STATISTICAL ANALYSIS PLAN

Study Device: RheOx™

Protocol Number: CS003

Protocol Version: 19APR2019

Protocol Title: A Feasibility Study: A Safety Evaluation of the RheOx™ on Patients with Chronic Bronchitis in the United States

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1 INTRODUCTION

This Statistical Analysis Plan (SAP) provides a description of the statistical methods and procedures to be implemented for the analyses of data collected from the CS003 study entitled 'A Feasibility Study: A Safety Evaluation of the RheOx™ on Patients with Chronic Bronchitis in the United States'. Any deviations from this analysis plan will be substantiated by sound statistical rationale and will be documented in the final clinical study report.

All analyses described in this plan are considered a priori analyses in that they have been defined prior to lock/freeze of the database. Analyses designed after database lock or freeze are deemed post-hoc and will be considered exploratory. All post hoc analyses will be clearly identified in the clinical study report.

2 STUDY OBJECTIVES

The primary objective of this study is to assess the safety of RheOx in patients with chronic bronchitis. The secondary objective is to assess the clinical utility of RheOx in patients with chronic bronchitis.

3 STUDY OVERVIEW

3.1 Study Design

This is a prospective, single arm, feasibility study to assess the safety and clinical utility of RheOx in patients with chronic bronchitis in the United States.

Patients undergo the RheOx Bronchial Rheoplasty procedure in two bronchoscopic sessions; the first to treat the right lung (Bronchoscopy 1 / index procedure) and the second to treat the left lung (Bronchoscopy 2) approximately 4-weeks later. Study follow-up visits occur at 1-week following each treatment and at 1-month, 3-months, 6-months, 10-months, 12-months, and 2, 3, 4 and 5 years after the second treatment.

For a detailed schedule of procedures, refer to the Schedule of Events table in the study protocol.

3.2 Study Endpoints

3.2.1 Safety

The primary safety analysis is the incidence of serious adverse events (SAE) of interest through 12 months defined as the following:

- Death
- COPD exacerbation, as defined as an acute worsening in respiratory symptoms requiring additional therapy, that requires a hospital stay of greater than 24 hours
- Pneumothorax within 2 days of either Gala Treatment procedure
- Pneumonia within 7 days of either Gala Treatment procedure, as defined as an increase in respiratory symptoms, fever, sputum production and or purulence with radiographic confirmation
- Respiratory Failure as defined as a requirement for mechanical ventilatory support for > 24 hours
- Arrhythmia requiring intervention or sustained ($\geq$ 30 seconds) ventricular tachycardia

In addition to the primary safety analysis, additional pre-specified safety analyses will be performed in order to assess the totality of the safety profile of RheOx. Other, prespecified safety analyses include the incidence of treatment emergent adverse events (AE) and SAEs and an analysis of COPD exacerbations by severity.

3.2.2 Clinical Utility

The clinical utility endpoints include:

- The change from baseline at 6 and 12 months in St. George's Respiratory Questionnaire (SGRQ)
- The change from baseline at 6 and 12 months in COPD Assessment Test (CAT)
- Hospitalization rate (not including the planned bronchoscopy procedures) from discharge from the initial RheOx Bronchial Rheoplasty procedure (Visit 2) through 12 months

3.2.3 Other Endpoints

In addition, the protocol also prespecified the following exploratory measures for assessment including changes from baseline to follow-up in:

- Responder rates utilizing established clinically meaningful thresholds for SGRQ (4 points) and CAT (2 points)

- Change in other QOL measures including CASA-Q and EXACT-PRO
- Change in lung function as measured by FEV_1 and FVC
- Change in sleep patterns as assessed by the Insomnia Sleep Index (ISI)
- Change in cough count as assessed by a cough counting monitor
- Mucin concentrations (MUC5AC, MUC5B) from induced sputum samples
- Quantitative High-Resolution CT Scan (HRCT) metrics including airway volume, total airway count, and lobar volumes
- Device performance.

4 STATISTICAL METHODOLOGY

4.1 Sample Size Determination

Since this is an early feasibility study, no formal sample size calculations were conducted. Up to 30 patients will be enrolled and treated with the study device to assess the effect of the investigational device in the target population. This sample size was based upon clinical judgement rather than statistical considerations.

4.2 Analysis Populations

4.2.1 Evaluable Population

The Evaluable Population will include all patients who received at least one RheOx treatment. All analyses will be based on the evaluable population.

4.3 Patient Disposition

Counts and percentages of patients who complete the study and who withdraw from the study, with the reason for withdrawal, will be presented. For the patients who withdraw early from the study or who are excluded from certain populations, reasons for withdrawal or exclusion, and the last date of study participation will be listed. Patient enrollment and disposition will also be provided by site.

4.4 Protocol Deviations

All protocol deviations information including patient ID, date /visit (if applicable), and the type of deviations will be listed. Deviations will further be categorized as major and minor based on the following definitions.

A major protocol deviation will be defined as failure to adhere to the protocol, study specific

procedures or clinical investigation plan requirements which could impact the rights, safety or welfare of the patients and/or the completeness, accuracy and integrity of the study data. Examples include failure to obtain signed consent prior to trial treatment, enrolled patient not meeting eligibility criteria, or breach of patient confidentiality.

A minor protocol deviation will be defined as a divergence from approved study design or study which does not affect the patient's rights, safety, or welfare, and/or the completeness, accuracy, and integrity of the study data. Examples include patient visit outside the scheduled follow-up window, or test not completed per protocol.

Protocol deviations will be categorized based on deviation type (e.g., visit performed out of window, missed visit) and deviation category (minor or major). The number of occurrences and percent of patients experiencing each category of deviation will be reported.

4.5 Demographic and Baseline Characteristics

Descriptive summaries of demographic and baseline characteristics will be presented. If multiple assessments for a given variable are available, Baseline measurements refer to the last measurement collected prior to the index procedure visit (Visit #2).

Demographic and baseline characteristics include age, gender, race, weight, height, smoking history (pack-years), GOLD stage and other measures of respiratory status, COPD medications, quality of life (CAT and SGRQ), and body mass index (BMI). Continuous variables (e.g., age, weight, BMI) will be summarized by patient count, mean, standard deviation (SD), median, inter-quartile range (IQR), minimum, and maximum. Categorical variables (e.g., race, gender) will be summarized by the number and percentage of patients in the corresponding categories.

4.6 Device Performance

Device performance will be assessed through an analysis of device malfunctions, the duration of the procedure in minutes (bronchoscope insertion to removal), device time in minutes (RheOx catheter insertion to removal), the number of device activations, and the post procedure hospital stay. Device performance will be summarized descriptively using counts, mean, SD, median, IQR, minimum and maximum where applicable.

4.7 Prior and Concomitant Medications

Prior and concomitant medications will be categorized using the World Health Organization (WHO) Drug Dictionary and listed. In addition, COPD related medications (i.e., long acting

beta and muscarinic antagonists, inhaled corticosteroids) will be summarized at baseline and follow-up to assess the impact on study outcomes of any changes in medical management over the course of the study.

4.8 Safety Analyses

Treatment emergent AEs and SAEs will be summarized and listed. Treatment emergent AEs (TEAE) are defined as those adverse events occurring during or after bronchoscopy #1 (Visit 2). No inferential statistical testing of the safety data will be conducted.

4.8.1 Serious Adverse Events of Interest

The primary safety analysis is the incidence of treatment emergent serious adverse events of interest through 12 months. Serious adverse events of interest are defined in the study protocol and in Section 3.2.1 above.

The count and percent of patients experiencing each of the events listed in Section 3.2.1 above and a composite summary of patients experiencing any of these events through the 12-month visit will be summarized. Events will also be summarized within discrete time periods (as described in section below) from bronchoscopy #1 (Visit #2) through 12 months in order to assess the procedure effect.

4.8.2 Adverse Events

All reported AEs will be coded and classified by system organ class and lower level term (LLT) using the Medical Dictionary for Regulatory Activities (MedDRA).

The relationship to the device and/or procedure, system organ class, lower level term (LLT), and verbatim text for all adverse events will be listed. All treatment emergent AEs and SAEs will be summarized by the system organ class, LLT, and time interval. Device and/or procedure related adverse events will be summarized in a similar manner.

The following time intervals will be used:

- Treatment Emergent: Any event that occurred the day of or following Bronchial Rheoplasty 1 procedure through end of study.
- Treatment Recovery Period: Any event occurring the day of Bronchial Rheoplasty 1 procedure through 30 days following Bronchial Rheoplasty 2 procedure.
- 3 Months: Any event occurring during follow-up period through 90 days after Bronchial Rheoplasty 2, excluding treatment recovery period.

- 6 Months: Any event occurring during the follow-up period between 91 days and 180 days after Bronchial Rheoplasty 2.
- 12 Months: Any event occurring during the follow-up period between 181 days and 365 days after Bronchial Rheoplasty 2.
- 2 Years: Any event occurring during the follow-up period between 366 days after Bronchial Rheoplasty 2 and 730 days after Bronchial Rheoplasty 2.
- 3 Years: Any event occurring during the follow-up period between 731 days and 1095 days after Bronchial Rheoplasty 2.
- 4 Years: Any event occurring during the follow-up period between 1096 days and 1460 days after Bronchial Rheoplasty 2.
- 5 Years: Any event occurring during the follow-up period between 1461 days and study completion.

SAEs and/or AEs leading to the discontinuation of study will also be listed.

4.8.2.1 Other Safety Analyses

Because of their importance in the studied patient population, COPD exacerbations will further be analyzed by severity (mild, moderate, and severe) based on commonly accepted clinical definitions as defined in GOLD 2018 Report. The count, percent of patients experiencing an event, and event rate per patient year of follow-up will be summarized overall and by severity.

4.9 Clinical Utility Analyses

Clinical utility, a secondary objective of the study, will be primarily assessed through the SGRQ, CAT, and post-procedure hospitalization rates. Details of the conduct of those analyses are provided below.

4.9.1 St. George's Respiratory Questionnaire (SGRQ)

SGRQ total score and changes from baseline will be summarized by scheduled time point using descriptive statistics. The mean, standard deviation (SD), median, and inter-quartile range (IQR) will be reported. Statistical testing to evaluate change from baseline using methods consistent with the statistical assumptions required to support the analyses may also be conducted for exploratory purposes. P-values from a Sign test corresponding to non-parametric approach to test whether the median differs from zero and confidence intervals will be reported.

4.9.2 COPD Assessment Test (CAT)

CAT total score and changes from baseline will be summarized by scheduled time point using descriptive statistics. The mean, SD, median, and IQR will be reported. Statistical testing to evaluate change from baseline using methods consistent with the statistical assumptions required to support the analyses may also be conducted for exploratory purposes. P-values from a Sign test corresponding to non-parametric approach to test whether the median differs from zero and confidence intervals will be reported.

4.9.3 Hospitalization Rates

Hospitalization rates will be reported on a per-patient and per-event basis. The per-patient hospitalization rate is the proportion of patients who were re-admitted post-discharge, excluding the two Bronchial Rheoplasty procedures. An individual patient will only be counted once no matter how many times they are readmitted during the follow-up period. The total number of hospitalizations will also be reported along with the rate calculated as the number of events per patient-year of follow-up.

4.9.4 Other Endpoints

The following describes the analysis plan for other, prespecified, exploratory measures of clinical utility as defined in the study protocol and in Section 3.2.3 above.

Continuous variables (e.g., FEV1, FVC) will be summarized by mean, SD, median, and IQR. Categorical variables (e.g., responder rates) will be summarized by the number and percentage of patients in each of the corresponding categories. Statistical testing to evaluate change from baseline using methods consistent with the statistical assumptions required to support the analyses may also be conducted for exploratory purposes. P-values from a Sign test corresponding to non-parametric approach to test whether the median differs from zero and confidence intervals will be reported.

4.9.4.1 Responder Rates

The proportion of patients meeting the following improvement thresholds at follow-up will be summarized:

- at least 2-point decrease (improvement) in CAT total score
- at least 4-point decrease (improvement) in CAT total score
- at least 2-point decrease in the sum of the first two questions of the CAT

- at least 2-point decrease in CAT total score and a 1-point decrease in either of the first two questions of the CAT
- at least 4-point decrease (improvement) in SGRQ total score
- at least 8-point decrease (improvement) in SGRQ total score

4.9.4.2 Cough and Sputum Assessment Questionnaire (CASA-Q)

CASA-Q scores for each domain and changes from baseline (cough symptom, cough impact, sputum symptom and sputum impact) will be summarized at each timepoint using descriptive statistics as described in Section 4.9.4 above.

4.9.4.3 Pulmonary function

Pulmonary function test results including forced vital capacity (FVC), forced expiratory volume one second (FEV_1), and FEV_1 / FVC ratio will be summarized using descriptive statistics as described in Section 4.9.4 above. Change from baseline to follow-up will also be summarized.

4.9.4.4 CT Scan

High-Resolution CT Scan (HRCT) scans will be performed at Baseline, 1 Month (prior to the second Bronchial Rheoplasty procedure), and 6 Months visits. Results of quantitative post-processing of the HRCTs including airway volume, total airway count, and lobar volumes will be summarized by visit. For each patient, the assessment from left and right lung will be averaged so each patient contributes one value for each timepoint. Changes from baseline to follow-up will also be summarized.

4.9.4.5 Optional Measures

Exploratory measures including the Insomnia Sleep Index (ISI), cough counting, mucin concentrations (MUC5AC, MUC5B) from induced sputum samples, and EXACT-Pro were included in the protocol as optional measures. Insufficient data are available for these tests to warrant analysis of these data; thus, no data will be summarized for these measures.

5 GENERAL INFORMATION

5.1 Statistical Software

The creation of analysis datasets and all statistical analyses will be performed using SAS® version 9.4 or higher.

5.2 Handling of Missing Data

Patient compliance with required follow up will be tabulated and reported as described in section 4.3. All analyses (tables and figures) will be conducted using all available data. No imputation or other evaluation of missing data will be performed.

5.3 Post -Hoc Analysis

Additional post-hoc analyses (e.g., subgroup, multivariable) may be performed. The details of these analyses will be documented in the clinical study report.

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Table #14.1.1 Patient Disposition

All Patients

Patient Status	
Number of patients consented	xx
Excluded	xx/xx (xx.x%)
In Screening	xx
Enrolled (Treated)	xx/xx (xx.x%)
In Follow-up	xx/xx (xx.x%)
Completed Study	xx
Exited Study	xx
Withdrawn by Investigator	xx
Subject Withdrew Consent	xx
Death	xx
AE / SAE (other than death)	xx
Lost to Follow-up	xx
Other	xx

Table #14.1.2 Patient Follow-up Status

All Patients

Visit	Completed Visit (N)	Not Completed* (N)
Bronchoscopy 1	n (%)	n (%)
Bronchoscopy 2	n (%)	n (%)
1 Month	n (%)	n (%)
3 Months	n (%)	n (%)
6 Months	n (%)	n (%)
12 Months	n (%)	n (%)
2 Years	n (%)	n (%)
3 Years	n (%)	n (%)
4 Years	n (%)	n (%)
5 Years	n (%)	n (%)

* All causes including death

Table # 14.1.3 Patient Enrollment and Disposition by Site

All Patients

Site	Total Patients	Consented	Excluded	Enrolled (Treated)	In Follow-up	Completed Study	Exited Study
101 - University of Pittsburgh	xx	xx	xx	xx	xx	xx	xx
102 - University of Alabama	xx	xx	xx	xx	xx	xx	xx
103 - Temple Lung Center	xx	xx	xx	xx	xx	xx	xx
104 - University of Iowa	xx	xx	xx	xx	xx	xx	xx
105 - University of Chicago	xx	xx	xx	xx	xx	xx	xx
106 - Mayo Clinic - Florida	xx	xx	xx	xx	xx	xx	xx
107 - Beth Israel Deaconess	xx	xx	xx	xx	xx	xx	xx
109 - MedStar Health Research Institute	xx	xx	xx	xx	xx	xx	xx
Total	xx	xx	xx	xx	xx	xx	xx

Table # 14.1.4 Protocol Deviations

Evaluable Population

Deviation Category	Deviation Type	Number of Deviations
Major		xx
	Inclusion/Exclusion Criteria Not Met	x
Minor		xx
	Visit performed out of window	x

Table # 14.1.5 Demographics and Baseline Clinical Characteristics
Evaluable Population

Characteristic	**Evaluable Population (N)**
Age	
n	xx
Mean (SD)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x
Gender, n (%) Male	xx (xx.x%)
BMI	
n	xx
Mean (SD)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x
Race, n (%)	
American Indian or Alaska Native	xx (xx.x%)
Asian	xx (xx.x%)
Black or African American	xx (xx.x%)
Native Hawaiian or Pacific Islander	xx (xx.x%)
White	xx (xx.x%)
Other	xx (xx.x%)
Smoking History (Pack-years)	
n	xx
Mean (SD)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x
FEV1 % Predicted	
n	xx
Mean (SD)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x
FEV1/FVC (%)	

Characteristic	Evaluable Population (N)
n	xx
Mean (SD)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x
GOLD Stage, n (%)	
I	xx (xx.x%)
II	xx (xx.x%)
III	xx (xx.x%)
IV	xx (xx.x%)
NA (FEV1/FVC > .7)	xx (xx.x%)
TLC % Predicted	xx
n	xx.x (x.xx)
Mean (SD)	xx.x (xx.x, xx.x)
Median (IQR)	xx.x, xx.x
Min, Max	xx
RV % Predicted	
n	xx
Mean (SD)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x
RV/TLC (%)	xx
n	xx.x (x.xx)
Mean (SD)	xx.x (xx.x, xx.x)
Median (IQR)	xx.x, xx.x
Min, Max	xx
% Emphysema (-950 HU)	
n	xx
Mean (SD)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x
6MWT (meters)	
n	xx
Mean (SD)	xxx.x (x.xx)

Characteristic	Evaluable Population (N)
Median (IQR)	xxx.x (xx.x, xx.x)
Min, Max	xxx.x, xxx.x
CAT Total Score	
n	xx
Mean (SD)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x
CAT Cough Score	
n	xx
Mean (SD)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x
CAT Phlegm Score	
n	xx
Mean (SD)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x
SGRQ Total Score	
n	xx
Mean (SD)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x
SGRQ Symptoms Score	
n	xx
Mean (SD)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x
Pharmacological Treatment, n (%)	
Short Acting Only	xx (xx.x%)
LABA Only or LAMA Only*	xx (xx.x%)
LABA/LAMA*	xx (xx.x%)
ICS/LABA or ICS/LABA/LAMA*	xx (xx.x%)

Characteristic	Evaluable Population (N)
ICS Only*	xx (xx.x%)
Oral Roflumilast	xx (xx.x%)
COPD Exacerbation Rate (events per patient year, 1 year prior to Treatment)	x.xx
All	
N Events	xx
Mean (SD)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x
Severe	
N Events	xx
Mean (SD)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x
Moderate	
N Events	xx
Mean (SD)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x

* With or without short-acting bronchodilator

Table # 14.2.1 Procedure Results
Evaluable Population

Parameter	Treatment 1 (Right Lung) (N procedures)	Treatment 2 (Left Lung) (N procedures)	Overall (N total procedures)
Bronchoscopy Time (minutes)			
n	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
RheOx Procedure Time (minutes)			
n	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Number of Activations Delivered During Treatment Procedure			
n	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Post-Procedure Overnight Hospital Stay (Days)			
n	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Table # 14.2.2 Concomitant Medications through 12 Months
Evaluable Population

ATC Level 2 ATC Level 4	Baseline n/N (% patients) [# meds] (N)	Treatment Recovery Period [1] n/N (% patients) [# meds] (N)	3 Months [2] n/N (% patients) [# meds] (N)	6 Months [3] n/N (% patients) [# meds] (N)	12 Months [4] n/N (% patients) [# meds] (N)	Post-Treatment Total Through 12 Months [5] n/N (% patients) [# meds] (N)
ATC Level 2	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]
ATC Level 4	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]
ATC Level 4	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]
ATC Level 4	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]
ATC Level 2						
ATC Level 4						
ATC Level 4						
ATC Level 4						

[1] Any concomitant medication after Bronchial Rheoplasty 1 procedure through 30 days following Bronchial Rheoplasty 2 procedure.
[2] Follow-up period through 3 months after Bronchial Rheoplasty 2, excluding either treatment recovery period.
[3] Follow-up period between 3 months and 6 months after Bronchial Rheoplasty 2.
[4] Follow-up period between 6 months and 12 months after Bronchial Rheoplasty 2.
[5] All concomitant medications after Bronchial Rheoplasty 1 procedure through 12 months after Bronchial Rheoplasty 2.

Table # 14.2.3 Concomitant Medications Post 12 Months

ATC Level 2 ATC Level 4	2 Years [1] n/N (% patients) [# meds] (N)	3 Years [2] n/N (% patients) [# meds] (N)	4 Years [3] n/N (% patients) [# meds] (N)	5 Years [4] n/N (% patients) [# meds] (N)	Post-12 Months Total [5] n/N (% patients) [# meds] (N)
ATC Level 2	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]
ATC Level 4	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]
ATC Level 4	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]	xx/xx (xx.x%) [xx]
ATC Level 2					
ATC Level 4					
ATC Level 4					
ATC Level 4					

[1] Follow-up period between 12 months and 2 years after Bronchial Rheoplasty 2.
[2] Follow-up period between 2 years and 3 years after Bronchial Rheoplasty 2.
[3] Follow-up period between 3 years and 4 years after Bronchial Rheoplasty 2.
[4] Follow-up period between 4 years and 5 years after Bronchial Rheoplasty 2.
[5] All concomitant medications after 12 months through 5 years after Bronchial Rheoplasty 2.

Table # 14.2.4 Quality of Life Outcomes through 12 Months
Evaluable Population

Parameter (CAT, SGRQ, CASA-Q)	Baseline	1 Month	3 Months	6 Months	12 Months
Observed value					
N	xx	xx	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Change from Baseline					
N		xx	xx	xx	xx
Mean (SD)		xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median (IQR)		xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Min, Max		xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Pvalue (95% CI)		x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)

Table # 14.2.5 Quality of Life Outcomes Post 12 Months
Evaluable Population

Parameter (CAT, SGRQ, CASA-Q)	2 Years	3 Years	4 Years	5 Years
Observed value				
N	xx	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Change from Baseline				
N	xx	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Pvalue (95% CI)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)

Table #14.2.6 HRCT Scan Quantitative Analysis
Evaluable Population

Visit/ Statistics	**Baseline**	**1 Month**	**6 Months**
Parameter			
Observed Value			
N	xx	xx	xx
Mean (SD)	xx.x (x.xx)	xx.x (x.xx)	xx.x (x.xx)
Median (IQR)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Change from Baseline			
N		xx	xx
Mean (SD)		xx.x (x.xx)	xx.x (x.xx)
Median (IQR)		xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
Min, Max		xx.x, xx.x	xx.x, xx.x
Pvalue (95% CI)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)

Table #14.2.7 Pulmonary Function Testing through 12 Months
Evaluable Population

Parameter (FEV_1,FVC,FEV_1/FVC)	**Baseline**	**1 Month**	**3 Months**	**6 Months**	**12 Months**
Observed value					
N	xx	xx	xx	xx	xx
Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
Median (IQR)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
Min, Max	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx
Change from Baseline					
N		xx	xx	xx	xx
Mean (SD)		x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
Median (IQR)		x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
Min, Max		x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx
Pvalue (95% CI)		x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)

Table #14.2.8 Pulmonary Function Testing Post 12 Months
Evaluable Population

Parameter (FEV_1,FVC,FEV_1/FVC)	**2 Years**	**3 Years**	**4 Years**	**5 Years**
Observed value				
N	xx	xx	xx	xx
Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
Median (IQR)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
Min, Max	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx
Change from Baseline				
N	xx	xx	xx	xx
Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
Median (IQR)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)	x.xx (x.xx, x.xx)
Min, Max	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx	x.xx, x.xx

Table # 14.2.9 Responder Analyses
Evaluable Population

Visit	3 Months (N)	6 Months (N)	12 Months (N)	2 Years (N)	3 Years (N)	4 Years (N)	5 Years (N)
Patient Meeting Criteria #1							
n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Patient Meeting Criteria #2							
n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Patient Meeting Criteria #3							
n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Patient Meeting Criteria #4							
n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Table # 14.3.1 Serious Adverse Events of Interest and Hospitalizations
Evaluable Population

	Treatment Recovery Period[1] n(%)[events] (N)	**3 Months[2]** n(%)[events] (N)	**6 Months[3]** n(%)[events] (N)	**12 Months[4]** n(%)[events] (N)	**Total Events through 12 Months[5]** n(%)[events] (N)
Death	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
COPD Exacerbation	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
Pneumothorax	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
Pneumonia	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
Respiratory Failure	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
Arrythmia	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
Total					
Hospitalizations					
n (%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Rate per pt-yr (n events)	x.xx [xx]	x.xx [xx]	x.xx [xx]	x.xx [xx]	x.xx [xx]

[1] Any event occurring after Bronchial Rheoplasty 1 procedure through 30 days following Bronchial Rheoplasty 2 procedure.
[2] Follow-up period through 3 months after Bronchial Rheoplasty 2, excluding either treatment recovery period.
[3] Follow-up period between 3 months and 6 months after Bronchial Rheoplasty 2.
[4] Follow-up period between 6 months and 12 months after Bronchial Rheoplasty 2.
[5] All treatment-emergent events occurring after Bronchial Rheoplasty 1 procedure through 12 months after Bronchial Rheoplasty 2.

Table # 14.3.2 High Level Summary of Non-Serious Adverse Events
Evaluable Population

	Total Events through 12 Months[1] n(%)[events] (N)
Number of Subjects with AEs	xx (x.x%) [xx]
Number of Subjects with Related AEs	xx (x.x%) [xx]
Number Subjects Withdrawn Due to an AE	xx (x.x%) [xx]
AE Severity	xx (x.x%) [xx]
Mild	xx (x.x%) [xx]
Moderate	xx (x.x%) [xx]
Severe	xx (x.x%) [xx]
AE Relationship to Procedure	xx (x.x%) [xx]
Probably Related	xx (x.x%) [xx]
Possibly Related	xx (x.x%) [xx]
Not Related	xx (x.x%) [xx]
AE Relationship to Device	xx (x.x%) [xx]
Probably Related	xx (x.x%) [xx]
Possibly Related	xx (x.x%) [xx]
Not Related	xx (x.x%) [xx]
AE Outcome	xx (x.x%) [xx]
Resolved	xx (x.x%) [xx]
Resolved with sequelae	xx (x.x%) [xx]
Ongoing	xx (x.x%) [xx]
Death	xx (x.x%) [xx]

[1] All treatment-emergent events occurring after Bronchial Rheoplasty 1 procedure through 12 months after Bronchial Rheoplasty 2.

Table # 14.3.3 High Level Summary of Serious Adverse Events
Evaluable Population

	Total Events through 12 Months[1] n(%)[events] (N)
Number of Subjects with SAEs	xx (x.x%) [xx]
Number of Subjects with Related SAEs	xx (x.x%) [xx]
Number Subjects Withdrawn Due to an SAE	xx (x.x%) [xx]
SAE Severity	xx (x.x%) [xx]
Mild	xx (x.x%) [xx]
Moderate	xx (x.x%) [xx]
Severe	xx (x.x%) [xx]
SAE Relationship to Procedure	xx (x.x%) [xx]
Probably Related	xx (x.x%) [xx]
Possibly Related	xx (x.x%) [xx]
Not Related	xx (x.x%) [xx]
SAE Relationship to Device	xx (x.x%) [xx]
Probably Related	xx (x.x%) [xx]
Possibly Related	xx (x.x%) [xx]
Not Related	xx (x.x%) [xx]
SAE Outcome	xx (x.x%) [xx]
Resolved	xx (x.x%) [xx]
Resolved with sequelae	xx (x.x%) [xx]
Ongoing	xx (x.x%) [xx]
Death	xx (x.x%) [xx]

[1] All treatment-emergent events occurring after Bronchial Rheoplasty 1 procedure through 12 months after Bronchial Rheoplasty 2.

Table # 14.3.4 Non-Serious Adverse Event Summary through 12 Months

Evaluable Population

Relationship/ Adverse Event	**Treatment Recovery Period n(%)[event] [1] (N)**	**3 Months n(%)[event] [2] (N)**	**6 Months n(%)[event] [3] (N)**	**12 Months n(%)[event] [4] (N)**	**Total Events through 12 Months n(%)[event] [5] (N)**
Number of TEAEs	xx	xx	xx	xx	xx
Number of Subjects with any TEAEs	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
Number of Subjects	xx	xx	xx	xx	xx
All Adverse Events	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
SOC	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
LLT	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
LLT	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
Device-Related Only[6]					
SOC					
LLT					
LLT					
Procedure-Related Only[6]					
SOC					
LLT					
LLT					
Device-Related and Procedure-Related[6]					
SOC					
LLT					
LLT					

[1] Any event occurring after Bronchial Rheoplasty 1 procedure through 30 days following Bronchial Rheoplasty 2 procedure.
[2] Follow-up period through 3 months after Bronchial Rheoplasty 2, excluding either treatment recovery period.
[3] Follow-up period between 3 months and 6 months after Bronchial Rheoplasty 2.
[4] Follow-up period between 6 months and 12 months after Bronchial Rheoplasty 2.
[5] All treatment-emergent events occurring after Bronchial Rheoplasty 1 procedure through 12 months after Bronchial Rheoplasty 2.
[6] Events are considered device-related or procedure-related if judged by the treating investigator to be possibly, probably or definitely related to the device or procedure, respectively.

Table # 14.3.5 Non-Serious Adverse Event Summary Post 12 Months

Evaluable Population

Relationship/ Adverse Event	**2 Years [1]** n(%) [events] N	**3 Years [2]** n(%) [events] N	**4 Years [3]** n(%) [events] N	**5 Years [4]** n(%) [events] N	**Post-12 Months Total[5]** n(%) [events] N
Number of TEAEs	xx	xx	xx	xx	xx
Number of Subjects with any TEAEs	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
Number of Subjects	xx	xx	xx	xx	xx
All Adverse Events	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
SOC	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
LLT	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
LLT	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
Device-Related Only[6]					
SOC					
LLT					
LLT					
Procedure-Related Only[6]					
SOC					
LLT					
LLT					
Device-Related and Procedure-Related[6]					
SOC					
LLT					
LLT					

[1] Follow-up period between 12 months and 2 years after Bronchial Rheoplasty 2.
[2] Follow-up period between 2 years and 3 years after Bronchial Rheoplasty 2.
[3] Follow-up period between 3 years and 4 years after Bronchial Rheoplasty 2.
[4] Follow-up period between 4 years and 5 years after Bronchial Rheoplasty 2.
[5] All treatment-emergent events occurring after 12 months through 5 years after Bronchial Rheoplasty 2.
[6] Events are considered device-related or procedure-related if judged by the treating investigator to be possibly, probably or definitely related to the device or procedure, respectively.

Table #14.3.6 Serious Adverse Event Summary through 12 Months

Evaluable Population

Relationship/ Adverse Event	Treatment Recovery Period n(%)[event] [1] (N)	3 Months n(%)[event] [2] (N)	6 Months n(%)[event] [3] (N)	12 Months n(%)[event] [4] (N)	Total Events through 12 Months n(%)[event] [5] (N)
Number of TESAEs	xx	xx	xx	xx	xx
Number of Subjects with any TESAEs	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
Number of Subjects	xx	xx	xx	xx	xx
All Serious Adverse Events	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
SOC	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
LLT	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
LLT	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
Device-Related Only[6]					
SOC					
LLT					
LLT					
Procedure-Related Only[6]					
SOC					
LLT					
LLT					
Device-Related and Procedure-Related[6]					
SOC					
LLT					
LLT					

[1] Any event occurring after Bronchial Rheoplasty 1 procedure through 30 days following Bronchial Rheoplasty 2 procedure.
[2] Follow-up period through 3 months after Bronchial Rheoplasty 2, excluding either treatment recovery period.
[3] Follow-up period between 3 months and 6 months after Bronchial Rheoplasty 2.
[4] Follow-up period between 6 months and 12 months after Bronchial Rheoplasty 2.
[5] All treatment-emergent events occurring after Bronchial Rheoplasty 1 procedure through 12 months after Bronchial Rheoplasty 2.
[6] Events are considered device-related or procedure-related if judged by the treating investigator to be possibly, probably or definitely related to the device or procedure, respectively.

Table # 14.3.7 Serious Adverse Event Summary Post 12 Months

Evaluable Population

Relationship/ Adverse Event	**2 Years [1]** n(%) [events] (N)	**3 Years [2]** n(%) [events] (N)	**4 Years [3]** n(%) [events] (N)	**5 Years [4]** n(%) [events] (N)	**Post-12 Months Total [5]** n(%) [events] (N)
Number of TEAEs	xx	xx	xx	xx	xx
Number of Subjects with any TEAEs	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
Number of Subjects	xx	xx	xx	xx	xx
All Adverse Events	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
SOC	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
LLT	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
LLT	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]	xx (xx.x%) [xx]
Device-Related Only[6]					
SOC					
LLT					
LLT					
Procedure-Related Only[6]					
SOC					
LLT					
LLT					
Device-Related and Procedure-Related[6]					
SOC					
LLT					
LLT					

[1] Follow-up period between 12 months and 2 years after Bronchial Rheoplasty 2.
[2] Follow-up period between 2 years and 3 years after Bronchial Rheoplasty 2.
[3] Follow-up period between 3 years and 4 years after Bronchial Rheoplasty 2.
[4] Follow-up period between 4 years and 5 years after Bronchial Rheoplasty 2.
[5] All treatment-emergent events occurring after 12 months through 5 years after Bronchial Rheoplasty 2.
[6] Events are considered device-related or procedure-related if judged by the treating investigator to be possibly, probably or definitely related to the device or procedure, respectively.

Table # 14.3.8 COPD Exacerbation Rates
Evaluable Population

COPD Exacerbation (LLT) Event Rate per Patient-Year +/- SD [events]	Baseline (12 Months prior to Treatment) (N)	Post-Treatment Total (12 Months Post Treatment) [1] (N)	Post-Treatment Total, Excluding Treatment Recovery Period [2] (N)	Treatment Recovery Period [3] (N)	3 Months [4] (N)	6 Months [5] (N)	12 Months [6] (N)
All	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]
Moderate	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]
Severe	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]	x.xx +/- x.xx [xx]

[1] All treatment-emergent events occurring after Bronchial Rheoplasty 1 procedure through 12 months after Bronchial Rheoplasty 2.
[2] All treatment-emergent events occurring after Bronchial Rheoplasty 1 procedure through 12 months after Bronchial Rheoplasty 2, excluding treatment recovery period.
[3] Any event occurring after Bronchial Rheoplasty 1 procedure through 30 days following Bronchial Rheoplasty 2 procedure.
[4] Follow-up period through 3 months after Bronchial Rheoplasty 2, excluding either treatment recovery period.
[5] Follow-up period between 3 months and 6 months after Bronchial Rheoplasty 2.
[6] Follow-up period between 6 months and 12 months after Bronchial Rheoplasty 2.

7 LIST OF DATA LISTINGS

No.	Title
16.2.1	Patient Disposition
16.2.2	Protocol Deviations
16.2.3	Concomitant Medications
16.2.4	Adverse events

Listing 16.2.1 Patient Disposition

Site Number	Patient ID	ICF date	Meet all INC /EXC?	List of criteria not met	Evaluable population	Bronchoscopy 1 Date	Bronchoscopy 2 Date	Last visit /Visit date	Study Exit Date	Reason for study exit

Listing 16.2.2 Protocol Deviation

Site Number	Patient ID	Deviation Category	Deviation Type	Related Visit	Description of Deviation
		Major/Minor	Missed Visit	3 Months	

Listing 16.2.3 Concomitant Medications

Site Number	Patient ID	Medication/ Coded Term/Therapeutic Class	Start date/study day	Stop Date/ study day	Route	Steroid Taper?	Dose (unit)	Frequency	Indication	For AE? AE#

Listing 16.2.4 Adverse Events

Site Number	Patient ID	SOC	LLT	Verbatim	Start date/study day	Stop Date/ study day	SAE ?	Criteria for SAE	Relatedness to Device	Relatedness to Procedure	Severity	COPD Exacerbation? / COPD Severity	Action taken	Outcome	TEAE ?