# STATISTICAL ANALYSIS PLAN (SAP)

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| **Study name** | **The INSPECT Study** |
| **Protocol Number** | **SEN_ONCO_1** |
| **SPONSOR** | **SENSOME SAS**<br>2-12 rue du Chemin des Femmes<br>91300 MASSY, FRANCE |
| **SAP version** | **V1** |
| **Date** | **7 March 2025** |

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

| | Name | Function | Date/Signature |
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# 1 Abbreviations and Definitions

| Term | Definition |
|---|---|
| ADE | Adverse Device Effect |
| AE | Adverse event |
| BLE | Bluetooth Low Energy |
| BSS | BioSpy System |
| CIP | Clinical Investigation Plan |
| CIR | Clinical Investigation 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 |
| PET scan | Positron Emission Tomography scan |
| SADE | Serious Adverse Device Effect |
| SAE | Serious Adverse Event |
| SAP | Statistical Analysis Plan |

# 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 Investigation Report (CIR) for Clinical Investigation Plan number SEN_ONCO_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_INSPECT_V4*, version 4 dated 4 July 2024). 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 CIR.

# 3 Study objective

The objective of the study is to evaluate the feasibility of the BioSpy System (BSS) sensor to differentiate tissues that are encountered during bronchoscopic biopsy of endobronchial tumors and peripheral lung nodules and masses. The evaluation will be performed at 3 different levels: i) the ability of the system to record measurements in the lesion; ii) the ability of the system to differentiate the lesion from healthy tissue; and iii) the ability of the system to differentiate various lesion types.

# 4 Study design and plan

This study is a prospective, single-centre, non-randomized, feasibility study in subjects presenting for bronchoscopic biopsy of lesions suspicious for lung cancer. Up to 30 patients will be enrolled at two centers: one center in Australia (up to 15 patients) and one center in France (up to 15 patients). The follow-up duration for each subject is until 12 hours (+/-4hrs) post-procedure or until discharge of the 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/Baseline | Bronchoscopic procedure | 12 hrs (+/- 4hrs) post study procedure or Discharge ***** |
|---|---|---|---|
| Inclusion/Exclusion criteria | X | | |
| Demographics & Medical History incl. | X | | |
| Pregnancy test* | X | | |
| Vital Signs (as per hospital normal practice) | X | X | |
| Patient Information/ informed consent | X | | |
| Imaging exams | PET scan / CT scan / MRI ** | CT scan / fluoroscopy** | |
| Biopsy procedure (number, location, biopsy | | X | |

| Parameter/Examination | Screening/Baseline | Bronchoscopic procedure | 12 hrs (+/- 4hrs) post study procedure or Discharge ***** |
|---|---|---|---|
| medical device, ROSE outcome, …) | | | |
| Histopathology analysis of the biopsy samples*** | | X | |
| AE/SAE**** | | X | X |

* according to site specific standard of care (e.g. test, verbal communication)

** PET scan / CT scan / MRI / fluoroscopy acquired as per normal hospital practice will be collected

*** Images of scanned slices (histology, cytology etc) and analysis reports will be collected.

**** In case of (S)AE, supporting information may be collected via the CRF, such as concomitant medication, lab values, vital signs, and de-personalised copies of source documents.

***** Patients will be followed at 12 hrs (+/- 4 hrs) post procedure or discharge (what comes first)

# 5 Endpoints

## *5.1 Primary Endpoint*

The Primary Performance Endpoint is defined as the ability of BioSpy System to acquire electrophysiological measurements in the relevant tissues during bronchoscopic biopsy. 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 BSS 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 BSS in the lesion.

This proportion will be determined by:

$$\frac{number\ of\ patients\ with\ at\ least\ one\ non-anomalous\ electrophysical\ measurement}{number\ of\ patients\ in\ which\ the\ probe\ was\ inserted\ in\ the\ bronchoscope}$$

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

Furthermore, a 95% confidence interval will be estimated.

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

## 5.2 Secondary Endpoints

Secondary endpoints are:

1. The ability of BioSpy System to differentiate the lesion (nodule or mass) from healthy tissue (bronchial tissue, lung parenchyma, …). The impedance measurements of BSS will be compared to the physician's assessment based on available imaging (visual control, ultrasound, fluoroscopy etc…)
2. The ability of BioSpy System to differentiate various lesion types such as, but not limited to:
    - Tumoral tissue
    - Inflamed tissue
    - Necrotic tissue
    - Fibrosis

Tissue differentiation will be reported qualitatively by visualizing two impedance components (modulus and phase) measured by the BSS throughout the intervention. To establish a common baseline for comparing patients, each individual spectrum will be normalized using the measurements from the probe placed in saline solution. This visualization will enable the detection of unique characteristics of individual tissue profiles (e.g., parenchyma vs. tumor). Furthermore, it will allow to observe transitory zones between adjacent biological compartments (e.g., entering and exiting the lesion). This analysis will be performed per patient.

# 6 Study population

## 6.1 Inclusion/Exclusion criteria

### 6.1.1 Inclusion criteria

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

1. Age > 18 years
2. Subjects with lesions eligible for lung biopsy under general anesthesia.
3. Lesion localization:
    a. Central or proximal lesions ≥ 10 mm in diameter confirmed by imaging (CT scan and/or PET scan) and/or endobronchial visual control; or
    b. Peripheral lesions ≥ 20 mm in diameter confirmed by imaging (CT scan and/or PET scan) and/or ultrasound analysis (RP EBUS with central localization of the ultrasound probe) during the procedure.
4. Written Informed Consent to participate in the study.

### 6.1.2 Exclusion criteria

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

1. Target lesion <10 mm for central and <20 mm for peripheral lesions (as determined on previous imaging)
2. Contra-indication to bronchoscopy procedures
3. Contra-indication to general anesthesia
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)

## 6.2 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 whose eligibility could not be (re)confirmed on the day of the study procedure is being considered as a screen failure.

The bronchoscopy procedure will be performed as per normal clinical practice except for the study procedure. The **study procedure** will take place during the bronchoscopy procedure and includes the following:

- Preparation of the study device, including installation of the tablet.
- Insertion of the study device in the biopsy needle.

- Making the electrophysiological measurements: at least one measurement in the lesion is to be recorded, preferably more (up to 10). Note that the interpretation of the measurement in terms of lesion type is not displayed to the user. As a consequence, the use of the BioSpy System has no effect on the bronchoscopy procedure, the user not being able to modify his/her judgment based on the BSS display.
- Removal of the study device from the biopsy needle.

### *6.3 Analyses populations and Analysis set(s)*

At most 30 subjects will be enrolled in 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 BSS was not used in the subject.

Treated Population

All patients in which the BSS probe went through the bronchoscope. 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 BSS will be used. The evaluation of tissue differentiation capabilities (see secondary endpoints) will be performed on this population set.

# 7 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 since 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 6.2). 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 BSS sensor to differentiate tissues.

# 8 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 lesion types, the interpretation of the measurements collected during the INSPECT study cannot be displayed to the physician during the study. As a consequence, the use of the BioSpy System has no effect on the bronchoscopy procedure, the user not being able to modify his/her judgment based on the BSS display. In conclusion, regarding the measurements, the BSS is used solely to record impedance measurements of various relevant lesions. The interpretation of these measurements in terms of lesion 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 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 one expert in the field. 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.

# 9 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 (lungs, other) at screening, including the date and time.
- Tobacco, cannabis and alcohol history (usage, amount)
- Lifestyle habits important to mention
- Medical history data (COPD, pneumonia, pulmonary hypertension/oedema/embolism, pneumothorax, cancer and other) with their start date and if the treatment is ongoing or not
- Imaging exams (CT, MRI, PET-scan or other) performed at screening and findings (pulmonary lesion yes/no and if yes size and location of the lesion)

- Intervention parameters (date, anaesthesia time, time of first insertion and last removal of the bronchoscope and BSS, location and size of the lesion(s), devices used (type, name, brand, reference, diameter), imaging used, number of biopsy samples taken, number of lesion and number of lesion's site in which study device is used, ROSE outcome if available)
- Sample analysis (histology and cytology results)
- AE, SAE, SADE (diagnosis, seriousness, severity, timing, relationship to study device / study procedure / bronchoscopy procedure, action taken and outcome)
- Device Deficiencies (device, timing, disposition, description and action taken, led to AE)
- 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 BSS
- CT scan and/or fluoroscopy images (if available as per routine practice)
- Report(s) of histology analysis
- Images of scanned slices of histology/cytology
- Study device inspection after use

# 10 Statistical analysis methods

## *10.1 Statistical procedures*

The objective of this study is to differentiate lesions based on the electrophysiological measurements provided by the BSS. A visual representation of two electrophysiological components will be reported as a function of time for each patient over the full intervention. Further analysis may build on this exploratory data analysis step.

## *10.2 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.

## *10.3 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.

## *10.4Software*

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

## *10.5Sensitivity analysis*

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

## *10.6Handling 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 BSS, 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 biopsy needle 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 that shows a constant raw digital signal different from 0 (at the exclusion of saturated signal/air) across channels for at least one frequency point, (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 throughout the intervention is considered anomalous; all measurements made with this electrode pair will be excluded from the dataset.
- Anomalies related to invalid reference measurements that are reported as too-high dispersion across electrode pairs in the reference saline solution. Persistence of the anomaly until the first lesion measurement requires exclusion from all measurements from the concerned electrode pairs.
- Unreliable data points, defined by electrophysical measurement from an electrode pair at one frequency point that show an analog signal outside the sensor's minimum reliable range. Depending on the analysis methodology, the whole measurement from that electrode pair might be removed.

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

## *10.7Handling 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. 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, 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.

## *10.8Timing 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.

## *10.9Patient accounting and study disposition*

A complete accounting of patient participation in the study will be presented in a table. The purpose of this table is to provide an accounting 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 table will display the number and percentage of patients that:

- Were enrolled
- Underwent the study procedure
- Completed the 12 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)

The listing with reasons patients did not undergo the study procedure will contain the individual reason. A separate listing sorted by patient number will include the reason for withdraw for all patients who discontinue prematurely.

## *10.10 Demographic data*

Captured demographic and baseline variables will be displayed in tables for the Treated Population. These tables summarize the patient population with respect to gender and age in years at the time of entry into the study. Results of the medical history, tobacco, cannabis and alcohol history will be presented in a separate table. A detailed listing will be added with patient demographic data.

## *10.11 Safety 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 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 bronchoscopy procedure (study procedure excluded). 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 deficiencies 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.

## *10.12 Performance analysis*

Descriptive statistics will be presented in a table for the primary endpoint for the Treated Population.

For secondary endpoints, tissue differentiation for the Treated Population will be reported qualitatively by visualizing two impedance components (modulus and phase) measured by the BSS throughout the intervention. This analysis will be performed per patient.

## *10.13 Study procedure and device accountability*

Procedural characteristics (intervention parameters) and lesion characteristics will be summarized for the Treated Population using descriptive statistics in separate tables.

A summary of study device accountability for the Treated 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 biopsy devices used during the bronchoscopy intervention (amount, type) will be presented in a listing.

### *10.14 Imaging exams*

A summary of all imaging exams for the Treated Population will be captured by the investigator in the eCRF. Imaging exams performed at screening to characterize the lesion will be presented in a table.

### *10.15 Clinical evaluation*

Results of the physical examination at screening for the Treated Population will be presented in a separate listing.

### *10.16 Sample analysis*

Histology and cytology results of all analysed samples will be reported for the Treated Population in a separate table.

## 11 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 - TP
3. Imaging exams (CT, MRI, PET-scan, Other, None) performed at screening and findings (pulmonary lesion detected Y/N, Left/Right, Central/Peripheral, Intrathoracic lymphadenopathy Y/N, for PET-scan SUV Max Positive/Negative) - TP
4. Patient medical history - TP
5. Patient tobacco / alcohol / cannabis / lifestyle history - TP
6. Procedural success (Primary endpoint) - TP
7. Number of SAEs/AEs/SADEs and type, severity, relationship to study device and/or study procedure and/or bronchoscopy procedure, treatment, outcome - TP
8. Intervention parameters (time between first insertion and last removal of the bronchoscope and BSS, location and size of the lesion(s), devices used (type, name, brand, reference, diameter), number of biopsy samples taken, number of lesion and number of lesion's site in which study device is used) - TP
9. Sample analysis (histology and cytology results: results for abnormal tissue, type of tissue and tumor) - TP

10. Study device accountability - Total number of devices used, Number of devices used per patient, Number of devices inserted into the patient - TP
11. Device deficiencies - TP
12. Results of the sensitivity analysis, if applicable - TP

**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 physical examination at screening- TP
6. Findings of imaging exams at screening (type of imaging, pulmonary lesion detected Y/N, Left/Right, Central/Peripheral, Intrathoracic lymphadenopathy Y/N, for PET-scan SUV Max Positive/Negative) - TP
7. Intervention parameters (all) - TP
8. Sample analysis – TP
9. Study device accountability (hardware) including inspection after use - TP
10. Study device accountability (software) - TP
11. All AEs - TP
12. Device deficiencies - TP
13. CIP deviations - ITT

**Figures:**

1. Secondary endpoint - TP

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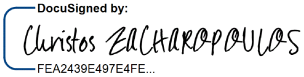
| Christos ZACHAROPOULOS<br>christos@sensome.com<br>Security Level: Email, Account Authentication (None) | DocuSigned by:<br>  <br>FEA2439E497E4FE...<br>Signature Adoption: Pre-selected Style<br>Using IP Address: 213.41.92.186 | Sent: 5/2/2025 11:27:06 AM<br>Viewed: 5/2/2025 11:28:45 AM<br>Signed: 5/2/2025 11:30:18 AM |
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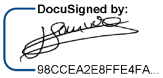
| Julie Lafaurie<br>julie@sensome.com<br>Clinical and Preclinical Lead<br>Sensome<br>Security Level: Email, Account Authentication (None) | DocuSigned by:<br>  <br>98CCEA2E8FFE4FA...<br>Signature Adoption: Uploaded Signature Image<br>Using IP Address: 92.169.82.75 | Sent: 5/2/2025 11:27:07 AM<br>Viewed: 5/2/2025 11:27:17 AM<br>Signed: 5/2/2025 11:27:25 AM |
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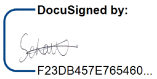
| Lise SCHAUB<br>lise@sensome.com<br>Security Level: Email, Account Authentication (None) | DocuSigned by:<br>  <br>F23DB457E765460...<br>Signature Adoption: Uploaded Signature Image<br>Using IP Address: 213.41.92.186 | Sent: 5/2/2025 11:27:08 AM<br>Viewed: 5/12/2025 4:12:37 PM<br>Signed: 5/12/2025 4:12:44 PM |
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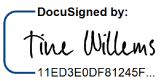
| Tine Willems<br>tine@twrite.be<br>CEO<br>Security Level: Email, Account Authentication (None) | DocuSigned by:<br>  <br>11ED3E0DF81245F...<br>Signature Adoption: Pre-selected Style<br>Using IP Address: 109.131.77.176 | Sent: 5/2/2025 11:27:08 AM<br>Viewed: 5/2/2025 2:12:13 PM<br>Signed: 5/2/2025 2:12:23 PM |
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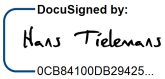
| Signer Events | Signature | Timestamp |
|---|---|---|
| Hans Tielemans<br>hans@sensome.com<br>Clinical Lead<br>Sensome<br>Security Level: Email, Account Authentication (None) | DocuSigned by:<br>  <br>0CB84100DB29425...<br><br>Signature Adoption: Pre-selected Style<br>Using IP Address:<br>2a02:1808:6f:322d:4041:ad2:97ec:f7bf | Sent: 5/12/2025 4:12:47 PM<br>Viewed: 5/13/2025 1:12:19 PM<br>Signed: 5/13/2025 1:12:35 PM |

**Electronic Record and Signature Disclosure:**
Not Offered via Docusign

| In Person Signer Events | Signature | Timestamp |
|---|---|---|

| Editor Delivery Events | Status | Timestamp |
|---|---|---|

| Agent Delivery Events | Status | Timestamp |
|---|---|---|

| Intermediary Delivery Events | Status | Timestamp |
|---|---|---|

| Certified Delivery Events | Status | Timestamp |
|---|---|---|

| Carbon Copy Events | Status | Timestamp |
|---|---|---|

| Witness Events | Signature | Timestamp |
|---|---|---|

| Notary Events | Signature | Timestamp |
|---|---|---|

| Envelope Summary Events | Status | Timestamps |
|---|---|---|
| Envelope Sent | Hashed/Encrypted | 5/2/2025 11:27:08 AM |
| Certified Delivered | Security Checked | 5/13/2025 1:12:19 PM |
| Signing Complete | Security Checked | 5/13/2025 1:12:35 PM |
| Completed | Security Checked | 5/13/2025 1:12:35 PM |

| Payment Events | Status | Timestamps |
|---|---|---|

| Electronic Record and Signature Disclosure |
|---|

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| | |
|---|---|
| Operating Systems: | Windows® 2000, Windows® XP, Windows Vista®; Mac OS® X |
| Browsers: | Final release versions of Internet Explorer® 6.0 or above (Windows only); Mozilla Firefox 2.0 or above (Windows and Mac); Safari™ 3.0 or above (Mac only) |
| PDF Reader: | Acrobat® or similar software may be required to view and print PDF files |
| Screen Resolution: | 800 x 600 minimum |
| Enabled Security Settings: | Allow per session cookies |

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