

**PROCUREMENT SERVICES**

**Prior Information Notice**

**Briefing Document**

**CONTRACT TITLE: Supply of a Clinical Data Management System and a Randomization System**

**CONTRACT REFERENCE:** **NU/1518**

**1. Newcastle University and the Clinical Trials Unit**

Newcastle University can trace its origins to a School of Medicine and Surgery, established in Newcastle upon Tyne in 1834. As one of the UK's leading universities, our reputation rests on the quality of our teaching, our outstanding research, and our work with the regional and local community, businesses and industry.

The University is structured into 3 faculties: Humanities and Social Sciences (HaSS); Medical Sciences (FMS) and Science, Agriculture and Engineering (SAgE).

The University strives to achieve the highest ethical standards in all areas of its activities. Therefore the University is committed to buying, supporting, using and promoting fairly traded goods wherever possible in keeping with its Fairtrade status.

Further information about the University is available from our website at [www.ncl.ac.uk](http://www.ncl.ac.uk)

The Faculty of Medical Sciences comprises seven institutes and five schools, based on sites throughout Newcastle and with collaborations across the North East of England.

Based with Newcastle University's Faculty of Medical Sciences, the Newcastle Clinical Trials Unit works in partnership with investigators across all disease types, phases of research and methodologies in order to deliver high quality research.

The Newcastle Clinical Trials Unit (NCTU) was established in 2003 to provide support for the design and management of clinical trials and other well-designed clinical studies. It gained full registration status in 2007 as a UK Clinical Research Collaboration (CRC) registered CTU. The main focus of the Unit is on academically led non-commercial studies but it will also currently supports investigator initiated commercially funded studies.

**2. Prior Information Notice (PIN)**

The University intends to purchase a Clinical Trials Data Management System (CDMS) and a Randomization System. Prior to advertising an Invitation to Tender (ITT) the University has issued a PIN for the purpose of engaging with the supply market to understand the different systems available. The information gained from the PIN will be used to inform the specification contained in the ITT.

The CDMS will be used to support trials where data capture will be at multiple sites and for trials from Phase I to IV, scaling from single sites to multi-site trials. Access to and roles within the CDMS and Randomization System will be determined by staff within the NCTU.

The University wishes to meet with or hold a conference call with suppliers to:

1. View a demonstration of supplier systems and understand the functionality and analysis tools available;
2. Review systems compliance with the legislative requirements contained within:
* EU Clinical Trials Directive 2001/20/EC.
* The Medicines for Human Use (Clinical Trials) Regulations 2004, and subsequent amendments;
* Guideline for Good Clinical Practice E6(R2) ;
* FDA 21 CFR Part 11;
* Data Protection Act 2018
* Information Governance Toolkit
* Access via secure SSL connections
1. Understand supplier pricing models and obtain indicative quotes for internal budgetary requirements.