SIGNATURE PAGE FOR ANALYSIS PLAN

Sponsor: TransMedics, Inc.

Study Number: OCS-LUN-012017

Version: 1.0

Protocol Title: International Trial to Evaluate the Safety and Effectiveness of the Portable Organ Care System (OCS™) Lung System for Recruiting, Preserving and Assessing Non-Ideal Donor Lungs for Transplantation (EXPAND II Trial)

	Signature	Date
[redacted]		

STATISTICAL ANALYSIS PLAN

International Trial to Evaluate the Safety and Effectiveness of the Portable Organ Care System (OCS™) Lung System for Recruiting, Preserving and Assessing Non-Ideal Donor Lungs for Transplantation (EXPAND II Trial)

Protocol OCS-LUN-012017

December 18, 2017

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LIST OF ABBREVIATIONS

Term	Definition
ABG	Arterial Blood Gas
AE	Adverse Event
BOS	Bronchiolitis Obliterans Syndrome
DCD	Donation after Cardiac Death
ECMO	Extracorporeal Membrane Oxygenation
EVLP	Ex-Vivo Lung Perfusion
FiO_2	Fraction of inspired oxygen
ICU	Intensive Care Unit
IFU	Instructions for Use
LAS	Lung Allocation Score
MedDRA	Medical Dictionary for Regulatory Activities
OCS	Organ Care System
PaO_2	Partial pressure of O2 in arterial blood
PAP	Pulmonary Artery Pressure
PCWP	Pulmonary Capillary Wedge Pressure
PEEP	Positive End Expiratory Pressure
PGD	Primary Graft Dysfunction
PP	Per Protocol
PT	Preferred Term
SAE	Serious Adverse Event
SOC	System Organ Class
T0, T24, T48, T72	Time after transplant (0, 24,48, 72 hours)

1. INTRODUCTION

This analysis plan provides a detailed description of the safety and effectiveness analyses, summary tables, and by-patient data listings planned in the analysis of the data in the OCS-LUN-012017 study ["International Trial to Evaluate the Safety and Effectiveness of the Portable Organ Care System (OCS™) Lung System for Recruiting, Preserving and Assessing Non-Ideal Donor Lungs for Transplantation (EXPAND II Trial)", [redacted]].

2. STUDY OBJECTIVE

The objective of this study is to evaluate the safety and effectiveness of the OCS™ Lung System to recruit, preserve and assess donor lungs that may not meet current standard donor lung acceptance criteria from one or more of the following characteristics:

- Donor $PaO_2/FiO_2 \leq 300$ mmHg at the time of the offer; or
- Expected cross-clamp time of > 6 hours for the second lung; or
- Donor after Cardiac Death (DCD donor); or
- Donor age ≥ 55 years old.

3. STUDY DESIGN

3.1. Overview

This is a prospective, pivotal, international, single-arm trial of donor lungs and donor lung transplant recipients.

The proposed clinical trial seeks to evaluate the safety and effectiveness of the OCS™ Lung System for donor lungs that today may not be transplanted due to the limitations associated with cold storage technique (such as ischemia and the inability to evaluate organ function following cold preservation). The results of the OCS™ Lung System with non-ideal donor lungs in this study will be compared to the results for both the control arm of the INSPIRE trial and to the results of the NOVEL study of the XVIVO EVLP system.

Subjects will be followed for up to 36 months from the date of transplantation. The details of the follow-up are summarized in Appendix 4 of the Protocol as follows:

- All subjects will be followed from transplant to discharge.
- Patient survival will be documented on Day 30 post-transplant and at initial hospital discharge following transplantation (if longer than 30 days).
- Patient survival and clinical diagnosis of BOS will be documented at 6, 12, 24, and 36 months patient follow-up (these are post-market follow-up timepoints) per Appendix 4 of the Protocol.

3.2. Method of Assigning Subjects to Treatment

Not applicable.

3.3. Blinding

Not applicable.

3.4. Determination of Sample Size

The sample size for this trial was determined based on providing adequate statistical power for hypothesis testing of the two co-primary effectiveness endpoints. All sample size calculations were performed using PROC POWER in SAS.

For the first co-primary endpoint, the calculations assumed a one-sided exact binomial test, an alpha level of 0.025, a control-based rate of 0.939 with a margin of 0.12 (to derive the performance goal of 0.819), a true survival rate for OCS™ of 0.939, and desired power of 90%. Based on these specifications, the required sample size was determined to be 84 transplanted recipients.

For the second co-primary endpoint, the calculations assumed a one-sided exact binomial test, an alpha level of 0.025, a performance goal of 0.54, a utilization rate of 72% for OCS™, and desired 90% power. Based on these specifications, the required sample size was determined to be 84 transplanted recipients

In order to ensure that a sufficient number of subjects are evaluable in the per-protocol population of the trial, 90 transplanted recipients in the study are expected to provide adequate power to evaluate the two co-primary effectiveness objectives given the assumptions described.

Due to multiple primary endpoints, the Hochberg Method will be used to control familywise error. The p-values for each of the co-primary endpoints will be ordered from highest to lowest. If the highest p-value is less than 0.025 then both endpoints achieve statistical significance and the null hypothesis of each co-primary endpoint can be rejected. If not, then the lower of the two p-values will be assessed against a significance level of 0.0125. If the adjusted significance level of 0.0125 is applied to any of the co-primary endpoints, the power of that analysis will be greater than 85%. Therefore, the study will be considered successful in either of the two scenarios described above.

With regard to the primary safety endpoint, the pre-specified safety margin of 0.7 events per patient, the estimated mean of 0.29 events per patient (with an estimated standard deviation of 2.0), a one-sided alpha of 0.025, and the sample size of 90 transplanted recipients results in power greater than 90% when considering a one-sample t-test on the mean.

3.5. Changes to the Protocol-Specified Analyses

Not applicable.

4. EFFECTIVENESS AND SAFETY ENDPOINTS

4.1. Primary Effectiveness Endpoint

The study will evaluate two co-primary effectiveness endpoints:

- Patient survival at both 30 days and at initial hospital discharge post-transplantation, whichever occurs later. The basis for this endpoint is the control arm of the INSPIRE trial with a 12% margin.
- Utilization Rate, defined as the number of donated lungs instrumented on OCS™ that meet inclusion/exclusion criteria for the trial and acceptance criteria for transplantation after OCS™ Lung assessment divided by the total eligible donor lungs instrumented on the OCS™ Lung System. The basis for this endpoint is the utilization rate reported for XVIVO in the NOVEL Trial.

Survival at initial hospital discharge post-transplantation is considered to be survival during the initial hospital admission for the transplant procedure through the date of discharge, if it is longer than 30 days.

4.2. Secondary Effectiveness Endpoints

The study will evaluate the following secondary effectiveness endpoints:

- Incidence of Primary Graft Dysfunction (PGD) Grade 3 at T72 hours
- Incidence of PGD Grade 3 within the initial 72 hours post-transplantation
- Incidence of Primary Graft Dysfunction (PGD) Grades 2 or 3 at T72 hours
- Incidence of PGD Grades 2 or 3 within the initial 72 hours post-transplantation.

4.3. Other Endpoints

- Total ischemia and cross-clamp times
- Duration of initial post-transplant invasive mechanical ventilation
- Length of initial post-transplant ICU stay
- Length of initial post-transplant hospital stay
- PGD Scores at T0, T24, T48, and T72 hours post-transplantation
- Incidence of BOS at 6, 12, 24, and 36 months post-transplantation (including post-market follow-up)
- All-cause mortality at 6, 12, 24, and 36 months post-transplantation (including post-market follow-up)
- Lung graft-related mortality at 6, 12, 24, and 36 months post-transplantation (including post-market follow-up).

4.4. Primary Safety Endpoint

The primary safety endpoint is the number of lung graft-related serious adverse events through the 30-day follow-up or until initial hospital admission (if longer than 30 days) after transplantation per subject. This endpoint is defined to consist of the following serious adverse events (at most one per type):

- Biopsy proven moderate or severe acute rejection
- Respiratory failure requiring prolonged intubation or reintubation
- Bronchial anastomotic complications
- Major pulmonary-related infection.

A more complete description is provided in Appendix 3 of the Protocol.

5. STATISTICAL CONSIDERATIONS

5.1. General Methodology

All statistical analyses will be performed and all tables and listings will be produced using SAS® Version 9.4 or higher.

The study was designed for 90 transplanted recipients in the U.S. and world-wide (Europe, Australia and Canada).

Continuous variables will be summarized using descriptive statistics, specifically the mean, median, standard deviation, minimum and maximum. Categorical variables will be summarized using frequencies and percentages. All statistical tests will be performed at the 0.05 significance level, unless otherwise specified in this document.

All data collected will be included in the data listings. Data listings will be sorted either by recipient ID or by donor ID, as appropriate. All date fields will be presented in a format of ddmmmyyyy (e.g., 01Jan2017) in the listings.

5.2. Adjustments for Covariates

No adjustments for covariates will be made in the statistical analyses.

5.3. Handling of Dropouts and Missing Data

Missing outcomes, although not expected, will be addressed through multiple imputation so that analyses are based on complete data. The following covariates will be used to impute missing outcomes:

- Donor PaO2/FiO2 ratio at the time of the offer: (≤ 300, > 300)
- Expected cross-clamp time for the second lung: (≤ 6 hours, > 6 hours)
- Donor after cardiac death (DCD donor): (Yes, No)
- Donor Age: (< 55 years, ≥ 55 years)
- Recipient Gender: (Male, Female)

- Recipient Age

5.4. Interim Analyses

No interim analyses will be performed.

5.5. Multiple Comparisons / Multiplicity

No adjustments for multiple comparisons/multiplicity will be made.

5.6. Examination of Subgroups

No subgroup analyses are planned.

6. ANALYSIS POPULATIONS

6.1. Transplanted Recipient Population

The transplanted recipient population will consist of all subjects who are transplanted in the trial. Additional supportive analyses of all effectiveness and safety endpoints will be based on the transplanted recipient population.

6.2. Per-Protocol (PP) Population

The Per-Protocol (PP) population will consist of all subjects **who are transplanted** without a major protocol violation. Major protocol violations would be considered:

- Ineligible for the study according to the recipient inclusion and exclusion criteria
- Ineligible for the study according to the donor organ inclusion and exclusion criteria
- Failure to complete adequate post-transplant assessments to support the primary effectiveness and primary safety endpoints
- Failure to follow the IFU for the OCS™ Lung System
- Failure to meet Donor Lung Acceptance for Transplantation after assessment on the OCS™ Lung System, as outlined in Section 6.5 of the Protocol.

The primary analysis of all effectiveness endpoints will be based on the PP population, which is appropriate given that the comparator rate is derived from the Control arm of the PP population from the INSPIRE trial. Supportive analyses will be conducted using the Transplanted Recipient population.

7. SUBJECT AND DONOR LUNG DISPOSITION

The numbers of consented subjects, screen failures as defined in section 6.3 of the protocol, subjects in the PP Population, and subjects in the Transplanted Recipient Population will be presented. The display will also present the number and percentage of patients who completed the study, who withdrew from the study early, both overall

and by time period (before Day 30, between Day 30 and 6 months, and between 6 months and 12 months), and the reason for withdrawal.

Donor lung disposition details will be summarized for eligible donor subjects using frequencies and percentages.

8. PROTOCOL DEVIATIONS

Protocol deviations will be summarized by type of deviation and overall using counts and percentages.

9. DEMOGRAPHIC AND BASELINE CHARACTERISTICS

Recipient demographic and baseline characteristics will be summarized for the PP and Transplanted Recipient Populations. Frequencies and percentages will be presented for gender, ethnicity, race, blood type, and type of status (urgent, high-urgent, or LAS). Descriptive statistics will be presented for age, height, weight, and lung allocation score (if type of status is LAS) Recipient height and weight will also be summarized, stratified by gender.

Donor demographics, baseline characteristics, and donor inclusion criteria will be summarized for the donors of the PP and Transplanted Recipient Populations. Frequencies and percentages will be presented for gender, ethnicity, race, blood type, and donor inclusion criteria. Descriptive statistics will be presented for age, height, and weight.

Indications for transplant, risk factors, and medical history for the recipient at screening will be summarized for the PP and Transplanted Recipient Populations using descriptive statistics for continuous variables and frequencies and percentages for categorical variables.

Donor medical history will be summarized for the donors of the PP and Transplanted Recipient Populations using descriptive statistics for continuous variables and frequencies and percentages for categorical variables.

Donor cause of death (anoxia, cerebrovascular/CNS, head trauma, chest trauma, aspiration, cardiac, or other) and whether the donor experienced cardiac arrest will be summarized for the donors of the PP and Transplanted Recipient Populations using frequencies and percentages.

Findings from the final donor bronchoscopy prior to retrieval, the inspection and palpation of lungs in the donor's chest, and donor lung imaging will be summarized for the donors of the PP and Transplanted Recipient Populations using frequencies and percentages.

Final donor arterial blood gas (ABG) (PaO_2, FiO_2, PEEP, and the PaO_2/FiO_2 ratio) test results, at the time of lung offer, will be summarized for the donors of the PP and Transplanted Recipient Populations using descriptive statistics.

10. DONOR OPERATIVE CHARACTERISTICS AND OCS BLOOD GASES AT THE TIME OF ACCEPTANCE BEFORE TRANSPLANT

Donor operative characteristics will be summarized using descriptive statistics for continuous variables and frequencies and percentages for categorical variables.

OCS blood gas (PaO_2, FiO_2, PEEP, and the PaO_2/FiO_2 ratio) test results will be summarized by timepoint (initial and final assessments on the OCS Lung System) using descriptive statistics.

These analyses will be performed for the donors lungs of the PP and Transplanted Recipient Populations.

11. TRANSPLANT CHARACTERISTICS AND RECIPIENT POST-TRANSPLANT ICU STAY

Transplant characteristics will be presented using descriptive statistics for continuous variables and frequencies and percentages for categorical variables.

ICU stay will be presented using descriptive statistics for the initial ICU stay duration, the re-admission ICU stay duration from ICU arrival to clinical order of discharge, and the re-admission ICU stay duration from ICU arrival to actual discharge, and frequencies and percentages for whether the recipient was readmitted to the ICU (during the first 30 days post transplant or initial hospital discharge, which ever occurs later) per Appendix 4 of the protocol.

These analyses will be performed for the PP and Transplanted Recipient Populations.

12. ANALYSIS OF EFFECTIVENESS ENDPOINTS

12.1. Co-Primary Effectiveness Endpoint #1

The first co-primary hypothesis is that the proportion of transplanted recipients of lungs preserved using the OCS™ Lung System surviving at Day 30 and at initial hospital discharge post-transplantation (whichever occurs later) is greater than a performance goal based on the corresponding proportion of patients in the Per-Protocol population of the Control arm of the INSPIRE trial (0.939) with a margin of 0.12 (12%).

The determination of the margin (12%) is based on the following:

- The estimate observed in the Control arm of the INSPIRE trial [93.9% (169/180)] serves as the target for the first co-primary endpoint.
- The 99% exact binomial confidence interval around the INSPIRE outcome (87.8% to 97.6%) provides an indication of conservative variability for eligible organs under standard of care with a lower bound about 6% away from the target.

- The lack of historical data and limited knowledge with respect to non-ideal donor lung transplantation suggests a 12% margin (i.e., doubling the lower bound distance of 6% associated with the INSPIRE estimate).

The formal statistical hypothesis test is as follows:

H_{01}: $\pi_{OCS\ Lung} \leq 0.819$

H_{11}: $\pi_{OCS\ Lung} > 0.819$

where $\pi_{OCS\ Lung}$ is the proportion of transplanted recipients alive Day 30 and at initial hospital discharge.

This co-primary effectiveness endpoint will be summarized for the PP and Transplanted Recipient Populations using a count and percentage with an exact 95% confidence interval for the percentage based on the binomial distribution. A one-sided exact binomial test at the 0.025 significance level will be performed to test the null hypothesis, H_{01}.

12.2. Co-Primary Effectiveness Endpoint #2

The second co-primary hypothesis is that the Utilization Rate (defined in Section 4.1 above) is greater than a performance goal of 0.54 (54%), which is based on the utilization rate reported for XVIVO in the NOVEL Trial. The formal statistical hypothesis test is as follows:

H_{02}: $\pi_{OCS\ Lung} \leq 0.54$

H_{12}: $\pi_{OCS\ Lung} > 0.54$

where $\pi_{OCS\ Lung}$ is the observed utilization rate in the EXPAND trial.

The appropriateness of the performance goal of 54% is based on the following:

- The 54% rate is the only published data available on utilization rate for non-ideal donor lungs.
- The donor lung inclusion/exclusion criteria are similar to those used for the XVIVO NOVEL study. Where differences exist, they tend to make the donor lungs more challenging for EXPAND II vs NOVEL. For example:
  - EXPAND II will enroll DCD donors with any PaO_2/FiO_2 ratio, while the NOVEL study only included DCD donors with PaO_2/FiO_2 ratio ≥ 300 mmHg.
  - EXPAND II will include older donors (age > 55 years) while NOVEL did not have an inclusion criterion based on donor age. Donor age > 55 years old is known to have a negative impact on outcomes after lung transplantation.
- Finally, this co-primary endpoint is designed to show superiority of the OCS™ Lung System to the XVIVO EVLP device. Demonstrating superiority to the only published data on utilization in the non-ideal donor lung population is a rigorous and appropriate test of a new technology.

This co-primary effectiveness endpoints will be summarized for the PP and Transplanted Recipient Populations using a count and percentage with an exact (Clopper-Pearson) 95% confidence interval for the true percentage based on the binomial distribution. A one-sided exact binomial test at the 0.025 significance level will be performed to test the null hypothesis, H_{02}.

12.3. Secondary Effectiveness Endpoints

The study will evaluate the following secondary effectiveness endpoints:

- Incidence of Primary Graft Dysfunction (PGD) Grade 3 at T72 hours
- Incidence of PGD Grade 3 within the initial 72 hours post-transplantation
- Incidence of Primary Graft Dysfunction (PGD) Grades 2 or 3 at T72 hours
- Incidence of PGD Grades 2 or 3 within the initial 72 hours post-transplantation.

The secondary effectiveness endpoints will be summarized for the PP and Transplanted Recipient Populations using counts and percentages and an exact (Clopper-Pearson) 95% confidence interval for the true percentage based on the binomial distribution.

12.4. Other Effectiveness Endpoints

Other effectiveness endpoints are as follows:

- Total ischemia and cross-clamp times
- Duration of initial post-transplant invasive mechanical ventilation
- Length of initial post-transplant ICU stay
- Length of initial post-transplant hospital stay
- PGD Scores at T0, T24, T48, and T72 hours
- Incidence of BOS at 6, 12, 24, and 36 months post-transplantation (including post-market follow-up)
- All-cause mortality at 6, 12, 24, and 36 months post-transplantation (including post-market follow-up)
- Lung graft-related mortality at 6, 12, 24, and 36 months post-transplantation (including post-market follow-up).

These endpoints will be summarized for the PP and Transplanted Recipient Populations using descriptive statistics and 95% confidence intervals for the true mean based on the t-distribution for continuous endpoints and using counts and percentages and exact (Clopper-Pearson) 95% confidence intervals for categorical endpoints.

Survival will also be displayed using the Kaplan-Meier product-limit method.

13. SAFETY ANALYSES

13.1. Adverse Events

Safety will be analyzed principally by examination of the frequency of adverse events. In particular, the primary safety endpoint is the number of lung graft-related serious adverse events (SAEs) up to the 30-day follow-up or until initial hospital admission (if longer than 30 days) after transplantation per subject will be analyzed. This endpoint is defined to consist of the following adverse events (at most one per type), if they are serious adverse events.

- Biopsy proven moderate or severe acute rejection
- Respiratory failure requiring prolonged intubation or reintubation
- Bronchial anastomotic complications
- Major pulmonary-related infection

The primary safety hypothesis is that the mean number of lung graft-related SAEs up to the 30-day follow-up after transplantation is less than a performance goal based on the corresponding mean in the Per-Protocol population of the Control arm of the INSPIRE trial (0.29 events per subject) with a margin of 0.7 events. Specifically:

H_{0s}: $\mu_{OCS\ Lung} \geq 0.99$

H_{1s}: $\mu_{OCS\ Lung} < 0.99$

where $\mu_{OCS\ Lung}$ is the mean number of lung graft-related SAEs through 30 days post-transplantation among transplanted recipients.

This endpoint will be summarized using descriptive statistics, specifically the mean, median, standard deviation, minimum, maximum, and a 95% confidence interval for the mean based on the t-distribution. A one-sided one-sample t-test at the 0.025 significance level will be performed to test the null hypothesis, H_{0s}.

In addition, the numbers and percentages of subjects experiencing at least one adverse event (AE), at least one severe AE, at least one device-related AE (an AE that is probably or definitely related to the investigational device or for which the relationship is missing), at least one unanticipated AE, at least one serious AE, and at least one lung graft-related serious AE, and the number and percentage of deaths will be tabulated. Also, the number and percentage of adverse events and the number and percentage of subjects experiencing adverse events will be tabulated by system organ class (SOC) and preferred term (PT) using MedDRA. A similar analysis will be performed for serious AEs. The number and percentage of AEs will be tabulated by SOC and PT and the relationship of the adverse event to the device (related versus not related, where AEs with a probable or definite relationship to the investigational device are classified as related, and AEs with a possible, unlikely, or unrelated relationship are classified as not related) and by SOC and PT and severity.

The safety analyses will be performed for the Transplanted Recipient Population.

13.2. Medications (medications related to Serious Adverse Events only)

The number and percentage of subjects in the Transplanted Recipient Population taking any medications for SAEs reported within the first 30 days or until initial hospital discharge (which ever occurs later) will be presented. The number and percentage of subjects taking any medications for these reported SAEs will also be tabulated by therapeutic category and generic name. Descriptive statistics will be presented for the duration of use for each type of medication administered. If the same medication is used multiple times, the duration of use is the sum of the durations of all periods. Patients who do not use a given type of medication will be excluded from the analysis for that type of medication. If a patient is continuing to use a given type of medication at the time of completion/discontinuation, the time of completion/discontinuation will be considered the stop time for that patient for that type of medication in calculating the duration of use.

The number and percentage of subjects in the Transplanted Recipient Population will be presented using each type of immunosuppressive therapy (ATG, OKT3, IL2 receptor agonist, cyclosporine, tacrolimus, azathioprine, mycophenolate, steroids, sirolimus, eurolimus, other, and any immunosuppressive medication) at any of the following timepoints: induction, Day 7, or discharge.

14. OTHER ANALYSES

Kaplan-Meier estimated freedom from BOS and BOS-free survival time probabilities will be presented for the following nominal timepoints: Day 30, 6 months, 12 months, 24 months, and 36 months.

Chest radiograph data at transplant and post-transplant timepoints will be summarized using descriptive statistics.

Recipient bronchoscopy data at discharge, 6 months, 12 months, 24 months, and 36 months will be summarized using frequencies and percentages. Transbronchial biopsy results at discharge, 6 months, 12 months, 24 months, and 36 months will be summarized using frequencies and percentages. Recipient pulmonary function test results at discharge (or up to the first 90 days post transplant if not done at discharge), 6 months, 12 months, 24 months, and 36 months will be summarized using descriptive statistics. Recipient data at the 6, 12, 24 and 36 month follow-up visits (was patient withdrawn from the study since the last visit and, if so, the reason for withdrawal, did recipient survive, did the lung graft survive, was there a diagnosis of post-lung transplant Bronchiolitis Obliterans Syndrome since the last visit, was recipient hospitalized since the last follow-up visit) will be summarized using frequencies and percentages.

The number and percentage of patients having mechanical circulatory or ventilator support (i.e., ECMO, any ventilator support, any support) within 30 days post-transplant or until initial discharge (whichever occurs later) will be presented. For each type of support, the table will present descriptive statistics for the time from surgery to the start of the first occurrence of support and for the duration of support. Patients who do not

use a given type of support will be excluded from the analyses for that type of support. If a patient is continuing to use a given type of support at the time of completion / discontinuation, the time of completion / discontinuation will be considered the stop time for that patient for that type of support in calculating the duration of support. If the same support is used multiple times, the duration of support will be the sum of the durations for all periods.

The analyses described above will be performed for the PP and Transplanted Recipient Populations.

OCS parameters at the initial assessment at the beginning of OCS preservation and at the final assessment at the end of OCS preservation will be summarized for the PP and Transplanted Recipient Populations using descriptive statistics.

Donor lung OCS instrumentation data for the PP and Transplanted Recipient Populations will be presented using descriptive statistics for continuous variables and frequencies and percentages for categorical variables.

OCS perfusion times (lung preservation duration on the OCS Lung System) for the PP and Transplanted Recipient Populations will be presented using descriptive statistics.

15. REFERENCES

None.