Statistical Analysis Plan

A Multicenter Study of the NEUWAVE Flex Microwave Ablation System in the Ablation of Medically Inoperable Primary Soft Tissue Lesions of the Lung: An Initial Experience

Protocol Number: NEU_2017_06

Protocol Version: Amendment 2 (Version 3.0), 25JUL2018

SAP Version: 1.0
SAP Revision Date: 29JAN2020

Revision History

Version Number	Version Date	Reasons for Revision
1.0	29JAN2020	Original Document

Table of Contents

This is the Statistical Analysis Plan (SAP) for the final analysis of data collected under Protocol NEU_2017_06. This SAP describes, in detail, the statistical methodology and statistical analyses for the above-mentioned protocol.

The original study protocol planned to continue study enrollment until 40 subjects were ablated (approximately 20 subjects ablated by interventional pulmonologists and 20 subjects ablated by thoracic surgeons) and completed Visit 3 (30 days ± 7 days after the first ablation procedure). However, study enrollment was temporarily halted after 10 subjects were enrolled to convene a meeting of the Data Safety Monitoring Board (DSMB) following the death of one subject. While the DSMB recommended that the study could continue enrollment, the decision was made to permanently stop study enrollment and follow the 10 previously-enrolled subjects through the end of the study follow-up period of 1 year post-ablation. As such, this decision impacts several of the analyses originally planned in the study protocol and those changes will be identified in the appropriate sections throughout this SAP.

1 Study Overview

1.1 Study Objectives

The primary objective of the study was to evaluate the NeuWave Flex Microwave Ablation System in transbronchial ablation procedures for adult subjects with a medically inoperable primary soft tissue lesion, based on the following assessments:

a. Device user experience survey
b. Technical success
c. Technique efficacy

Device user experience was collected from the treating physician who completed the User Experience Survey following each ablation procedure throughout the study, when applicable. The survey focused on procedure workflow and the user's assessment on ease/difficulty of using the device. The device user experience was designed to augment the Product Development Specialist's understanding of the usability of the Flex system and determine which enhancements, if any, are needed.

The secondary objectives were the following:

1. To evaluate safety through the monitoring of device-related and procedure-related adverse events (AEs) and all serious adverse events (SAEs), from start of ablation through 1-year post-ablation.
2. To establish device and procedure effectiveness by following subjects for 1-year post-ablation to ensure completeness and durability of treatment effect, based on standard endpoints in microwave ablation, as follows:
    a. Primary efficacy rate
    b. Secondary efficacy rate
    c. Local soft lesion recurrence

d. Length of hospital stay, measured from post-ablation to discharge
e. Hospital readmission rate.

3. To calculate hospital readmission rate, defined as any readmission to the hospital within 30 days of the first ablation procedure (Visit 2A).

The exploratory objectives were the following:

1. To assess the quality of life post microwave ablation of the lung throughout the 1 year ± 1 month follow-up period.
2. To assess the level of pain during the initial 30 days ± 7 days post-ablation.

1.2 Study Design

This was a prospective, multi-center, single-arm study for NEUWAVE Flex Microwave Ablation System in the ablation of soft tissue lesions of the lung for medically inoperable subjects, or those who elect not to have surgery. Prospective subjects were informed about the nature of the research, given the informed consent form (ICF) to read, and given the opportunity to ask any questions about the study. Once the subject understood the content of the ICF, s/he was asked to provide written consent. Individuals scheduled for microwave ablation of the lung were to be enrolled after providing informed consent and meeting study entry criteria, known as the inclusion and exclusion criteria. Subjects were to be followed for approximately 1 year following the first ablation procedure for safety and effectiveness outcomes.

2 Treatment Assignment

This was a single-arm study where all enrolled subjects underwent transbronchial microwave ablation with the NeuWave Flex Microwave Ablation System.

3 Randomization and Blinding Procedures

This was a single-arm, open-label study. No randomization occurred and no blinding procedures were required.

4 Interval Windows

Interval windows are not defined for the purpose of analysis in this study outside of the visit windows that are provided in the Schedule of Assessments in Table 1 of the final protocol. There will be no assigning of observations to time points outside of the visit to which they are recorded in the electronic Case Report Forms (eCRFs). Data collected in Unscheduled Visit forms will be listed as such.

5 Levels of Significance

No hypotheses are specified for this study and no p-values are being calculated. Therefore, no level of significance is specified. All estimation of endpoints will be performed using 95% confidence intervals.

6 Analysis Sets

The study protocol identified two analysis sets:

- The Full Analysis Set (FAS) will consist of all subjects who are enrolled in the study and receive ablation through the flexible probe. The FAS was planned to be the primary analysis set for safety and effectiveness endpoints.
- The Per Protocol (PP) Analysis Set will consist of all subjects who are enrolled in the study and receive ablation through the flexible probe and have no major protocol deviations. Effectiveness analyses were planned to be repeated for the Per Protocol Set.

Given the decision to stop study enrollment at 10 subjects, only the Full Analysis Set will be defined for summarizing effectiveness and safety data in this study. A Per Protocol Analysis Set will not be defined.

7 Sample Size Justification

No formal hypotheses were planned to be tested in this study, and hence, a target sample size of 40 subjects (with an approximate equal distribution of device use by interventional pulmonologists and thoracic surgeons) was deemed adequate for a preliminary investigation of the feasibility of this procedure, as well as for providing sufficient information for appropriately sizing a subsequent study.

From a safety perspective, the AEs of interest in this study included: pneumothorax (requiring tube drainage), hemorrhage (bleeding requiring medical intervention), post-ablation syndrome, pain, pleural effusion (requiring tube drainage), infection, pneumonia, abscess, and bronchopleural fistula. A target sample size of 40 subjects provided a high likelihood of observing events in this composite and would allow for an initial evaluation of the frequency of occurrence relative to published literature in similar procedures.

As stated earlier, enrollment was stopped after 10 subjects received ablation and the original planned target of 40 subjects was not achieved.

8 Data Safety Monitoring Board

A DSMB was appointed by the Sponsor to review, on a regular basis, safety data from the study. The DSMB was to advise the Sponsor regarding the continuing safety of subjects and those yet to

be recruited to the study. Based on accumulating data from the study, the DSMB was to recommend whether to continue, suspend, modify, or stop the study. The composition, responsibilities, frequency of DSMB meetings, handling of emergency situations, and documentation of DSMB meetings was specified in the DSMB Charter and proceedings from DSMB meetings are maintained with the Sponsor.

9 Analyses to be Conducted

9.1 General Conventions

Subject data will be summarized using listings and tables. All eCRF data will be listed per subject for all subjects. Descriptive statistical analyses will be provided for pre-specified study endpoints. Summaries for continuous variables will include number of observations (n), mean, standard deviation, median, minimum, and maximum. Summaries for categorical variables will include number and percentage.

Analyses will be conducted using SAS software version 9.4 or higher. During the course of analysis programming of tables that are mocked up in this SAP, minor modifications may become necessary. Examples of these minor modifications include, but are not limited to, re-wording of a footnote, addition of a footnote, re-labeling of a column, or addition or removal of a column from a listing. In cases where modifications to tables or listings are not related to a change in statistical analysis methodology or conclusions that could be made on the originally proposed methodology, then no amendment of the SAP is necessary. Any final analyses that differ from what has been specified in this document will be identified within the final statistical output and documented within the clinical study report.

9.2 Disposition of Study Subjects

Subject disposition will be summarized in total using counts and percentages. The number and percentage of subjects completed and discontinued will be tabulated along with the specific reasons for discontinuation.

9.3 Demographic, Baseline, and Subject Health Status Characteristics

Summary statistics of subject demographics and baseline characteristics (age, gender, childbearing potential, race, ethnicity, and body mass index) will be presented in total for the Full Analysis Set. Subject medical history will be summarized by Medical Dictionary for Regulatory Activities (MedDRA) system organ class and preferred term.

9.4 Primary Endpoint Analyses

Device user experience feedback was collected from the treating physician who were to complete the User Experience Survey following each ablation procedure. The questionnaire was focused on procedure workflow and the user's assessment on ease/difficulty of using the device. Per the study

protocol, summary statistics were to be provided for each question in the survey; however, given the overall reduced sample size, only responses to the Probe Placement, Ablation Procedure, and General System Feedback sections will be summarized. All data collected on the User Experience Survey will be listed.

The number and percentage of subjects achieving technical success will be summarized and an exact 95% confidence interval will be presented. A similar summary will be presented for technique efficacy.

9.5 Secondary Endpoint Analyses

The study protocol indicates that summaries will be provided for the primary and secondary efficacy rates as well as hospital readmission rates. However, data relevant to these endpoints will only be listed given the reduction in overall sample size. The number and percentage of subjects experiencing target lesion recurrence at any time during following will be summarized and an exact 95% confidence interval will be estimated, but the Kaplan-Meier analysis described in the study protocol will not be performed.

9.6 Safety Analyses

Safety will be assessed through the incidence of AEs and SAEs, which will be coded using MedDRA. The number and percentage of subjects reporting AEs and SAEs will be summarized at the MedDRA system organ class and preferred term level. Similar summaries will also be provided for AEs and SAEs related to the study device, as well as for AEs and SAEs related to the study procedure. Related events are those where the relationship is indicated as Unlikely, Possibly, Probably, or Causal. Summaries of all AEs and SAEs reported within the first 30 days after the initial ablation procedure will be generated. All reported adverse events will be listed.

9.7 Additional Endpoint Analyses

Counts and percentages will be provided for subject performance status as measured by the Eastern Cooperative Oncology Group (ECOG) classification at each visit. Summary statistics will be provided for the numeric pain rating scale measurement and hematology parameters at each visit. Pulmonary function tests will be summarized with summary statistics at each visit where they are measured and the change from the Screening visit measurement will also be summarized. Responses to each question of the EORTC QLQ-LC 13 will be summarized at each visit where the questionnaire was administered. Responses to the EORTC QLQ-C 30 will be listed.

Target lesion details including lesion type, lesion sub-type, size (largest and smallest diameter), location, distance from pleura, and shape will be summarized with statistics appropriate for categorical or continuous variables. Non-target lesion data will be listed. Selected information from the ablation procedure (duration of procedure, duration of ablation delivery, type of anesthesia, maximum power applied, and maximum temperature observed) will also be summarized with statistics appropriate for categorical or continuous variables.

Summary statistics will be presented for evaluations made by the independent reviewer for selected fields relating to ablation of the target lesion (largest diameter, smallest diameter, lesion location, distance from pleura, ablation margin, technical success, technique efficacy, and target lesion recurrence at any visit). All other target lesion data and all non-target lesion data from the independent reviewer will be listed.

9.8 Plans for Interim Analysis

No formal interim analyses were planned or performed for this study outside of the data reviews that were pre-specified per the DSMB charter.

9.9 Handling of Missing Data

All summaries will be performed only on subjects who receive ablation through the flexible probe. There will be no imputation of data for early terminated subjects or for missing data within the database.

9.10 Sensitivity Analyses

No sensitivity analyses were planned per the study protocol given the absence of any hypotheses to be tested in this descriptive study and none will be performed.

9.11 Subgroup Analysis

No subgroup analyses are planned for this study.

9.12 Assessment of Site Homogeneity

No summaries or adjustments by study site are planned for this study.

Appendix: Table Shells and List of Listings to be Generated

Table shells are provided, below, for all summaries to be generated for this study. Additionally, a list of all listings to be created is provided corresponding to the eCRFs that were used during this study. All fields collected will be listed.

Table 1
Subject Disposition
All Subjects

	Total
Signed Informed Consent	xx
Full Analysis Set	xx (xx.x%)
Completed the Study	xx (xx.x%)
Discontinued from the Study	xx (xx.x%)
Reason for Discontinuation	
Withdrawal of consent	xx (xx.x%)
Surgical	xx (xx.x%)
Adverse Event	xx (xx.x%)
Death	xx (xx.x%)
Lost to Follow-up	xx (xx.x%)
Physician Decision	xx (xx.x%)
Other	xx (xx.x%)

Note: All percentages are based on the number of subjects in the Full Analysis Set as the denominator.

<< Programming note: Only discontinuation reasons actually observed are to be displayed. Full Analysis Set includes all subjects who have a non-missing date of ablation on the Ablation Procedure CRF. >>

Table 2
Subject Demographics and Vital Signs
Full Analysis Set

Characteristics	Overall (N = ##)
Race	
White	xx (xx.x%)
Black or African American	xx (xx.x%)
American Indian or Alaska Native	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)
Asian	xx (xx.x%)
Other	xx (xx.x%)
Ethnicity	
Hispanic or Latino	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)
Not reported	xx (xx.x%)
Age (years)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Gender	
Male	xx (xx.x%)
Female	xx (xx.x%)
Childbearing Potential	
Of childbearing potential	xx (xx.x%)
Permanently sterilized	xx (xx.x%)
Postmenopausal	xx (xx.x%)
Body Mass Index (kg/m2)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x

<<< Programming note: Percentages for childbearing potential are based on the number of females in the study. >>>

Table 3
Protocol Deviations
Full Analysis Set

Characteristics	Overall (N = ##)
Total Number of Protocol Deviations	xxx
Specific Types of Protocol Deviations [1]	
Informed Consent Process	xx (xx.x%)
Inclusion/Exclusion Criteria	xx (xx.x%)
Study Procedure	xx (xx.x%)
Visit Out of Window	xx (xx.x%)
Other	xx (xx.x%)
Sponsor Assessment of Protocol Deviations [1]	
Minor	xx (xx.x%)
Major	xx (xx.x%)
Number (%) of Subjects With at Least 1 Protocol Deviation [2]	xx (xx.x%)

1. Denominator used is the total number of protocol deviations reported.
2. Denominator used is the total number of subjects in the column header.

Table 4
Medical History by System Organ Class and Preferred Term
Full Analysis Set

System Organ Class	Preferred Term	Overall (N = ##)
Total		xx (xx.x%)
System Organ Class 1		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Preferred Term 2	xx (xx.x%)
	Preferred Term 3	xx (xx.x%)
System Organ Class 2		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Preferred Term 2	xx (xx.x%)
System Organ Class 3		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Preferred Term 2	xx (xx.x%)
	Preferred Term 3	xx (xx.x%)
System Organ Class 4		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Preferred Term 2	xx (xx.x%)

Table 5
ECOG Performance Status Over Time
Full Analysis Set

ECOG Score	Visit 1/ Screening	Visit 2A/ Day 0	Visit 3/ Day 30	Visit 4/ Month 6	Visit 5/ Month 12
0 – Fully active	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 – Restricted in physically strenuous activity	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 – Ambulatory, capable of self care, unable to work	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Capable of only limited self care	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – Completely disabled	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

<<< Programming note: The number of observed responses at each time point are summarized. No imputation will be performed for subjects not responding at a given visit. >>>

Table 6
Target Lesion Details – Visit 2A/Day 0
Full Analysis Set

Characteristics	Overall (N = ##)
Lesion Type	
NSCLC medically inoperable	xx (xx.x%)
NSCLC medically operable; declined surgery	xx (xx.x%)
Other	xx (xx.x%)
Lesion Sub-type	
Squamous cell carcinoma	xx (xx.x%)
Adenocarcinoma	xx (xx.x%)
Large cell carcinoma	xx (xx.x%)
Other	xx (xx.x%)
Lesion Location	
RUL	xx (xx.x%)
RML	xx (xx.x%)
RLL	xx (xx.x%)
LUL	xx (xx.x%)
LLL	xx (xx.x%)
Other	xx (xx.x%)
Lesion Shape	
Sphere	xx (xx.x%)
Ellipse	xx (xx.x%)
Triangular	xx (xx.x%)
Multilobar	xx (xx.x%)
Other	xx (xx.x%)
Distance from Pleura (cm)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Largest Diameter (cm)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x

Table 6
Target Lesion Details – Visit 2A/Day 0
Full Analysis Set

Characteristics	Overall (N = ##)
Smallest Diameter (cm)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Technical Success	
Yes	xx (xx.x%)
95% Exact Confidence Interval	xx.x%, xx.x%

Table 7
Ablation Procedure Details
Full Analysis Set

Characteristics	Overall (N = ##)
Type of Anesthesia	
General	xx (xx.x%)
Conscious sedation	xx (xx.x%)
Deep conscious sedation	xx (xx.x%)
Maximum Power Applied (watts)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Maximum Temperature Observed (Celsius)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Duration of Procedure (minutes)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Duration of Ablation Delivery (minutes)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Device Used	
Flex 6 Probe	xx (xx.x%)
Flex 4 Probe	xx (xx.x%)

Table 7
Ablation Procedure Details
Full Analysis Set

Characteristics	Overall (N = ##)
Final Ablation Zone, smallest diameter (cm)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Total Number of Probe Repositions	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x

Table 8
Technique Efficacy and Target Lesion Recurrence
Full Analysis Set

Characteristics	Overall (N = ##)
Technique Efficacy at Day 30	
Yes	xx (xx.x%)
95% Exact Confidence Interval	xx.x%, xx.x%
Target Lesion Recurrence Day 30 Through Month 12	
Yes	xx (xx.x%)
95% Exact Confidence Interval	xx.x%, xx.x%

Table 9
User Experience Survey
Full Analysis Set

Characteristics	Overall (N = ##)
Able to Pass Flex Probe through EWC as Expected	
Yes	xx (xx.x%)
No	xx (xx.x%)
Time to Place Probe in Acceptable Position (minutes)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Number of 3D Scans for Probe Placement	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Distance From Probe to Center of Lesion (mm)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Probe Repositioned After Initial Ablation for More Ablation	
Yes	xx (xx.x%)
No	xx (xx.x%)
Performing Ablation With NeuWave Flex System is Predictable	
1 – Disagree	xx (xx.x%)
2	xx (xx.x%)
3	xx (xx.x%)
4	xx (xx.x%)
5 - Agree	xx (xx.x%)

Table 9
User Experience Survey
Full Analysis Set

Characteristics	Overall (N = ##)
Ablation With NeuWave Flex System is Simple to Use	
1 – Disagree	xx (xx.x%)
2	xx (xx.x%)
3	xx (xx.x%)
4	xx (xx.x%)
5 - Agree	xx (xx.x%)
Technical Success can be Achieved Similar to a Percutaneous Approach	
1 – Disagree	xx (xx.x%)
2	xx (xx.x%)
3	xx (xx.x%)
4	xx (xx.x%)
5 - Agree	xx (xx.x%)
Confidently Locate the Probe and Targeted Lesion Using my Imaging Tools	
1 – Disagree	xx (xx.x%)
2	xx (xx.x%)
3	xx (xx.x%)
4	xx (xx.x%)
5 - Agree	xx (xx.x%)
Confidently Locate the Ablation Zone Created During Flex Ablation Procedure	
1 – Disagree	xx (xx.x%)
2	xx (xx.x%)
3	xx (xx.x%)
4	xx (xx.x%)
5 – Agree	xx (xx.x%)

Table 10
Pulmonary Function Tests and Change From Screening Over Time
Full Analysis Set

Parameter Statistic	Visit 1/ Screening	Visit 4/ Month 6	Change From Visit 1 to Visit 4	Visit 5/ Month 12	Change From Visit 1 to Visit 5
FeNO (ppb)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum, Maximum	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
DLCO (mL/min/mmHg)					
n	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Minimum, Maximum	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
DLCO (%)					
SpO2 (%)					
FVC (mL)					
FVC (%)					
FEV1 (mL)					
FEV1 (% of predicted)					
FEV1/FVC (% of predicted)					
Plethysmographic TLC (mL)					
Plethysmographic TLC (% of predicted)					
Plethysmographic FRC (mL)					
Plethysmographic FRC (% of predicted)					
Gas Dilution TLC (mL)					
Gas Dilution TLC (% of predicted)					
Gas Dilution FRC (mL)					
Gas Dilution FRC (% of predicted)					

<<< Programming note: The number of observed responses at each time point are summarized. No imputation will be performed for subjects not responding at a given visit. >>>

Table 11
Hematology Tests Over Time
Full Analysis Set

Parameter Statistic	Visit 1/ Screening	Visit 3/ Day 30	Visit 4/ Month 6	Visit 5/ Month 12
RBC (M/uL)				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xxx	x.xxx	x.xxx	x.xxx
Median	xx.x	xx.x	xx.x	xx.x
Minimum, Maximum	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
WBC (K/uL)				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xxx	x.xxx	x.xxx	x.xxx
Median	xx.x	xx.x	xx.x	xx.x
Minimum, Maximum	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Neutrophils (%)				
Lymphocytes (%)				
Monocytes (%)				
Eosinophils (%)				
Basophils (%)				
Hemoglobin (g/dL)				
Hematocrit (%)				
Mean Corpuscular Volume (fL)				
Platelet Count (K/uL)				
PTA (%)				
APTT (seconds)				
PT (seconds)				
INR (ratio)				

<<< Programming note: The number of observed responses at each time point are summarized. No imputation will be performed for subjects not responding at a given visit. >>>

Table 12
Numeric Pain Rating Scale Over Time
Full Analysis Set

Parameter Statistic	Visit 1/ Screening	Visit 2A/ Day 0	Visit 2B/ Day 1	Visit 3/ Day 30
Self-Reported Pain Intensity in the Last 24 Hours				
n	xx	Xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
Standard Deviation	x.xxx	x.xxx	x.xxx	x.xxx
Median	xx.x	xx.x	xx.x	xx.x
Minimum, Maximum	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Note: A pain score of 0 indicates no pain, 5 indicates moderate pain, and 10 indicates worst possible pain.

Table 13
EORTC QLQ-LC 13
Full Analysis Set

Characteristics	Visit 1/ Screening (N = ##)	Visit 2A/ Day 0 (N = ##)	Visit 2B/ Day 1 (N = ##)	Visit 3/ Day 30 (N = ##)	Visit 4/ Month 6 (N = ##)	Visit 5/ Month 12 (N = ##)
How much did you cough?						
Not at all	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
A little	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Quite a bit	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Very much	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No response	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Did you cough up blood?						
Not at all	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
A little	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Quite a bit	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Very much	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No response	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Were you short of breath when you rested?						
Were you short of breath when you walked?						
Were you short of breath when you climbed stairs?						
Have you had a sore mouth or tongue?						
Have you had trouble swallowing?						
Have you had tingling hands or feet?						
Have you had hair loss?						
Have you had pain in your chest?						
Have you had pain in your arm or shoulder?						
Have you had pain in other parts of your body?						
Did you take any medication for pain?						
If yes, how much did it help?						

Note: Responses given refer to during the past week.

Table 14
Adverse Events by System Organ Class and Preferred Term
Full Analysis Set

System Organ Class	Preferred Term	Overall (N = ##)
Total		xx (xx.x%)
System Organ Class 1		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Preferred Term 2	xx (xx.x%)
	Preferred Term 3	xx (xx.x%)
System Organ Class 2		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Preferred Term 2	xx (xx.x%)
System Organ Class 3		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Preferred Term 2	xx (xx.x%)
	Preferred Term 3	xx (xx.x%)
System Organ Class 4		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Preferred Term 2	xx (xx.x%)

The following tables will have the same format as Table 14:

Table 15	Serious Adverse Events by System Organ Class and Preferred Term Full Analysis Set
Table 16	Adverse Events Related to the Study Device by System Organ Class and Preferred Term Full Analysis Set
Table 17	Serious Adverse Events Related to the Study Device by System Organ Class and Preferred Term Full Analysis Set
Table 18	Adverse Events Related to the Study Procedure by System Organ Class and Preferred Term Full Analysis Set
Table 19	Serious Adverse Events Related to the Study Procedure by System Organ Class and Preferred Term Full Analysis Set
Table 20	Adverse Events Related to the Study Device Within 30 Days of the Initial Ablation Procedure by System Organ Class and Preferred Term Full Analysis Set
Table 21	Serious Adverse Events Related to the Study Device Within 30 Days of the Initial Ablation Procedure by System Organ Class and Preferred Term Full Analysis Set

Table 22
Target Lesion Details – Independent Reviewer
Full Analysis Set

Characteristics	Overall (N = ##)
Lesion Location	
RUL	xx (xx.x%)
RML	xx (xx.x%)
RLL	xx (xx.x%)
LUL	xx (xx.x%)
LLL	xx (xx.x%)
Other	xx (xx.x%)
Distance from Pleura (cm)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Largest Diameter (cm)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Smallest Diameter (cm)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Ablation Margin, Smallest Diameter (cm)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x

Table 22
Target Lesion Details – Independent Reviewer
Full Analysis Set

Characteristics	Overall (N = ##)
Technical Success – Visit 2A/Day 0	
Yes	xx (xx.x%)
95% Exact Confidence Interval	xx.x%, xx.x%
Technique Efficacy at Day 30	
Yes	xx (xx.x%)
95% Exact Confidence Interval	xx.x%, xx.x%
Target Lesion Recurrence Day 30 to Month 12	
Yes	xx (xx.x%)
95% Exact Confidence Interval	xx.x%, xx.x%

The following listings will be generated for this study:

Listing 1	Inclusion/Exclusion Criteria All Subjects
Listing 2	Inclusion/Exclusion Criteria – Ablation Visit All Subjects
Listing 3	Study Visits All Subjects
Listing 4	Study Visit Details All Subjects
Listing 5	Demographics All Subjects
Listing 6	Pregnancy Test All Subjects
Listing 7	Medical History All Subjects
Listing 8	Surgical History All Subjects
Listing 9	Radiation History All Subjects
Listing 10	Vital Signs All Subjects
Listing 11	ECOG Performance Status All Subjects
Listing 12	Pain Rating Scale (NPRS) All Subjects
Listing 13	Pulmonary Function Tests All Subjects
Listing 14	Hematology All Subjects
Listing 15	Genetic Markers Testing All Subjects

Listing 16	EORTC QLQ-C 30 All Subjects
Listing 17	EORTC QLQ-LC 13 All Subjects
Listing 18	Target Lesion Details All Subjects
Listing 19	Non-Target Lesion Details All Subjects
Listing 20	Target Lesion Details Central Reviewer All Subjects
Listing 21	Non-Target Lesion Details Central Reviewer All Subjects
Listing 22	Ablation Procedure All Subjects
Listing 23	Imaging All Subjects
Listing 24	User Experience Survey All Subjects
Listing 25	Discharge All Subjects
Listing 26	UB-04 All Subjects
Listing 27	Concomitant Procedures All Subjects
Listing 28	Concomitant Medications All Subjects
Listing 29	Adverse Events All Subjects
Listing 30	Protocol Deviations All Subjects
Listing 31	Death All Subjects

Listing 32	Subject Completion/Discontinuation All Subjects