Laser **A**blation of **A**bnormal **N**eurological **T**issu**e** using **R**obotic **N**euroBlate® System (LAANTERN) Prospective Registry Protocol

(NCT02392078 23Mar2022)

PROTOCOL SIGNATURE PAGE

Laser **A**blation of **A**bnormal **N**eurological **T**issu**e** using **R**obotic **N**euroBlate® System (LAANTERN) Prospective Registry Protocol

I have read this protocol and agree to adhere to the requirements. I will provide copies of this protocol and all pertinent information to the study personnel under my supervision and my hospital institutional review board (IRB). I will discuss this material with them and ensure the conduct of the study according to this protocol, including applicable laws, regulatory requirements, general standards of good clinical practice and any other instructions provided by the Sponsor and the IRB.

Site Name

Site Investigator (Printed Name)

Site Investigator (Signature)

Date

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1 DEFINITIONS

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence, unintended disease or injury, untoward clinical signs (including abnormal laboratory findings) in subjects, users or other person, whether or not related to the medical device.
Engel Classification	Class I: Free of disabling seizures • IA: Completely seizure-free since surgery • IB: Non disabling simple partial seizures only since surgery • IC: Some disabling seizures after surgery, but free of disabling seizures for at least 2 years • ID: Generalized convulsions with antiepileptic drug withdrawal only Class II: Rare disabling seizures ("almost seizure-free") • IIA: Initially free of disabling seizures but has rare seizures now • IIB: Rare disabling seizures since surgery • IIC: More than rare disabling seizures after surgery, but rare seizures for at least 2 years • IID: Nocturnal seizures only Class III: Worthwhile improvement • IIIA: Worthwhile seizure reduction • IIIB: Prolonged seizure-free intervals amounting to greater than half the follow-up period, but not less than 2 years Class IV: No worthwhile improvement • IVA: Significant seizure reduction • IVB: No appreciable change • IVC: Seizures worse
ILAE (International League Against Epilepsy) Classification	• Class 1: Completely seizure free; no auras • Class 2: Only auras; no other seizures • Class 3: 1 to 3 seizure days per year; ± auras • Class 4: 4 seizure days per year to 50% reduction of baseline seizure days; ± auras • Class 5: Less than 50% reduction of baseline seizure days; ± auras • Class 6: More than 100% increase of baseline seizure days; ± auras
Index Procedure	First NeuroBlate® System procedure after signing the LAANTERN Informed Consent Form.

Term	Definition
Karnofsky Performance Scale (KPS)	The KPS will be collected for brain malignancy subjects only, and for subjects 16 years and older. The scale runs from 100 to 0, where 100 is "perfect" health and 0 is death: 100 - Normal; no complaints; no evidence of disease. 90 - Able to carry on normal activity; minor signs or symptoms of disease. 80 - Normal activity with effort; some signs or symptoms of disease. 70 - Cares for self; unable to carry on normal activity or to do active work. 60 - Requires occasional assistance but is able to care for most of his personal needs. 50 - Requires considerable assistance and frequent medical care. 40 - Disabled; requires special care and assistance. 30 - Severely disabled; hospital admission is indicated although death not imminent. 20 - Very sick; hospital admission necessary; active supportive treatment necessary. 10 - Moribund; fatal processes progressing rapidly. 0 - Dead
Lansky Performance Scale (LPS)	The LPS will be collected for brain malignancy subjects only, and for subjects between 1 year and 16 years of age. The scale runs from 100 to 0, where 100 is "perfect" health and 0 is death: 100 – Fully active, normal 90 – Minor restrictions in strenuous physical activity 80 – Active, but gets tired more quickly 70 – Greater restriction of play *and* less time spent in play activity 60 – up and around, but active play minimal; keeps busy by being involved in quieter activities 50 – Lying around much of the day, but gets dressed; no active playing participates in all quiet play and activities 40 – Mainly in bed; participates in quiet activities 30 – Bedbound; needing assistance even for quiet play 20 – Sleeping often; play entirely limited to very passive activities 10 – Doesn't play; does not get out of bed 0 – Unresponsive
Serious Adverse Event (SAE)	Adverse Event that: (a) Led to death (b) Led to serious deterioration in the health of the subject, that either resulted in life-threatening illness or injury • A permanent impairment of a body structure or a body function • In-patient or prolongation of existing hospitalization • Medical or surgical intervention to prevent permanent impairment to a body structure or a body function (c) Led to fetal distress, fetal death or a congenital abnormality or birth defect

2 ABBREVIATIONS

Abbreviation	Term
AE	Adverse Event
CNS	Central Nervous System
eCRF	electronic Case Report Form
EDC	Electronic Data Capture
EQ-5D or EQ-5D -Y	EuroQol-5 Dimensions adult or youth version
FACT-Br or FACT-Peds-Br	Functional Assessment of Cancer Therapy-Brain adult or pediatric version
FDA	Food and Drug Administration
ICF	Informed Consent Form
ID	Identification Number
IFU	Instructions For Use
ILAE	International League Against Epilepsy
IRB	Institutional Review Board
KPS	Karnofsky Performance Scale
LITT	Laser Interstitial Thermal Therapy
LPS	Lansky Performance Scale
MRI	Magnetic Resonance Imaging
NBS	The NeuroBlate® System
OS	Overall Survival
PFS	Progression Free Survival
PI	Primary Investigator
QOL	Quality of Life
QOLIE-31 or QOLIE-48	Quality of Life in Epilepsy Inventory adult or pediatric version
SAE	Serious Adverse Event
VAS	Visual Analog Scale

3 BACKGROUND & PURPOSE

Laser interstitial thermal therapy (LITT) is a minimally invasive technique to necrotize intracranial abnormal tissues, originally introduced in 1983. Its use in neurosurgical procedures was historically limited by early technical difficulties related to the monitoring and control of the extent of thermal distribution. The development of magnetic resonance thermography and its application to LITT has allowed for real-time thermal imaging and feedback control during laser energy delivery, allowing for precise and accurate delivery of tissue hyperthermia. Improvements in laser probe design, surgical stereotactic targeting hardware, and computer monitoring software has accelerated acceptance and clinical utilization of LITT as a neurosurgical treatment alternative. There is limited outcome data available from utilization of current commercially available LITT systems.

The NeuroBlate® System (NBS) is a minimally invasive robotic laser thermotherapy tool that is manufactured by Monteris Medical. It employs a pulsed surgical laser to deliver targeted energy to abnormal brain tissue. With the NBS, a surgeon makes a small hole in the skull, approximately as wide as a pencil. A small probe is then used to deliver laser light energy to heat and destroy the target tissue. The NBS combines magnetic resonance imaging (MRI) and software-based visualization to necrotize targeted tissues in locations in the brain, either superficial or deep. During the procedure, a surgeon operates the ablation remotely through a computer module. An MRI-compatible robotic probe driver helps the surgeon precisely guide the laser probe to the planned ablation area and apply heat in controlled amounts, until the targeted tissue is destroyed.

To further understand performance and utilization of the NBS in current standard of care, a post-market multi-center registry, LAANTERN (Laser Ablation of Abnormal Neurological Tissue using Robotic NeuroBlate® system), is designed to collect baseline, procedural and follow-up data on subjects that are to undergo thermal therapy using the NBS. The LAANTERN registry is conducted in an observational manner with objectives designed for publication purposes.

4 STUDY DEVICE

Any commercially available component of NeuroBlate® System may be used for the registry which includes, probe, robotic probe driver, and software. For more details regarding system description and principle of operation, please refer to the most current Instructions for Use (IFU) found at https://www.monteris.com/ifu/

5 STUDY DESIGN OVERVIEW

This is a prospective multi-center registry that will include data collection at baseline (prior to NBS procedure, which is also referred as the index procedure), index procedure, discharge and up to 5 years of follow-up including data from additional NBS procedures. Up to 3,000 subjects may be enrolled at up to 50 study sites. Some subjects may be enrolled in sub-studies associated with LAANTERN as per site participation and sub-study specific consent.

5.1 STUDY OBJECTIVES

Objective 1: **Safety**
Observe safety profile described by NBS or surgical-related SAEs

Objective 2: **Reason for NeuroBlate®**

Objective 3: **Procedural Outcomes**

- Local Control
- Progression Free Survival
- Overall Survival
- Seizure Freedom
    - Engel and ILAE Classification

Objective 4: Cognitive & Quality of Life Outcomes
Collected for subjects based on their disease etiology and age.

5.2 STUDY POPULATION

Subjects who meet inclusion criteria and no exclusion criteria and sign the Informed Consent Form (ICF) (CL10030) will be considered enrolled in this study. At the time of enrollment, a unique identification number (ID) will be assigned to the subject and used to collect all study information via electronic Case Report Forms (eCRFs).

Inclusion Criteria:

1. Subject or legally authorized representative provides written authorization and/or consent
2. Subject who is to undergo thermal therapy by the NeuroBlate® System for treatment of their neurological disorder

Exclusion Criteria:

1. Subject who is, or is expected to be inaccessible for follow-up
2. Other concurrent medical or other condition (chronic or acute in nature) that, in the opinion of the investigator, may prevent participation or otherwise render patient ineligible for the study

6 INFORMED CONSENT (ICF)

The Sponsor will provide a template ICF to each site for IRB submission prior to the site initiation. This template may be modified to suit the requirements of the individual study site. The Sponsor must pre-approve all changes to the ICF prior to initial submission to the IRB. A copy of the IRB-approved ICF must be sent to the Sponsor and the original copy must be retained at the study site. If the ICF is amended by the reviewing IRB, the Sponsor must pre-approve all changes to the ICF prior to submission. In addition, a copy of the approved documents must be provided by the Investigator to the Sponsor prior to enrollment of subjects in the study.

The Investigator or assigned designee must administer this approved ICF to each prospective study subject and obtain the subject's signature or a legally authorized representative signature along with the date of consent prior to enrollment in the study. The ICF must be obtained in accordance with 21 CFR Part 50. Subjects must be informed about their right to withdraw from the study at any time and for any reason without sanction, penalty, or loss of benefits to which the subject is otherwise entitled and informed that withdrawal from the study will not jeopardize their future medical care. A copy of ICF must be given to each subject enrolled in the study. The institutional standard subject consent form does not replace the study ICF.

7 STUDY VISITS

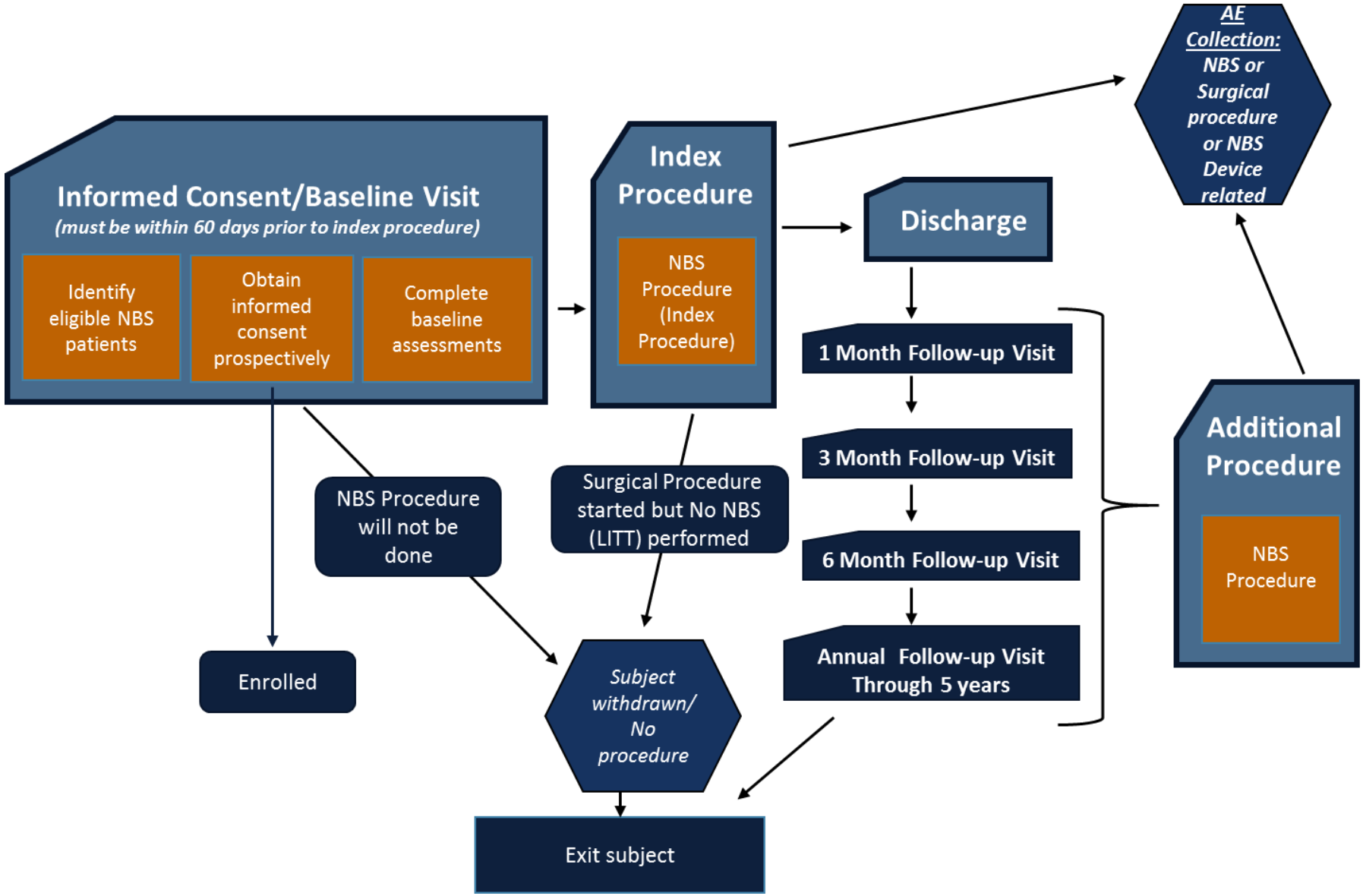
A subject follow-up schedule is intended to align with typical standard of care practices. Data may be collected during in-office subject visits or remotely (e.g. telephone, email, or mail), when feasible and appropriate. These modes of data collection aim to help facilitate robust and reliable long-term surveillance and survival data collection. For this standard of care registry, the visit windows are continuous, however target visit dates are provided below. Visits should be completed near the target visit date or be the most complete visit within the visit window. A visit window tool is available in the EDC system. Figure 1 indicates the sequence of subject visits.

Target Visit Dates:

- Baseline – within 60 days prior to the Index Procedure
- Index Procedure – Day 0
- Discharge – N/A
- 1 Month Follow-up Visit – Day 30
- 3 Month Follow-up Visit – Day 90
- 6 Month Follow-up Visit – Day 180
- 1 Year Follow-up Visit – Day 365
- 2 Year Follow-up Visit – Day 730
- 3 Year Follow-up Visit – Day 1095

- 4 Year Follow-up Visit – Day 1460
- 5 Year Follow-up Visit – Day 1825

Figure 1: Study Flow



7.1 DESCRIPTION OF STANDARD OF CARE ASSESSMENTS

Assessments are collected as conducted based on standard of care:

- Demographics and Health History
- Neurological Exam
- Gait
- Pain Score
- Karnofsky Performance Scale (KPS) or Lansky Performance Scale (LPS)
- Engel/ILAE Classification
- Pain Score; documenting head pain
- MRI scans
- Medications: Data collection will include change in dosage, frequency, and the type of medication for the following:
    - Steroids
    - Anticonvulsants (including antiseizure drugs)
    - Chemotherapy medication
    - Anticoagulation
    - Immunotherapy (e.g. bevacizumab, pembrolizumab)

7.2 REGISTRY REQUIRED QUESTIONNAIRES

Completion of questionnaires is required for this study. Questionnaires may be completed remotely via phone, mail or email if an office visit will not be completed. If a given questionnaire is not completed for a subject at Baseline, analysis of questionnaire data for this subject is not possible. Therefore, if the Baseline Questionnaire is not completed, this questionnaire is not required during follow-up and will not be compensated.

EuroQol-5D (EQ-5D) (All Subjects 16 years old and older); **EuroQol-5D-Y (EQ-5D-Y)** (All subjects 8-15 years old)

The EQ-5D provides simple, generic measure of health for clinical and economic appraisal. This questionnaire consists of 2 pages: 1) the EQ-5D-3L descriptive system and 2) the EQ Visual Analogue scale (EQ VAS). The descriptive system assesses subject's mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ VAS records the respondent's self-rated health on an approximately 20 cm vertical, visual analogue scale with endpoints labelled 'the best health you can imagine' and 'the worst health you can imagine'. The VAS will be utilized to assess subject pain at the lesion site or on head.

FACT–Br (CNS malignancy subjects only 18 years old and older) **FACT-Peds-Br-Adolescent** (12-17 years old) and **FACT-Peds-Br-Child** (7-12 years old)

Functional Assessment of Cancer Therapy-Brain (FACT-Br) is a commonly used instrument measuring general quality of life that reflects symptoms or problems associated with brain malignancies across 5 scales. FACT-Br is a brain tumor specific 50-item questionnaire for subjects who are not neurologically incapacitated. It will provide an overall QOL score as well as sub-scores for physical well-being, social/family well-being, emotional well-being, functional well-being and concerns relevant to subjects with brain tumors.

QOLIE-31 (Epilepsy subjects only >18 years old): **QOLIE-AD-48** (11-18 years old) **QOLCE-55** (Care Giver provider).

The Quality of Life in Epilepsy Inventory (QOLIE-31) contains seven multi-item scales that tap the following health concepts: emotional well-being, social functioning, energy/fatigue, cognitive functioning, seizure worry, medication effects, and overall quality of life. A QOLIE-31 overall score is obtained using a weighted average of the multi-item scale scores. The QOLIE-31 also includes a single item that assesses overall health.

The QOLIE-AD-48 is a survey of health-related quality of life for adolescents (11-18 years of age) with epilepsy.

The QOLCE-55 is a survey of health-related quality of life for pediatrics answered by their care giver.

7.3 ADDITIONAL NEUROBLATE PROCEDURES

In the case additional NeuroBlate® procedures are performed following the index procedure, this information will be collected on the Additional Procedure form. Any adverse events associated with these procedures will be collected on an Adverse Event form. Patient follow up schedule is based on the index procedure date. Procedure data and reportable adverse events will be collected on all additional NeuroBlate® System procedures completed after the Index Procedure.

7.4 VISIT SCHEDULE AND DATA COLLECTION

Table 1 summarizes the study visit schedule and data collection.

Table 1. Study Visit and Data Collection Schedule

	Baseline	Index Procedure	Discharge	1M	3M	6M	12M	Annual visits through 5 yrs.
Demographic and Medical History / Epilepsy Etiology	X							
Neurological Exam	X		X	X	X	X	X	X
Gait	X		X	X	X	X	X	X
Pain Score	X		X	X	X	X	X	X
Medication	X	X	X	X	X	X	X	X
KPS or LPS (Brain Malignancy only)	X		X	X	X	X	X	X
FACT-Br or Peds-FACT-Br or QOLIE-31 or QOLIE-48	X			X	X	X	X	X
EQ-5D or EQ-5D- Y	X			X	X	X	X	X
MRI		X (Pre and post-op)						
Index Procedure Data		X						
Reportable Adverse Events		X	X	X	X	X	X	X
Engel/ILAE Classification (Epilepsy subjects Only)				X	X	X	X	X
Additional Procedure Data		X	X	X	X	X	X	X
End of Study	End of Study form will be completed upon subject study completion or subject withdrawal (See Section 7.5)							

7.5 STUDY COMPLETION OR WITHDRAWAL

Subjects will complete the study once their 5-year follow-up visit is completed or if the subject was prematurely withdrawn prior to their 5-year visit.

The subject may be prematurely withdrawn from the study for the following reasons:

- Subject did not have NeuroBlate® Procedure.
- Subject Lost to Follow-up: All efforts shall be made to document at least 3 attempts to contact subject, which would include a certified letter to the subject. If attempts to contact the subject fail, the subject may be withdrawn from the study and considered lost to follow up.
- Subject Withdrawal: A subject may voluntarily withdraw from the study at any time.
- Investigator Withdrawal of Subject: An Investigator may withdraw a subject for reasons which may include noncompliance, failure to keep appointments, etc.
- Subject Death: If subject passed away, the expiration date will be considered the end of study date. All feasible attempts should be made to confirm date of death, as this is key for overall survival analysis.

8 ADVERSE EVENT REPORTING

It is the site's responsibility to report Adverse Events in compliance with their Institutional Review Board.

8.1 REPORTING OF ADVERSE EVENTS BY CLINICAL SITES

The following adverse events (AE) are considered reportable for this study, as determined by PI discretion:

NeuroBlate® System related AEs

- Adverse events related to the NeuroBlate® System Device (i.e. probe, robotic probe driver, software)

NeuroBlate® Procedure related AEs

- Adverse events that occur due to a NeuroBlate® (LITT) procedure and cannot be directly attributed to the NBS Device or surgical procedure

Surgical Procedure related AEs

- Adverse events that occur due to the surgical procedure and cannot be directly attributed to NeuroBlate® System or procedure (i.e. biopsy related event)

The following adverse events are considered not reportable for this registry:

- Planned hospitalization for a pre-existing condition without serious deterioration in health.
- Any expected postoperative complaints or symptoms such as pain at biopsy site, headaches, weakness, cerebral edema, and transient events (less than 30 days from procedure) that do not require intervention. If the event involves a clinically significant change in severity or duration of symptoms or requires clinical intervention that is different from ordinary postoperative care, the event is considered a reportable AE.

Reportable AEs must be described by duration (start and resolution dates), relationship to the NeuroBlate® System or surgical procedure, action taken to resolve the event, and outcome of the event. Additional information, such as procedural notes, treatment notes, or clinical summary may be requested as supporting documentation.

8.2 ADVERSE EVENT RELATEDNESS

The relationship of the AE to the NeuroBlate® System Device (NBS) or the NeuroBlate® (LITT) procedure or surgical procedure will be determined by the Primary Investigator (PI) based upon the following definitions.

Definite: The AE follows a reasonable temporal and causative sequence from receipt (or attempted receipt) of the device treatment or procedure.

Possible: The AE follows a reasonable temporal sequence from receipt of the device treatment or procedure and the possibility of device treatment or procedure involvement cannot be excluded. However, other factors such as underlying disease, concomitant medications, or concurrent treatment are presumable.

Not Related: The AE has no temporal sequence from receipt of the device treatment or procedure, or it can be explained by other factors, including underlying disease, concomitant medication, or concurrent treatment. Note: If the event is determined to be “Not Related” to either the NBS or the Surgical Procedure, it is not considered a reportable AE.

8.3 SAFETY COMMITTEE

A Safety Committee will be used to review reported events to provide unbiased third-party adjudication for publications.

9 PROTOCOL DEVIATIONS

A deviation is defined as an event that did not occur according to the registry protocol. For the purpose of this registry, and in consideration of standard of care practices across study sites, anticipated protocol deviations include: improper consenting of subject (i.e. consent not obtained and improper consenting) and not completing study required questionnaires (if not completed at baseline only one deviation needs to be completed for that subject or if completed at baseline but a subsequent visit or questionnaire is not completed then a deviation for the missed timepoint needs to be completed) A deviation is not required if a questionnaire is not completed because the subject does not meet the age requirement for the validated QOL.

All deviations will be reported to Monteris Medical. It is the site’s responsibility to report deviations in compliance with their Institutional Review Board.

10 DATA ANALYSIS

Data collected in this study is observational and there is no pre-defined study hypothesis. Descriptive statistics will be used to analyze data. Continuous variables will be summarized with means, standard deviations, minimums, and maximums. Categorical variables will be summarized in frequency distributions.

11 CORE LAB

MRIs will be collected according to the Study Visit Schedule. Standard of Care MRI imaging will be sent to the Imaging Core Lab for analysis as per the sponsor. The immediate pre-operative and immediate post operative images (to include T1 pre-contrast, T1 post-contrast, T2 FLAIR, and any other sequences obtained during these timepoints as per standard of care at that institution) are required for upload to Monteris. Per core lab or cohort specific needs, additional standard of care imaging at various timepoints may be requested by the sponsor in accordance with the site clinical trial agreement (CTA). The sponsor will not request MRI sequences or imaging at timepoints that are not considered standard of care per the institution. Please refer to the Image Acquisition Protocol for additional information.

12 STUDY MANAGEMENT

The study will be performed in accordance with all requirements set forth in the U.S. regulations, 21 Code of Federal Regulations (CFR) Parts 50 (Protection of Human Patients), 56 (Institutional Review Board), and applicable requirements from the reviewing IRB for the study at each site.

12.1 DATA COLLECTION AND MANAGEMENT

The study data will be hosted in an electric data capture (EDC) system. The EDC system will be compliant with the U.S. regulations, 21 CFR part 11, Electronic Records; Electronic Signatures.

All required data for this study will be collected on standardized Case Report Forms (CRFs).

Qualified study staff at each investigational site will perform primary data collection drawn from source document (e.g. hospital chart) review. All CRFs will be subject to review for omitted data, gross data inconsistencies, illegible data, and deviations. Any deficiencies or deviations will be reviewed, and any necessary action determined (e.g. data query, communication to the study center).

Data review (including crosschecks) will be performed and any discovered errors will be reported to the study site using the data correction and query process (as necessary). The study site will review the query, respond, and make any necessary corrections or comments. The data cleaning cycle will be repeated until all data are considered clean.

13 ADMINISTRATIVE RESPONSIBILITIES

13.1 SPONSOR RESPONSIBILITIES

The Sponsor's responsibilities for this study are to:

- Select qualified clinical investigators and study sites
- Provide study protocol training to participating study sites including the Investigator and staff conducting the study
- Provide financial support to each study site which is fair, reasonable, and equitable to fair market value
- Follow/promote all applicable regulatory standards per CFRs at each study site
- Own and control the use of the data, including review and approval of study-related publications/presentations, etc.

13.2 INVESTIGATOR RESPONSIBILITIES

The Primary Investigator for each site is responsible for ensuring the study is conducted according to:

- All signed agreements (including financial disclosures)
- The Study Protocol
- IRB guidelines
- Applicable FDA regulations

The Investigator for each site may not begin enrollment until Sponsor receives and approves (when necessary) required documents, including a completed and signed Investigator Agreement/Clinical Trial Agreement (or equivalent), Protocol Signature Page, IRB and ICF approvals.

It is acceptable for the Investigator to delegate one or more of the above functions to an associate or Sub-Investigator or trained Study Coordinator; however, the Investigator remains responsible for the proper conduct of the clinical investigation, including obtaining and documenting proper study informed consent, collecting all required data, submitting accurate and complete CRFs, etc.

At each site, appropriate procedures must be followed to maintain subject confidentiality according to appropriate local regulations (e.g. Health Insurance Portability and Accountability Act in the U.S.). Each site may have its own internal procedures or requirements for use and release of subject medical

information in research studies. Each Investigator is responsible for obtaining appropriate approvals, consents, or releases of medical information as dictated by their relevant patient privacy laws.

The study is not transferable to other sites attended by the Investigator unless prior approval is obtained from the appropriate IRB and the Sponsor.

13.3 INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL

Investigators must submit the study protocol and ICF to their reviewing IRB and obtain IRB written approval before being allowed to conduct and participate in the study. Each Investigator must submit to the Sponsor a copy of the IRB approval letter, specific to this protocol and addressed to Investigator, certifying study approval prior to enrolling subjects into the study. This approval letter should identify the study name, study protocol number (including revision number), the date of the approval as well as the expiration date of such an approval. The Investigator is also responsible for fulfilling any conditions of approval imposed by the IRB, and for maintaining continuation of the approval during the entire study period. The Investigator must provide the Sponsor with copies of such approvals.

13.4 CONFIDENTIALITY

All information and data sent to the Sponsor concerning subjects or their participation in this study will be considered confidential. All data used in the analysis and reporting of this evaluation will be used in a manner without identifiable reference to the subject.

13.5 DEVICE ACCOUNTABILITY

Device accountability will NOT be required as there are no investigational devices used in this study.

14 MONITORING

The Sponsor or a Sponsor representative will monitor the progress of the study as described in the Study Monitoring Plan. The Investigator consents to visits by the staff of the Sponsor or its representatives to review the study subject medical records, including any test or laboratory data that might have been recorded on diagnostic test media (e.g. MRI).

Subject Records

The Sponsor will request that any source documents to be submitted to the sponsor, sponsor representative be de-identified (subject's name and other personal identifiers must be removed and replaced with the study subject ID).

These source documents may include but not be limited to:

- Admission, procedural, and discharge reports/notes
- Completed questionnaires
- Documented pain/KPS scores
- Any documentation relevant to a protocol reportable AE/SAE
- Imaging

15 INVESTIGATOR REPORTS AND RECORDS REQUIREMENTS

The Investigator is responsible for the completion and submission to the Sponsor of all CRFs, AEs or other reportable study events (e.g. procedure related complications), and deviations from the protocol. If any action is taken by an IRB with respect to the study, the information must be forwarded to the Sponsor in a timely manner.

The Investigator shall prepare and submit complete, accurate, and in a timely manner, the reports listed in Table 2 below. In addition to this list, individual IRBs may add additional requirements and/or require a different notification time frame.

Table 2. Report Types

Type of Report	Notification prepared by Investigator for	Notification Time Frame
Reportable Serious Adverse Events as Described in Section 8	Sponsor	As soon as possible, preferably within 48 hours after discovery of event.
Death or Serious Adverse Event	IRB per policy	
Withdrawal of IRB Approval	Sponsor	Within five (5) working days.
Deviations to the Protocol	Sponsor IRB per policy	As soon as possible after occurrence of deviation.

All data must be stored and retained by the investigative site for a minimum of 2 years following a notification from Sponsor that all investigative sites are complete, terminated, or discontinued. Should the investigator withdraw from the responsibility of retaining study records, then custody of the records transfers to a person assuming responsibility. Sponsor will be notified in writing of new custodian by the investigative site.

16 USE OF INFORMATION AND PUBLICATION

The LAANTERN Registry will follow the Publication Plan (CL10084) which outlines the guidelines and expectations for LAANTERN publications. For primary manuscript(s) generated from this study, the National Principal Investigator of the study may be granted first and/or senior authorship. The order of subsequent authors will be determined by their contribution. The number of maximum names on the publication will depend on the maximum number of authors allowed by the publisher.

Manuscript ideas may be generated by any Investigator in the study. Investigators should submit publication ideas to the Sponsor for review. An Investigator may also want to publish the study experience from his/her own site. The Sponsor reserves the right to review and approve all publications and presentations utilizing the study data. The Investigator may proceed with the publication when notified by the Sponsor.

For publication purposes, this study will be submitted for inclusion in the clinical trial study at: https://clinicaltrials.gov/ct2/show/NCT02392078