# STATISTICAL ANALYSIS PLAN (SAP)

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|---|---|
| **Study name** | **The SEPARATE Study** |
| **Protocol Number** | **SEN_PAD_1** |
| **SPONSOR** | **SENSOME SAS**<br>2-12 rue du Chemin des Femmes<br>91300 MASSY, FRANCE |
| **SAP version** | **2** |
| **Date** | **12 November 2024** |

This Statistical Analysis Plan has been approved by the Statistician and the Sponsor. The following signatures document this approval.

| | Name | Function | Date/Signature |
|---|---|---|---|
| **Prepared by** | Julie LAFAURIE | Clinical and Preclinical Lead | DocuSigned by: 22-Nov-2024 98CCEA2E8FFE4FA... |
| **Reviewed by** | Tine WILLEMS | Biostatistician | DocuSigned by: Tine Willems 22-nov-2024 11ED3E0DE81245E... |
| **Reviewed by** | Christos ZACHAROPOULOS | Data Scientist | DocuSigned by: Christos ZACHAROPOULOS 22-Nov-2024 FEA2439E497E4EE... |
| **Approved by** | Hans TIELEMANS | Clinical Expert | DocuSigned by: Hans Tielemans 22-Nov-2024 0CB84100DB29425... |

| Version | Change |
|---|---|
| 1 | Creation |
| 2 | Section 5.2 – Secondary Endpoints: Change of prediction model development.<br>Section 8 – Analysis Variables: Wording adjusted, Addition of device inspection after use.<br>Section 9.1 – Statistical procedures: Paragraph deleted because redundant with section 5.2 (prediction model development and secondary endpoint analysis) |

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|---|---|
| | Section 9.5 – Sensitivity analysis: Acute/Chronic cases sensitivity analysis deleted because physician's assessment during the PAD procedure is more accurate (using the tagged measurements).<br>Section 10 – Description of Tables, Listings and Figures: Adjusted to better reflect the relevant analysis (variables more detailed, presentation in Tables and/or Listings better described). |

# TABLE OF CONTENTS

# 1 Abbreviations and Definitions

| Term | Definition |
|---|---|
| ABI | Ankle Brachial Index |
| ADE | Adverse Device Effect |
| AE | Adverse event |
| BLE | Bluetooth Low Energy |
| CIP | Clinical Investigation Plan |
| CSGS | Clotild® Smart Guidewire System |
| CSR | Clinical Study Report |
| CT scan | Computed Tomography Scan |
| DSA | Digital Subtraction Angiography |
| DSMB | Data Safety Monitoring Board |
| EC | Ethics Committee |
| (e)CRF | (Electronic) Case Report Form |
| ITT | Intent to treat |
| MRI | Magnetic Resonance Imaging |
| PAD | Peripheral Artery Disease |
| SADE | Serious Adverse Device Effect |
| SAE | Serious Adverse Event |
| SAP | Statistical Analysis Plan |
| TASC | TransAtlantic Inter-Society Consensus (on the Management of Peripheral Arterial Disease) |

# 2 Introduction

The purpose of this Statistical Analysis Plan (SAP) is to prospectively outline the types of analyses and presentations of the data that will form the basis for conclusions regarding this clinical investigation. The analyses defined in this plan should answer the safety and performance objectives outlined in the Clinical Investigation Plan (hereunder called CIP or protocol) and explain in detail how the data will be handled and analysed, adhering to commonly accepted standards and practices for biostatistical analysis in the medical device industry.

This document contains information to support the generation of a Clinical Study Report (CSR) for Clinical Investigation Plan number SEN_PAD_1, including detailed descriptions of the statistical methods to be applied, as well as the analysis summary tables and figures and patient data listings intended to present the analysis results. The analyses described are based on the final CIP (*CLI_INVEST_PLAN_SEPARATE_V3*, version 3 dated 1 September 2023). The SAP will be finalized prior to database lock and describes the statistical analysis as it is foreseen when the study is being planned. If circumstances should arise during the study rendering this analysis inappropriate, or if improved methods of analysis should arise, updates to the analyses may be made. Any deviations from the SAP after database lock, reasons for such deviations and all alternative or additional statistical analyses that may be performed, will be described in a SAP Addendum.

The planned analyses identified in this SAP may be included in regulatory submissions, medical presentations and manuscripts. Exploratory analyses, not identified in this SAP, may be performed to support the clinical development program. Any post-hoc or unplanned analyses that are performed but not identified in this SAP will be clearly identified in the CSR.

# 3 Study objective

The objective of the SEPARATE study is to evaluate the feasibility of the Clotild® Smart Guidewire System (CSGS) to provide electrophysiological measurements of various lesion tissues involved in Peripheral Artery Disease (PAD) with the goal of improving patient's outcome. The main goal of the study is to evaluate the feasibility of the CSGS sensor to differentiate tissues involved in Peripheral Artery Disease (PAD).

# 4 Study design and plan

This study is a prospective, single-centre, non-randomized, feasibility study in subjects presenting with PAD. Up to 30 patients, at one centre in Belgium – AZ Sint Blasius Hospital, Dendermonde, Belgium suffering from Chronic Total Occlusions or Acute Limb Ischemia will be included in this study. The follow-up duration is until 24 hours post-procedure per patient. Due to the exploratory nature of the trial, no hypotheses are set forward. The collected data will serve only for the exploratory purpose and will be used to develop statistical models to differentiate tissues.

An overview of all follow-up times and respective captured information can be consulted in table 1.

**Table 1. Study activity overview**

| Parameter/Examination | Screening[1] | Procedure | 24hrs (-12hrs.) Post-procedure |
|---|---|---|---|
| Inclusion/Exclusion criteria | X | X[2] | |
| Patient Information/ informed consent[3] | X | | |
| Physical examination (<2 weeks) | X | | |
| Demographics & medical history including time of claudication onset and Rutherford classification | X | | |

[1] To take place ≤4 weeks prior to the study procedure
[2] Eligibility to be reconfirmed prior to the study procedure
[3] If ICF was obtained >4 weeks prior to the screening visit, the patient will reconfirm his willingness to participate in the study by signing and personally dating the document again

| | | | |
|---|---|---|---|
| Pregnancy test[4] | X | | |
| Vital Signs | X | X | |
| Ankle Brachial Index (ABI) (<3 months) | X | | |
| Imaging exams | Echo / CT / CTA[5] | DSA[6] | |
| Study procedure | | X | |
| AE/SAE | | X | X |
| Concomitant medication | X | X | X |

# 5 Endpoints

## *5.1 Primary Endpoint*

The Primary Performance Endpoint is defined as the ability of Clotild® Smart Guidewire System to acquire electrophysiological measurements in the lesion and/or subintimal. Data of the 9 individual impedance measurements will be collected during the procedure and might be aggregated at the row level or sensor level (see

Figure **1**). This endpoint represents the procedural success rate being defined as the CSGS obtaining at least one non-anomalous impedance measurement in the lesion during the procedure. Given the feasibility nature of the study, a success rate of 60% is expected.

The primary endpoint will be defined as the proportion of patients in which at least one non-anomalous electrophysiological measurement was obtained by the CSGS in the lesion and/or subintimal.

This proportion will be determined by:

$$\frac{number\ of\ patients\ with\ at\ least\ one\ non-anomalous\ electrophysical\ measurement}{number\ of\ patients\ in\ which\ the\ guidewire\ went\ through\ the\ sheath}$$

or $$\frac{number\ of\ patients\ in\ performance\ population}{number\ of\ patients\ in\ treated\ population}$$

Furthermore, a 95% confidence interval will be estimated.

[4] According to the hospital's normal daily practice
[5] If available according to the hospital's normal practice, within 4 weeks of study procedure
[6] Images will be collected by the sponsor

**Figure 1: Schematic view of the sensor presenting the different scales of measurements.**

## 5.2 Secondary Endpoints

Secondary endpoints are the ability of Clotild® Smart Guidewire System to differentiate various tissues involved in Peripheral Artery Disease such as, but not limited to:

- arterial wall
- subintimal area
- clot (fresh / subacute / organised)
- plaque (soft / hard)
- hyperplasia

The ability to differentiate tissues will be reported by descriptive statistics.

Given that the labels of the in-vivo impedance measurements are not reliable enough to be used as ground truth (no intra-vascular imaging is used in this study), the impedance measurements will not be used to develop prediction models. As an alternative, tissue prediction models previously developed by Sensome (using both in-vivo / ex-vivo / stroke / PAD impedance data) will be applied blindly to the impedance dataset of this study. Prediction results will be reported as a calibrated probability of detecting the positive class across each row of the CSGS throughout the intervention course.

# Study population

## 5.3 Inclusion/Exclusion criteria

### 5.3.1 Inclusion criteria

Candidates for the study must meet the following inclusion criteria below:

1. Age > 18 years
2. Subjects with acute and chronic occlusions in the arteries of the lower limbs eligible for endovascular interventional procedures

3. Written Informed Consent to participate in the study.

### 5.3.2 Exclusion criteria

Candidates for this study will be excluded if ANY of the following conditions are present:

1. Target vessel aneurysm
2. Target vessel diameter <2mm
3. Lesions starting at the Common Iliac Artery
4. Any subject that is, according to the discretion of the investigator, not eligible for study participation
5. Known lactating or confirmation of positive pregnancy test according to site specific standard of care (e.g. test, verbal communication).

## 5.4 Treatments and subject enrolments

Patients are considered as enrolled once the patient has signed and dated the patient informed consent form as part of the informed consent process.

Patient having signed the informed consent form but however eligibility has not been confirmed on the day of the procedure is being considered a screen failure.

The PAD endovascular treatment will be performed as per normal clinical practice except for the study procedure. The **study procedure** will take place during the PAD endovascular treatment (PAD procedure) and includes the following:

- Preparation of the study device, including installation of the tablet.
- Insertion of the study device in the sheath.
- Making the electrophysiological measurements: at least one reference measurement in blood and one measurement in the lesion. Acquisitions can be performed at several locations to target the various tissues of interest. Note that the interpretation of the measurement in terms of tissue type is not displayed to the user. As a consequence, the use of the Clotild® Smart Guidewire System has no effect on the PAD procedure, the user not being able to modify his/her choice of treatment based on the CSGS display.
- Removal of the study device from the sheath.

## 5.5 Analyses populations and Analysis set(s)

At most 30 subjects with PAD will be enrolled in one site for this study.

Intention To Treat (ITT) Population

All patients who were enrolled, so all patients (or legally authorized representatives) who signed and dated the patient information consent form even though the CSGS was not used in the subject.

Treated Population

All patients in which the guidewire went through the sheath. This population will be used for safety evaluation.

Performance Population

To evaluate the sensor's ability to differentiate tissues, only data from subjects for which at least 1 non-anomalous acquisition in the lesion was captured by the CSGS will be used. The evaluation of tissue differentiation capabilities (see secondary endpoints) will be performed on this population set.

# 6 Statistical basis for sample size

The maximal total sample size is set at 30 subjects. Since this trial is an exploratory feasibility study, the sample size does not have to be statistically driven (there is no hypothesis). On top of that, it is possible to collect large sample of data sets from a small sample of study subjects thanks to the 9 electrodes arrays of the sensor (see

Figure **1**) and the possibility to collect multiple measurement points during the procedure (see section 5.4). Previous experience from the Clot Out study, a previous clinical study in stroke patients to direct a catheter through blood vessels and to measure electrophysiological parameters in the blood vessels during procedures, showed that a sample size of maximally 30 subjects will be enough to evaluate the feasibility of the CSGS sensor to differentiate tissues.

# 7 Bias

Since this is a single-arm study, no randomization is performed. Neither the investigator nor the patients are blinded for the treatment. Considering that the secondary endpoint of the study is to evaluate the feasibility of developing predictive models that will discriminate various tissue types, the interpretation of the measurements collected during the SEPARATE study cannot be displayed to the physician during the study. As a consequence, the use of the Clotild® Smart Guidewire System has no effect on the PAD procedure, the user not being able to modify his/her choice of treatment based on the CSGS display. In conclusion, regarding the measurements, the CSGS is used solely to record impedance measurements of various relevant tissues. The interpretation of these measurements in terms of tissue type is not displayed to the user.

To minimize bias, an independent Data Safety Monitoring Board (DSMB), also known as a Data Monitoring Committee (DMC), will be responsible for monitoring safety and performance aspects of the study. The DSMB will have scheduled meetings on a regular basis. Rules of operation and responsibilities will be outlined in the DSMB Charter. The DSMB consists out of an uneven number of experts in the field (minimum 1), enabling the assessment and conclusion with majority votes. If

needed, the DSMB may invite ad hoc team members, such as statistical support. These ad-hoc members will refrain of voting. To review safety events happening in the study – for some events, the DSMB may be requesting additional information from the investigational site to allow a comprehensive review.

The sponsor and/or their designee will oversee the progress of this clinical investigation and ensure it is conducted, recorded, and reported in accordance with: the clinical investigation plan, standard operating procedures, applicable country specific regulatory requirements and the International Conference for Harmonization Good Clinical Practice (ICH-GCP), the ISO 14155 (2020) regulations and guidelines. Protecting the rights of subjects, the safety of subjects, and the quality and integrity of the data collected and submitted. Clinical study data will be monitored to ensure the identification, documentation and analysis of all adverse events, compliance with the protocol, adherence to the terms of the participating Ethics Committee to protect the safety and rights of all trial subjects and compliance with applicable local regulations and to verify its accuracy. Data Management will send out queries to the site in case of inconsistencies, contradictions, suspicious values, or missing data.

# 8 Analysis Variables

The following variables will be collected by the investigator during the study visits in the **electronic CRF** (eCRF)):

- Informed consent data (date and time)
- Eligibility to inclusion and exclusion criteria
- Demographic data (age, gender)
- Physical examination pre-procedure (date and time, general appearance, skin, lungs, heart, extremities (PAD excluded), neurological or other)
- Tobacco and alcohol history (usage, amount)
- Vital signs at screening visit (weight, height, heart rate at rest, systolic and diastolic blood pressure) and at the beginning of the PAD procedure (heart rate at rest, systolic and diastolic blood pressure)
- Medical history data (hypertension, dyslipidaemia, coronary artery disease, cardiomyopathy, arrhythmia, renal dysfunction, stroke / TIA (type if applicable), diabetes (type of treatment if applicable), COVID, COVID vaccines and timing, medication usage)
- PAD history (location, date of first diagnosis, affected limb, treatment, and outcome for every detected lesion)
- PAD assessment (affected limb, Ankle brachial index and date of assessment, date of first onset of symptoms, date of assessment, type of onset, symptoms, Rutherford classification)
- Performed imaging exams (date and time, type, and findings)
- Lesion characteristics pre-procedure (amount, localization, length, type and date of assessment, suspected type of occlusion, reason for current treatment by endovascular procedure)

- Intervention parameters (date, thrombolytic medication and administration type, type of anaesthesia, TASC classification, puncture site and timing, usage of closing device, achievement of revascularization, type of complications)
- Lesion characteristics during procedure (number of measured lesions during study procedure, localization, length, characteristics, calcification, easiness to cross the lesion, suspected content, subintimal navigation, usage of re-entry devices)
- AE, SAE, SADE (diagnosis, seriousness, severity, timing, relationship to study device / study procedure / PAD procedure, action taken and outcome)
- Concomitant medication (dose, type, frequency, indication, route, timing)
- Device Deficiencies (device, timing, disposition, description and action taken, led to AE)
- Used devices (amount, type, name, brand, reference, diameter)
- Investigational device return after use (date, destination and method)
- Protocol violations or deviations (date, study visit, category, description)
- Study exit (date, completion of the study, reason for early termination (if applicable))

The following variables will be collected by the sponsor during/after the procedure:

- Electrophysiological measurements of the CSGS
- DSA images
- Imaging reports of CT, CTA or echo
- Device inspection after use

# 9 Statistical analysis methods

## *9.1 Statistical procedures*

The main objective of this study is to differentiate tissues based on the electrophysiological measurements provided by the CSGS. This will be established by building and evaluating prediction models. These prediction models are based on physical properties of the impedance measurements captured by the sensor, for which Machine Learning analysis might be applied.

## *9.2 Listing and descriptive statistics*

All original and derived parameters as well as population characteristics will be described. Data will be described using summary statistics as described in the sections below. Frequency counts (number of subjects [n] and percentages) will be made for each selected qualitative variable. Descriptive statistics (n, mean, standard deviation [SD], median, minimum and maximum) will be calculated for each selected quantitative variable (unless otherwise stated). In general, all data will be listed, sorted by subject, and when appropriate by visit number within subject.

## 9.3 Rounding and decimal places

The mean, standard deviation, and any other statistics other than quantiles, will be reported to one decimal place greater than the original data. Quantiles, such as median, or minimum and maximum will use the same number of decimal places as the original data. Estimated parameters, not on the same scale as raw observations (e.g. regression coefficients) will be reported to 3 significant figures.

## 9.4 Software

Statistical software packages like Python, SAS, SPSS or R will be used for the analysis.

## 9.5 Sensitivity analysis

The need for sensitivity analyses will be explored during the conduct of the study and updated in the SAP if applicable.

## 9.6 Handling of missing data and outliers

Every effort will be undertaken to fulfil all the requirements of the clinical investigation plan concerning the collection and management of data. No imputations of missing data will be done.

Regarding the impedance measurements captured by the CSGS, data might be missing or anomalous having an impact to the endpoints. Based on the Device Deficiency rate in a previous study (The Clot Out Study), the estimated amount is 40%. The missingness/anomaly might be due to the following reasons:

- Technical malfunctions, leading to missing data or anomalous data, among which device deficiency due to electrical connection dysfunction;
- Use error leading to missing data because measurements have not been acquired or to anomalous data because the sensor was covered by the catheter while the measurement was acquired.

The criteria to discard anomalous measurements include:

- Any acquisition associated with an error code raised by transmitter software (for instance due to loss of communication between sensor and transmitter) will be excluded from the analysis.
- Electrophysiological measurement from an electrode pair that shows a constant raw digital signal across acquisition frequencies (constant or piecewise constant with a single step) is considered anomalous and will be excluded.
- Electrophysiological measurement from an electrode pair that shows digital saturation consistently from the reference measurement to the first lesion measurement is considered anomalous; all remaining measurements made with this electrode pair will be excluded from the dataset.
- Anomalies related to invalid reference measurements are reported as too-high dispersion across electrode pairs in the reference measurement. Persistence of the anomaly untill the first lesion measurement requires exclusion from all measurements from the concerned electrode pairs.

Since the underlying assumption is completely missing at random, no imputation will be done for missing data.

## 9.7 Handling of noncompliance, withdrawals, and protocol deviations

No deviations from the protocol are permitted except under emergency circumstances to preserve the rights, safety and or well-being of a trial subject; in particular, it is recommended to make every effort to avoid deviations from the protocol including, but not limited, the following:

- Inclusion of a patient that does not meet the inclusion criteria;
- Inclusion of a patient that meets any of the exclusion criteria;
- Missing any data related to the study objectives;
- Follow-up being performed outside the protocol specified visit window.

Deviations shall be recorded in the eCRF and all deviations will be presented in a listing.

All subjects have the right to withdraw from participation at any point during the study and without prejudice of further treatment. Site staff should obtain written documentation from the subject that wishes to withdraw his/her consent for future follow-up visits and contact. If site staff are unable to obtain written documentation, all information regarding the subject's withdrawal must be recorded in the subject's medical record. In addition, the appropriate CRF must be completed for the subject and clear documentation of the subject's withdrawal must be provided to the sponsor. Reasons for subject withdrawal will be presented in a listing.

In addition, Principal Investigators also have the ability to terminate subject participation in the study. Reasons for termination can include: study completion, subject withdrawal, physician-directed subject withdrawal or death. A description of the reason for a subject's termination will be documented in the subject's medical records and the eCRF and will be listed.

## 9.8 Timing of the analysis (including interim analysis and/or sequential analysis if relevant)

Due to the exploratory nature of the trial, analysis of the trial data will be performed on a continuous basis. A final analysis of all study variable measurements is planned after all patients left the study, all data is monitored, queried, and the database is locked.

## 9.9 Patient accounting and study disposition

A complete accounting of patient participation in the study will be presented in a listing entitled 'Patient accounting and final study disposition'. The purpose of this listing is to provide an overview of patients from their entrance into the study through the final visit and to account for the evaluations of

patients in the analyses of performance and safety, including reasons for early study termination. The listing will display the patients that:

- Were enrolled
- Underwent the study procedure
- Completed the 24 hours post-procedure evaluation
- Discontinued from the study:
  - Withdrew Consent
  - Failure to meet inclusion and exclusion criteria
  - Physician decision
  - Adverse event
  - Discontinuation by sponsor
  - Other (list exact reason)

## *9.10Demographic data*

All captured demographic and baseline variables will be displayed in tables for the Treated Population. These tables summarize the patient population with respect to gender, age in years at the time of entry into the study, height (cm), weight (kg) and BMI. Results of the medical history, t will be presented in a separate table. PAD history and pre-procedural lesion characteristics will be presented in a separate table. A detailed listing will be added with patient demographic data.

## *9.11Prior and concomitant medication*

Prior and concomitant medication is captured in the eCRF. It will be coded according MedDRA guidelines and will be analyzed descriptively. Concomitant medications refer to all medications taken during the study, including medications continued from the pre-treatment screening period. Prior medications refer to all medications that were started and stopped prior to the first treatment with study device and will not be reported as concomitant.

Medications with missing start and stop dates, or having a start date prior to the start of study procedure and missing a stop date, will be counted as concomitant. Partial dates will be handled as follows:

- If the year of the study procedure is < the year of start of concomitant medication AND if the month and day of start of concomitant medication are missing AND if the medication stop date is not prior to the date of the study procedure, then the medication is considered concomitant;
- If the year of the study procedure = the year of start of concomitant medication AND if the month of the study procedure is < the month of start of concomitant medication AND if the day of start of concomitant medication is missing AND if the medication stop date is not prior to date of the study procedure, then the medication is considered concomitant.

A summary of the concomitant medications for the Treated Population will be listed. If thrombolytic medication is given prior to or during the procedure, it will be summarized separately in a table.

### *9.12Safety analysis*

All Adverse Events will be classified with the Lowest Level Term (LLT) from the MedDRA dictionary (version 24.0, March 2021). All adverse events with onset during the study period will be displayed in summary tables for the Treated Population. Tables will show the number of adverse events, the number and the percentage of patients affected by relation to usage of the device or the study procedure or to the PAD procedure (study procedure excluded) or underlying disease. Adverse events will be divided by seriousness. Severity, actions taken and outcome of the adverse events will be displayed in tables. Divisions will be made according to the timing of the event (during procedure, after procedure). All adverse events with descriptions of the event will be listed.

Device deficiency will be summarized. The number and percentage of patients experiencing 1 or more device deficiencies will be presented by the event description using counts and percentages. A detailed listing of a device deficiencies and malfunctions will be presented.

### *9.13Performance analysis*

Descriptive statistics will be presented for the primary endpoint for the Treated Population in a table and secondary endpoints for the Performance Population in a figure. Definitions of those endpoints are summarized in section 5.

### *9.14Study procedure and device accountability*

Procedural characteristics and lesion characteristics during PAD and study procedure and the time segments will be summarized for the Treated Population using descriptive statistics in separate tables.

A summary of study device accountability for the Treated Population population will be presented in a table and a complete listing of all study devices will be provided. This listing will be sorted by patient number. Other vascular devices used during the PAD intervention (amount, type) will be presented in a listing.

### *9.15Imaging exams*

A summary of all imaging exams for the Treated Population will be captured by the investigator in the eCRF.

### *9.16Clinical evaluation*

Results of the ABI and PAD assessment at screening for the Treated Population will be presented in a separate table.

# 10 Description of Tables, Listings and Figures

This section is to give precise details for each table, listing or figure to be produced.

**Tables:**

1. Study dates (first patient in – last patient out) - ITT
2. Patient demographics and baseline data (PAD assessment only: ABI, Symptoms onset, Rutherford classification, Lesion characteristics, Suspected type of occlusion) - TP
3. Patient medical history (only for PAD medical history): Y/N - TP
4. Patient medical history (detailed) - TP
5. Procedural success (Primary endpoint) - TP
6. Number of SAEs/AEs/SADEs and type, severity, relationship to study device and/or study procedure and/or PAD procedure, treatment, outcome - TP
7. Intervention parameters (Thrombolytic medication, Revascularization achieved Y/N, Complications, TASC classification) - TP
8. Measured lesion characteristics during procedure - TP (Location of the lesion, Length of the treated lesion, Calcification, Crossability, Suspected content of the lesion, Subintimal navigation) - TP
9. Study device accountability - TP: Total number of devices used, Number of devices used per patient, Number of devices inserted into the patient - TP
10. Device deficiencies - TP
11. Results of the sensitivity analysis, if applicable

**Listings:**

1. Patient demographic data - TP
2. Patient accounting and final study disposition - ITT
3. Patient compliance to in- and exclusion criteria - ITT
4. Patients not fulfilling in- or exclusion criteria - ITT
5. Patient baseline data (PAD assessment at screening) - TP
6. Intervention parameters (all) - TP
7. Measured lesion characteristics during procedure (all) - TP
8. Study device accountability (hardware) including inspection after use - TP
9. Study device accountability (software) - TP
10. Other vascular devices used during the procedure (besides CSGS) - TP
11. Treatment by thrombolysis and its outcome - TP
12. Device deficiencies - TP
13. All AEs - TP
14. CIP deviations - ITT
15. Concomitant medication per patient – TP

**Figures:**

1. Secondary endpoint - TP