STATISTICAL ANALYSIS PLAN

A Prospective Randomized Multi-Center Study of the Use of the LifePort® Liver Transporter (LLT) System with Vasosol® as Compared to Static Cold Storage in Orthotopic Liver Transplants (PILOT™: Perfusion to Improve Liver Outcomes in Transplantation)

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Prepared by:

ACCELERATING VALUE. IMPROVING OUTCOMES.

Precision for Medicine, Inc.
2 Bethesda Metro Center, Suite 850
Bethesda, MD 20814

Prepared for: Organ Recovery Systems

VERSION HISTORY

Version	Comment	Date
0.1	Initial draft	7/11/18
1.0	New Release Changes from draft 0.1, addresses recommendations from FDA The hypothesis of the upper limit changed from one-sided confidence interval to a two-sided 90% confidence interval for the difference between groups in EAD incidence rates is smaller than or equal to a non-inferiority margin (δ) Donor liver declined prior to transplant – Original designated recipient does not undergo liver transplantation. The timing of withdrawal (pre- or post-preservation) will be documented. Point estimates and 90% confidence intervals (Cis) for incidence rates will be provided by study arm along with point estimates and 90% Cis for differences in incidence rates between the study arms. As suggested by the FDA, we will implement the stratum-adjusted Cochran-Mantel-Haenszel (CMH) method for the EAD incidence rate difference. The Per-Protocol population will consist of all subjects in the Intent-To-Treat population who have completed a liver transplant procedure and completed the primary efficacy evaluations according to the procedures outlined in the clinical protocol and do not have any protocol deviations outlined in the protocol. Major deviations will include violations of inclusion/exclusion criteria, informed consent issues (not signed), missed follow-ups at key time points (seventh day or six months). The study will perform a poolability analysis across the nine sites. Any site with fewer than 10 patients will be pooled in this site-by-site analysis. Missing data should be minimal, but per the FDA's recommendation, a tipping point analysis can be implemented to handle missing values.	08-Dec-21

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1 Introduction

1.1 Background

For at least two decades, static cold storage of donor livers has been the standard of care for orthotopic liver transplantation (OLT). OLT after cardiac death or from elderly or steatotic donors, however, carries higher risks of serious post-transplantation complications, including re-transplantation and death. Kidney transplants, however, commonly utilize Hypothermic Machine Perfusion (HMP), in which a preservation solution is continuously circulated through the donor kidney, acting to preserve normal homeostasis as well as allowing for pre-transplant preparation for transplantation. Initial testing of HMP use in liver transplantation in animals and humans shows promising results and warrants further investigation of the safety and efficacy of this preservation method.

LifePort® Liver Transporter (LLT) System with Vasosol® is a portable, isolated liver perfusion and transport system, designed to support a donated liver and to maintain the organ in a near-normal physiologic state under hypothermic aseptic conditions, while simultaneously perfusing the liver until it is transplanted into a recipient patient. The LLT System and Vasosol® Machine Perfusion Solution are for investigational use only.

1.2 Rationale for the Study

The previous studies which evaluated the use of HMP with the LLT System confirmed the efficacy and safety of a prototype of the LLT System with Vasosol® for liver transplantation. This study is being initiated in order to evaluate the safety and effectiveness of the to-be-marketed LLT System with Vasosol® in order to confirm previous clinical findings.

2 Study Overview

2.1 Study Objectives

The primary objective of this study is to collect clinical data to provide reasonable assurance of safe and effective use of the LLT System with Vasosol® for the preservation of explanted livers, confirming findings of previous clinical studies conducted using a prototype of the LLT System with Vasosol®.

2.2 Acceptance Criteria

The incidence rates of Early Allograft Dysfunction (EAD) will be compared between the test group (hypothermic machine perfusion, or HMP, using the LLT System with Vasosol) and the control group (Static Cold Storage, or SCS) to demonstrate that EAD incidence is within a clinically reasonable margin. The hypothesis will be tested by evaluating whether the upper limit of the two-sided 90% confidence interval for the difference between groups in EAD incidence rates is smaller than or equal to a non-inferiority margin (δ). A non-inferiority margin δ of 7.5% will be considered as a clinically relevant margin to show non-inferiority.

2.3 Study Samples

Subjects will be recruited from patients undergoing isolated primary orthotopic whole liver transplantation.

2.3.1 Inclusion Criteria

Subjects must meet all of the following inclusion criteria to participate in this study:
For Recipients:

1. Subject is ≥ 18 years of age
2. Subject is active on the United Network of Organ Sharing (UNOS) waiting list for whole liver transplantation
3. Subject is de novo whole liver transplant recipient
4. Subject is able to read and understand the informed consent form (ICF) and has voluntarily provided written informed consent, or, if the subject's condition limits his/her ability to provide consent, written informed consent has been voluntarily provided by the subject's legally authorized representative

For Donors: All livers suitable for utilization, including:

1. Liver declined by local/regional centers
2. Donation after Cardiac Death (DCD)
3. Donor Risk Index (DRI) ≥ 1.6
4. Elevated liver function tests
5. Cardiopulmonary resuscitation (CPR) > 20 minutes

2.3.2 Exclusion Criteria

Any subject who meets any of the exclusion criteria will be excluded from participation in this study:

For Recipients:

1. Subject is < 18 years of age
2. Subject is a multi-organ transplant recipient
3. Subject is a previous liver transplant recipient
4. Subject is antibodies blood group (ABO) liver incompatible
5. Subject has severe systemic infection
6. Subject is human immunodeficiency virus (HIV) positive
7. Subject has acute/fulminant liver failure (defined as rapid development of acute liver failure with severe impairment of synthetic function and hepatic encephalopathy without obvious previous liver disease)
8. Subject is pregnant
9. Subject or subject's legally authorized representative declines study participation and/or refuses to provide informed consent

For Donors:

1. Donor is HIV positive
2. Cold Ischemic Time (CIT) is < 3 hours anticipated

2.4 Subject Withdrawal

Subjects may discontinue from the study at any time. A subject may be discontinued from the study for the following medical or administrative reasons:

- Donor liver declined prior to transplant – Original designated recipient does not undergo liver transplantation. The timing of withdrawal (pre- or post-preservation) will be documented.
- Subject Withdrawal of Consent – Subjects will be free to discontinue from the study at any time and for any reason but must notify the study site of their exit from the study.
- Adverse Event – If during the procedures the subject suffers an AE that, in the judgment of the Principal Investigator (PI), Sponsor or Medical Monitor, presents an unacceptable consequence or risk to the subject, the subject will be discontinued from further participation in the study.
- Subject does not undergo liver transplant
- Lost to Follow Up – Subjects discontinue from the study without notifying the study site.
- Serious Protocol Violation – If, during enrollment in the study, the subject fails to follow, violates, or refuses to participate in any of the procedures described in the protocol, then the subject will be discontinued from the study due to protocol violation. If, at any point during the study, a subject is determined to have been erroneously enrolled into the study, the subject will be discontinued from the study due to protocol violation.
- Other – If the above reasons are not applicable, "Other" will be selected as the option and the appropriate reason for subject withdrawal provided.

For subjects who discontinue or are withdrawn from the study for any reason, the PI will notify the Sponsor and will be required to attempt to determine whether any AE occurred since the last visit to the study site.

If the subject is withdrawn at a study visit, the procedures for an early termination visit will be conducted including an exit physical exam to assess their continued well-being.

2.5 Study Design

This study is a prospective, randomized, controlled study comparing hypothermic machine perfusion (HMP) of explanted livers as compared to control livers preserved via static cold storage (standard of care). The schedule of study events lists the procedures to be performed in each visit as specified in the protocol.

2.5.1 Randomization

Subjects meeting the study eligibility criteria and providing written informed consent will be prospectively enrolled into the LLT System group prior to their liver transplant procedure. After examination of the donor liver at the donor site, and initial acceptance by the transplant team for the recipient, the recipient will be randomized to receive a liver preserved via static cold storage (standard of care) or via HMP using the LLT System. Stratified randomization will be performed by lab MELD score and DCD liver type to balance the treatment and control groups as follows:

- Model for End Stage Liver Disease (MELD)-Na score (lab MELD): ≤30 or >30; and
- Liver donation after cardiac death (DCD): Yes or No.

Stratification factors of MELD-Na score category (≤30 or >30) and liver type (DCD Y/N) will be considered as one factor with four levels (strata). The four levels or strata are: MELD ≤30 and DCD Y; MELD ≤30 and DCD N; MELD >30 and DCD Y; and MELD >30 and DCD N. Within each strata, treatment assignments will be periodically balanced, and the assignments independent of each other. At the end of the study, the

treatment assignments in each stratum will be roughly balanced, yielding balance of the strata across the two treatment arms of liver preservation via HMP and liver preservation via standard cold storage.

Each randomized subject will receive a unique randomization number, and randomization will be performed utilizing the built-in randomization feature of the electronic data capture (EDC) system.

2.5.2 Blinding

Neither subjects nor investigators will be blinded. The central, independent pathologist analyzing the liver biopsy samples will be blinded to the method of preservation.

3 Study Endpoints

3.1 Primary Measures of Performance

The primary measure of performance for this study is the Early Allograft Dysfunction (EAD) defined as presence of one or more of the following:

- Total bilirubin ≥ 10 mg/dL at seven days post-transplant
- International normalized ratio (INR) ≥ 1.6 at seven days post-transplant
- Aspartate Aminotransferase (AST) or Alanine Aminotransferase (ALT) > 2000 IU/L within seven days of transplant

3.2 Secondary Measures of Performance

The secondary safety and effectiveness endpoints of this study are the following:

- PNF (primary non-function) defined as relisted for orthotopic liver transplant within seven days of transplant or leading to death within seven days of transplant without identification of cause such as surgical complications, hepatic artery thrombosis, portal vein thrombosis, or acute rejection, and same blood draw taken 24 hours to seven days after transplant showing:
    - AST ≥ 3000 and one or both of the following:
        - INR ≥ 2.5 or
        - Acidosis, defined as having arterial pH ≤ 7.30 or venous pH ≤ 7.25 and/or lactate ≥ 4 mMol/L
- Peak AST, ALT, INR, Serum creatinine (SCr), and total bilirubin (TBili) (every 6 hours for initial 24 hours, daily thereafter) within seven days post-transplant or discharge, whichever occurs earlier.
- Acute kidney injury (AKI) based on RIFLE criteria (≥ 2X SCr from baseline or decrease in Glomerular filtration rate (GFR) by > 50%; or Urine output < 0.5 mL/kg/hr for ≥ 12 hours) within seven days of transplant.
- Incidence within 3 months and 6 months post-transplant of any of the following:
    - Graft failure
    - Biliary complications
    - Vascular complications
    - Subject death

3.3 Additional Measures of Performance

Exploratory endpoints of this study are the following:

- Lactate clearance: arterial lactate 3, 6, 12, 24 hours after reperfusion
- Time to normality defined as: AST (12–38 IU/mL), ALT (7–41 IU/mL), TBili (0.3–1.3 mg/dL), SCr (0.6–1.12 mg/dL) and INR (0.87–1.16)
- Time from transplant to hospital discharge [days]
- Graft failure at 12 months
- Subject death at 12 months

There are no pre-defined acceptance criteria for these end points.

4 Statistical Methods

4.1 General Considerations

All analyses will be performed using SAS® Version 9.4 or higher. A synopsis of the methodology for determining sample size and for summary and statistical analyses of the data collected in this study is provided below. This statistical analysis plan (SAP) provides additional detailed description of the analyses and tables, listings, and figures that will be generated for this study.

Any significant changes to the primary analyses will be reflected in a protocol amendment. Deviations from this statistical analysis plan will be presented in the final clinical study report.

4.2 Sample Size Determination

The study is sized with respect to the primary effectiveness endpoint of the study, which is the incidence of Early Allograft Dysfunction (EAD). Expected incidences of EAD for the test arm and the control arm are assumed to be 15% and 30%, respectively, based on published results (see 4.2.1 below). Based on the statistical analysis and acceptance criterion, and an estimated attrition rate of 10%, a sample size of 70 subjects per study arm was determined to be sufficient to demonstrate non-inferiority at 80% power with a non-inferiority margin δ of 7.5% using closed form solutions for sample sizes for two-sided 90% confidence intervals for differenes in proportions as outlined by Chow et al. [1] .

4.2.1 Justification of Estimated Incidences of EAD for the Study

A prototype of the LLT System with Vasosol® to perform hypothermic machine perfusion (HMP) was evaluated in 20 patients as compared to matched control patients receiving a liver preserved via static cold storage.[1] The study included use of standard criteria donor (SCD) livers and extended criteria donor (ECD) livers, with a similar number of SCD and ECD livers in both groups (6 SCD livers and 14 EDC livers in HMP group, and 7 SCD livers and 13 EDC livers in the control group). Published outcomes stated EAD rates of 5% in the HMP group versus 25% in the control group.

[1] Guarrera J, Henry S, Samstein B, et al. Hypothermic machine preservation in human liver transplantation: The first clinical series. *Am J Transplant* 2010;10:372-81.

Another study evaluating the prototype of the LLT System with Vasosol® in 31 patients as compared to matched control patients receiving a liver preserved via static cold storage was conducted that included only ECD livers.[2] EAD rates were of 19% in the HMP group versus 30% in the control group.

Others have reported incidences of EAD for livers having undergone static cold storage at 23%,[3] 40%,[4] and 18% (for liver donation after brain death) to 45% (for liver donation after circulatory death).[5]

In summary, studies using the prototype LLT System with Vasosol® resulted in EAD rates of 5% to 19% versus EAD rates in the matched control groups of 25% to 30%. EAD rates in other studies of livers having undergone static cold storage have been reported to range up to 45%, with dependent factors including the health status of recipient and the quality of the donor liver. The present study allows inclusion of higher risk recipients (*i.e.,* ≥18 years of age, high MELD-Na scores), as well as use of marginal donor livers (*i.e.,* DCD, declined by local/regional centers, Donor Risk Index ≥ 1.6, elevated liver function tests, donor having undergone CPR). Therefore, the incidences of EAD in the present study are expected to be similar to those reported in the second study using the LLT System prototype as compared to control (19% and 30%, respectively). Specifically, for the present study, the EAD rate for livers undergoing HMP with the LLT System with Vasosol® is expected to be slightly improved at 15% because the study is not limited to use of extended criteria donor livers. The EAD rate for livers undergoing static cold storage is conservatively estimated at 30%, given the 30% incidence observed in the previous study and the reported EAD rates of up to 45% in other studies.

4.3 Analysis Populations

The following table describes the analysis populations for this study.

Table 1: Analysis Populations

Population Name	Definition
Intent to Treat (ITT)	The ITT population will consist of all subjects who have signed informed consent, been enrolled in the study, randomized, and the assigned liver preservation method has been initiated. Dropouts will be imputed as failures.

[2] Guarrera J, Henry S, Samstein B, Reznik E, et al. Hypothermic machine preservation facilitates successful transplantation of ‘‘orphan’’ extended criteria donor livers. *Am J Transplant* 2015;15:161-9.

[3] Olthoff K, Kulik L, Samstein B, et al. Validation of a current definition of early allograft dysfunction in liver transplant recipients and analysis of risk factors. *Liver Transpl* 2010;16:943-9.

[4] Barthel E, Raushfuss F, Hoyer H, et al. The PRAISE study: A prospective, multi-center, randomized, double blinded, placebo-controlled study for the evaluation of iloprost in the early postoperative period after liver transplantation. *BMC Surgery* 2013;13:1-8.

[5] Verhoeven C, Farid W, de Jonge J, et al. Biomarkers to assess graft quality during conventional and machine preservation in liver transplantation. *J Hepatol* 2014;61:672-84.

	Last observation carried forward (LOCF) will be utilized when analyzing EAD when INR is not available at day 7 time point.
Per Protocol (PP)	The PP population will consist of all subjects in the ITT population who have completed a liver transplant procedure and completed the primary efficacy evaluations according to the procedures outlined in the clinical protocol and do not have any protocol deviations outlined in the protocol (*i.e.,* study eligibility criteria not met, lack of informed consent, error in study group assignment, error in conduct of the trial, subject management or subject assessment). Major protocol deviations will include violations of inclusion/exclusion criteria, lack of informed consent, missed follow-up visits at key time points (seventh day or six months). Last observation carried forward (LOCF) will be utilized when analyzing EAD when INR, Bilirubin or AST/ALT are not available at day 7 time point.
Safety Population	The safety population will consist of all subjects in the ITT population who have an attempted liver transplant procedure, regardless of whether the transplant was successful.

4.4 Bias Minimization

Each randomized subject will receive a unique randomization number, and randomization will be performed utilizing the built-in randomization feature of the electronic data capture (EDC) system.

Blinding of subjects and investigators is precluded by the nature of the intervention. The central, independent pathologist analyzing the liver biopsy samples will be blinded to the method of preservation.

4.5 Handling of Missing Data

Although the missing data should be minimal, a tipping point analysis will be completed under the missing not at random (MNAR) assumption [3]. It is used to assess how severe departures from missing at random (MAR) must be in order to overturn conclusions from the primary analysis. If implausible departures from MAR in order to change the results from statistically significance ($p<=0.05$) to statistically insignificance ($p>0.05$), the results will be said to be robust to the departure from MAR assumption. The tipping point approach will be implemented using SAS procedures MI and MIANALYZE.

Implementing the tipping point approach will include the following steps with the first three steps being the standard multiple imputation (MI) steps:

1. The missing data are filled in m times to generate m complete data sets.

2. The m complete data sets are analyzed by using standard procedures.
3. The results from the m complete data sets are combined for the inference.
4. Repeat the steps #1 to generate multiple imputed data sets, with a specified shift parameter that adjust the imputed values for observations in the treatment group, not the control group).
5. Repeat the step 2 for the imputed data sets with shift parameter applied.
6. Repeat the step 3 to obtain the p-value to see if the p-value is still <=0.05.
7. Repeat the steps 4-6 with more stringent shift parameter applied until the p-value >0.05.

4.6 Planned Analyses

4.6.1 Primary Analysis

The Early allograft dysfunction (EAD) will be calculated as defined in Section 3.1. The incidence rates of EAD between the test arm using the LLT System and the control arm will be compared to demonstrate that EAD incidence is within a clinically reasonable margin. Specifically, the following hypothesis is being tested:

$$H_0: \mathrm{EAD}_{LLT} - \mathrm{EAD}_{Control} > \delta \text{ vs. } H_a: \mathrm{EAD}_{LLT} - \mathrm{EAD}_{Control} \leq \delta,$$

where EAD indicates EAD incidence rate and δ is the non-inferiority margin. The hypothesis will be tested by evaluating whether the upper limit of the two-sided 95% confidence interval for the difference in incidence rates is smaller than or equal to δ. The 95% confidence interval will be calculated using the stratum-adjusted Cochran-Mantel-Haenszel (CMH) method, with stratum consisting of the MELD-Na score category (≤30 or >30) and liver type (DCD Y/N).

A non-inferiority margin δ of 7.5% will be considered as a clinically relevant margin to show non-inferiority.

Point estimates and 95% confidence intervals (CIs) for incidence rates will be provided by study arm along with point estimates and 95% CIs for differences in incidence rates between the study arms.

This analysis will be performed on both the ITT population and the Per Protocol Population.

For the analysis performed on the ITT population, dropouts will be imputed as failures and last observation carried forward (LOCF) will be utilized when INR is not available at day 7 time point.

For the analysis performed on the PP population, dropouts will be imputed as failures and last observation carried forward (LOCF) will be utilized when INR, Bilirubin or AST/ALT are not available at day 7 time point.

4.6.2 Additional Analyses

4.6.2.1 Secondary Safety and Effectiveness Analyses

The study end points are defined in Section 3.2. For all binary outcomes, point estimates and 95% CIs for incidence rates will be provided by study arm along with point estimates and 95% CIs for differences in incidence rates between the study arms. For continuous outcomes, point estimates and 95% CIs for Least Squares means (LS means) will be provided by study arm along with point estimates and 95% CIs for differences in LS means between the study arms. LS means will be calculated using an ANCOVA with study

arm, MELD-Na score category (≤30 or >30) and liver type (DCD Y/N) as factors. This analysis will be performed on the Safety population.

4.6.2.2 Additional Safety Analysis

Prior to analysis, all adverse events (AEs) will be categorized according to those specified in the electronic case report forms (eCRFs). Based on these categories, AEs will be summarized by category and sub-category, as well as by relationship to the LLT System. Unanticipated AEs not defined in protocol ("other" AEs) will be coded using the MedDRA, version x.x coding dictionary. Based on these coded terms, AEs will be summarized using system organ class and preferred terms, as well as by relationship to the LLT System. These analyses will be performed on the Safety population.

4.6.2.3 Analysis of Demographics and Baseline Characteristics

Summary statistics for all demographic and baseline variables for the test and control arms will be provided to demonstrate that subjects enrolled in this study are representative of the Intended Use population. This analysis will be performed on the safety population, the ITT and the PP populations and provided overall and by study arm.

The following demographic variables will be considered:

- Donor age at time of donation
- Donor gender
- Donor Race/Ethnicity
- Donor Risk Index (DRI)
- Donor Type (Donation after Cardiac Death (DCD) or Donation after Brain Death; CPR performed)
- Recipient Age at time of transplant
- Recipient gender
- Recipient Race/Ethnicity
- Recipient BMI
- Recipient MELD-Na Score at time of organ offer (MELD ≤30 vs. MELD >30)
- Recipient MELD-Na Score at time of transplant

4.6.2.4 Analysis across Sites and Subgroups.

Individual site outcomes will be reported for the study end points defined in Section 3. Summary statistics for all demographic and baseline variables for the test and control arms will also be provided by site to demonstrate that subjects enrolled in this study are representative of the Intended Used population. Sites with fewer than 10 patients will be pooled together. Subgroup analyses by gender, age, and ethnic group will also be reported for the study end points.

4.6.3 Analyses of Non-Randomized Subjects Receiving Reallocated Livers

For non-randomized subjects receiving reallocated livers, a data listing will be provided and summary statistics will be generated. The data obtained for these subjects will not be considered for primary, secondary and additional analyses as specified in sections 4.6.1, 4.6.2, 4.6.3 and 4.6.4.

4.7 Ad-hoc Analyses

Ad-hoc analyses may be performed as deemed appropriate and will be documented in the statistical analysis report (Clinical Study Report).

4.8 References

[1] S. Chow, J. Shao and H. Wang, Sample Size Calculations In Clinical Research, 2nd ed., Chapman & Hall/CRC Biostatistics Series, 2008.

[2] R. Bohdana and O. Michael, "Implementation of Pattern-Mixture Models Using Standard SAS/STAT Procedures," in *PharmaSUG*, 2011.

[3] Deng, "On Biostatistics and Clinical Trials," 15 August 2015. [Online]. Available: http://onbiostatistics.blogspot.com/2015/08/tipping-point-analysis-multiple.html. [Accessed 9 May 2018].

5 List of Tables

6 Mock Tables

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Table 1
Recipient Demographics by Study Arm
ITT Population

	All Subjects (N=xxx)	HMP (N=xx)	SOC (N=xx)
Gender			
Female	xx (40.6%)	xx (39.9%)	xx (xx.x%)
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Age at Time of Transplant			
Mean	xx.x	xx.x	xx.x
95% CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Race			
White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Hispanic	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Native Hawaiian/Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
American Indian/Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Weight (kg)			
Mean	xx.x	xx.x	xx.x

	All Subjects (N=xxx)	HMP (N=xx)	SOC (N=xx)
95% CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Height (cm)			
Mean	xx.x	xx.x	xx.x
95% CI	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
MELD-Na Score at Time of Organ Offer	xx	xx	xx
MELD-Na Score at Time of Transplant	xx	xx	xx
MELD-Na Score at Time of Organ Offer			
>30	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
<=30	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
DCD			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)