

**RINTAG meeting**

24 May 2022

**Clinical Trials Unit Update**

**1. Status – Public**

**2. Executive Summary**

This paper provides an update on the clinical trials in organ donation and transplantation that NHSBT Clinical Trials Unit (CTU) are currently managing. There are currently 6 trials which are in set-up or recruitment, which are described in the table below.

Key highlights since previous RINTAG report:

- the SIGNET study continuing to open sites to recruitment. 67 of the planned 77 Trusts are now open, with SNOD teams recruiting 2,600 donors over a 4-year period.
- the PLUS study opened at all 7 UK liver transplant centres on 11 April. The CTU team are working with the Hub Operations team and participating sites to discuss any issues and feedback on the process. The tool developed by DDTs to flag eligible donors is working well.
- the COBALT study has now opened in Cambridge and Oxford, with a further 4 sites still in set-up. 2 participants have enrolled and completed their baseline assessments.
- the DeFat study is in set-up, the protocol and supporting documents have been submitted for REC approval
- the PITHIA trial (biopsy service) has completed and is now in the follow-up phase.

**3. Action Requested**

The Committee is asked to:

- Note the contents

**Table 1. Current OTDT studies managed by the CTU (in **set-up** or **recruitment**)**

<b>Trial Name</b>	<b>Trial Summary</b>	<b>Chief Investigator(s)</b>	<b>Sponsor</b>	<b>Progress</b>
DeFat	Delivery of Ex-situ deFatting Agents during normothermic liver perfusion for Transplantation– a randomised clinical trial.	Prof Peter Friend Mr Simon Knight Mr Syed Hussain Abbas	University of Oxford	In set up stage. There are 5 participating sites and the target is 60 livers. Received provisional opinion from the REC. Expected start date July 2022
COBALT	Cardiorespiratory Optimisation By AVF Ligation after Transplantation.	Prof Gavin Pettigrew	Cambridge University Hospitals NHS Foundation Trust & the University of Cambridge	HRA Approval received in Feb 2022. Cambridge opened to recruitment on 01 Apr 22. Oxford opened 15 May 22. Recruitment open until 30 Nov 22. Target of 40 participants.

PLUS	Utilisation of normothermic machine preservation in extended criteria livers – a national threshold-crossing study.	Prof Peter Friend Mr Simon Knight	University of Oxford	PLUS opened to recruitment on 11 April 2022. All 7 UK liver transplant centres are participating in the study. To date 59 livers were eligible for the study.
SIGNET	Statins for Improving orGaN outcomE in Transplantation.	Prof John Dark Dr Dan Harvey	The Newcastle upon Tyne Hospitals NHS Foundation Trust	SIGNET opened to recruitment on 14 September 2021. To date, 67 Level 1 & 2 donor Trusts (101 hospitals) have opened to recruitment, and 162 donors have been recruited to date.
PLUTO	Plasma-Lyte usage and assessment of kidney transplant outcomes in children.	Dr Wesley Hayes	Great Ormond Street Hospital for Children NHS Foundation Trust	There are 8 Trusts open to recruitment and so far, 120 patients have been randomised.
TWIST	Multicentre, Open-label Randomised Trial of Superficial Wound Drain on Surgical Site Infection in high Body Mass Index (BMI) Kidney Transplant Recipients.	Mr James Hunter	Oxford University Hospitals NHS Foundation Trust	The CTU are providing administrative support to CI to open participating centres. There are currently 11 centres open to recruitment and 207 participants recruited to the trial. Recruitment is expected to continue at a positive rate with the support from participating sites.

Completed since previous RINTAG report:

- PITHIA (Pre-Implantation Trial of Histopathology In renal Allografts).

**Author**

CTU Management team  
May 2022