) during the effectiveness evaluation period (Day 91-Day 365) following a single index ablation procedure with *additional failure modes*.

  The probability of freedom from failure at each monthly time point post blanking will be presented.

  Additional failure modes are listed below:
  - Acute procedural failure:
    - Failure to achieve entrance block in all pulmonary veins using the investigational device (except those that are silent and/or cannot be cannulated post-procedure) by the end of the procedure
  - Non-study device failure:
    - Use of a non-study device to treat pulmonary vein targets to achieve isolation of clinically relevant PVs (all PVs except those that are silent and/or cannot be cannulated post-procedure) during the index procedure
  - Any repeat ablation procedure for AF/AT/AFL (of unknown origin+) post the index procedure

- **12-Month freedom from symptomatic recurrence:** Kaplan-Meier estimates and plots will be used to characterize the time to first documented symptomatic atrial tachyarrhythmia (AF/AT/AFL or unknown origin+) episodes based on electrocardiographic data (12-lead ECG or ⩾30 seconds on ECG or sponsor provided Holter device) during the effectiveness evaluation period (Day 91-Day 365). The probability of freedom from failure at each monthly time point post blanking will be presented.

- **Hospitalization for Cardiovascular Events** through 12 months follow-up compared to 12 months prior to baseline. The number and percentage of subjects and number and percent of hospitalization for cardiovascular event in baseline and follow-up period will be summarized descriptively.

- **Reduction in DCCV**: Defined as reduction in DCCV for AF/AT/AFL (of unknown origin^{+}) 12 months post procedure compared to 12 months prior to

enrollment. Baseline and follow-up rates will be summarized descriptively. The DCCV reduction rate will be calculated as below.

CCI [redacted]

- **AAD Utilization by timing**: Defined as change in the proportion of subjects on AADs by timing compared to baseline. CCI [redacted]

8.13.3 Procedural Data

Additional procedural data will be summarized descriptively CCI [redacted]

9 Data Monitoring Committee (DMC)

A Data Monitoring Committee (DMC) will assess subjects' data for safety on regular intervals and make recommendations on study adaptations as described in the DMC Charter. An independent statistician will be responsible for conducting the interim analyses and reviewing the results with the designated DMC. The DMC charter will document the constitution, roles and responsibilities of the committee, sponsor, and the independent statistician.

10 Appendix I – Adaptive Design Simulation Report

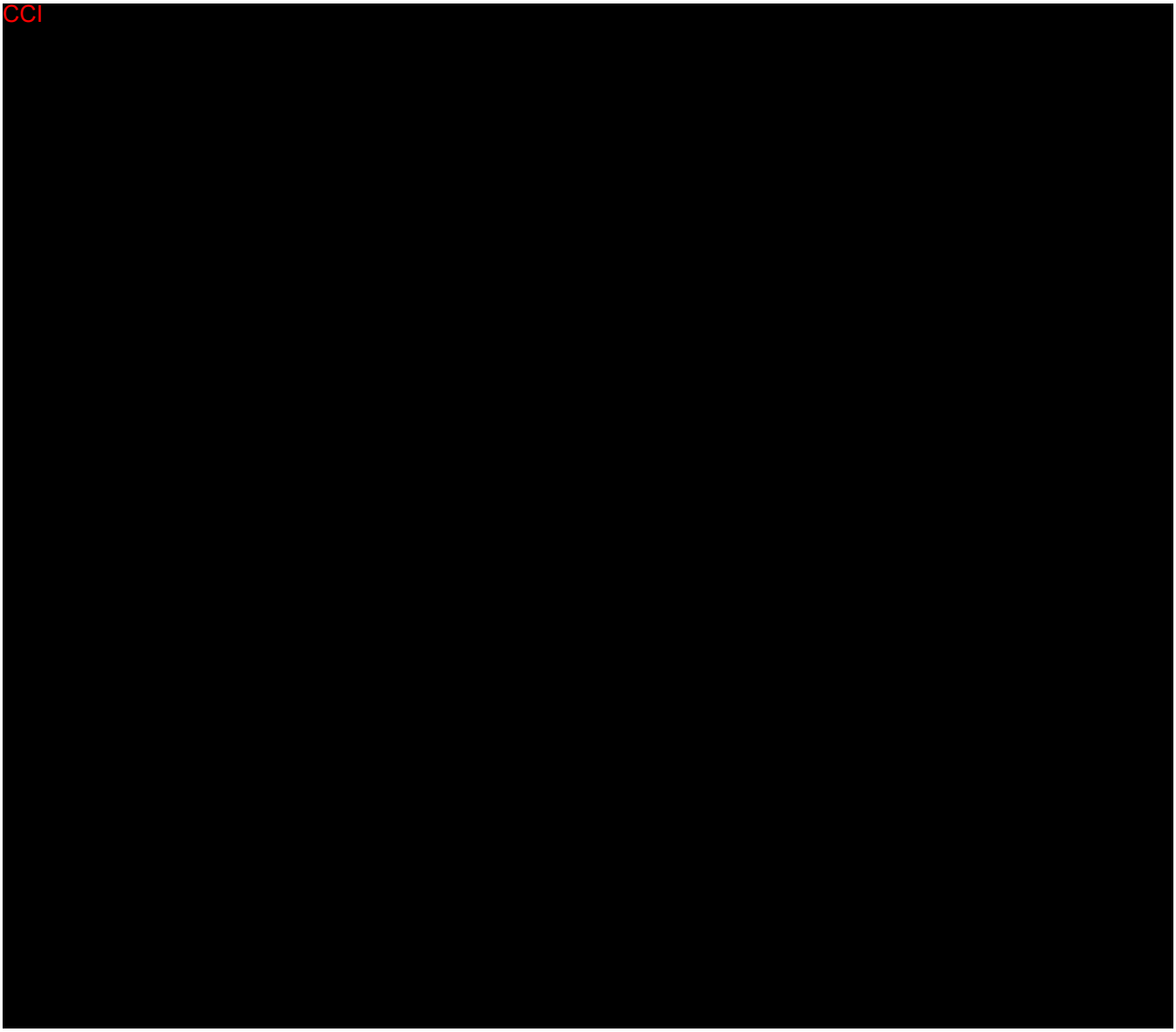
10.1 Study Overview

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10.2 Early Success Interim Analysis

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10.3 Justification for Using a 3-Month Safety Rate for Early Success Analysis

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10.4 Final Primary Safety and Effectiveness Analyses

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10.5 Power and Type-I Error Simulations

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Table 1 CCI

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Table 2 CCI

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Table 3 CCI

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Table 4 CCI

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Table 5 CCI

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Table 6 CCI

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Table 7 CCI

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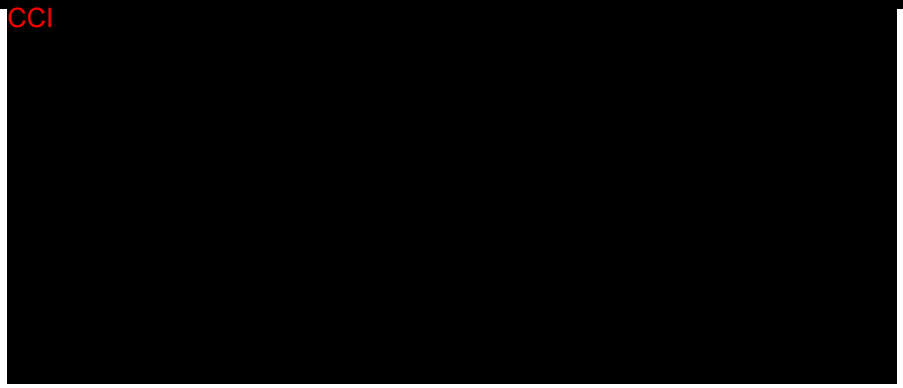
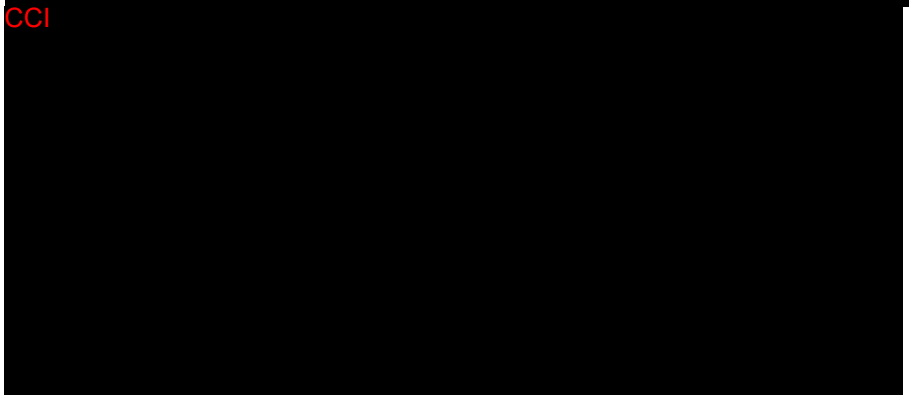


Table 8 CCI

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References

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