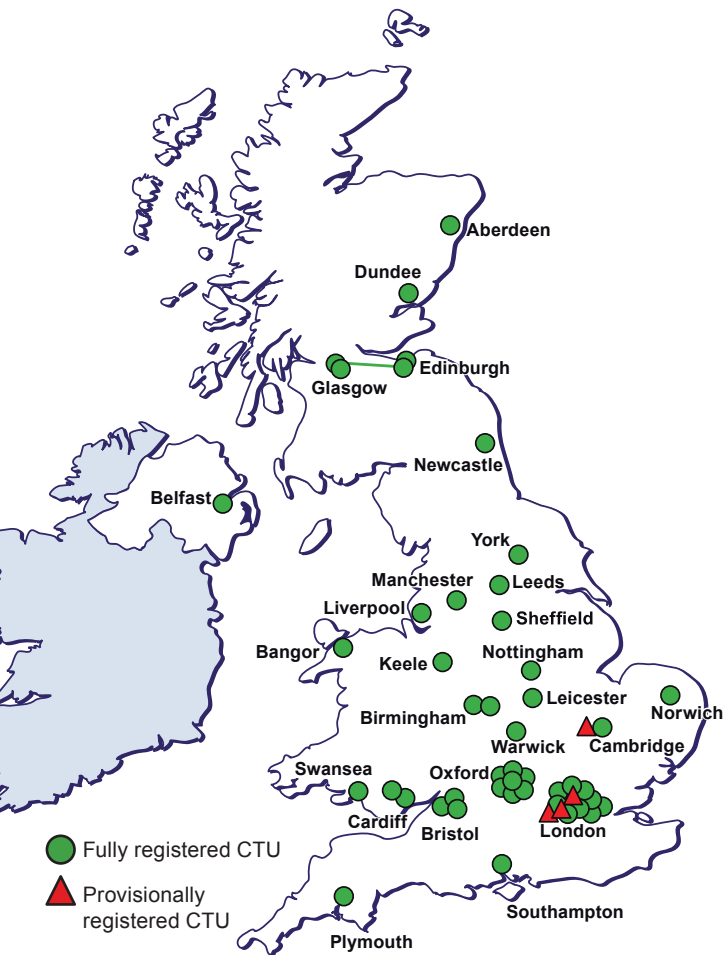


Identifying a CTU

The Network provides comprehensive information and direct access to high quality CTUs across the UK. Which have achieved UKCRC Registration status through our online Resource Finder available on our website www.ukcrc-ctu.org.uk. Our Resource Finder allows you to quickly search the details of our registered clinical trials units on the basis of location, services, experience in disease research area, study types conducted and methodological area to name just a few search categories!

The contact details for the Registered CTUs are available in the Resource Finder of our website.



When to contact a CTU

If you are interested in working with a Registered CTU, you should contact them as early as possible in the process. Ideally, this should be at least 3 months before a research grant deadline in order to provide the CTU with adequate time to schedule the work required and ensure the CTU is able to offer the full benefit of its experience and knowledge from the initial stages of study development.

Contact Details

For more information about the Network please contact:

UKCRC Registered CTU Network
Leeds Institute of Clinical Trials Research
University of Leeds
Leeds
LS29JT

Email: regctus@leeds.ac.uk
Website: www.ukcrc-ctu.org.uk



UKCRC
Registered
Clinical
Trials Units



The UKCRC Registered CTU Network is committed to providing its members with the information, guidance and representation in order to successfully support member activities in high quality, efficient, effective and sustainable clinical trials research in the UK.

UKCRC Registered CTUs

Our Registered Clinical Trials Units (CTUs) have shown demonstrable evidence of experience in leading the design, the central/national coordination and the overall analysis of multi-centred randomised controlled trials (phase II-IV) or other well-designed studies.

Key Roles of CTUs

Clinical Trials Units (CTUs) are specialist units which have been set up with a specific remit to design, conduct, analyse and publish clinical trials and other well-designed studies. They have the capability to provide specialist expert statistical, epidemiological and other methodological advice and coordination to undertake successful clinical trials.

In addition, most CTUs will have expertise in the coordination of trials involving investigational medicinal products which must be conducted in compliance with the UK Regulations governing the conduct of clinical trials resulting from the EU Directive for Clinical Trials.

CTUs which have been awarded UKCRC Registration were required to provide evidence to an international panel of experts of their capability to centrally coordinate multi-centre clinical trials (i.e. having overall responsibility for the design, development, recruitment, data management, publicity and analysis of a portfolio of trials), and that they had established robust systems to ensure conduct and delivery of clinical trials to the highest quality standards.

Functions and services provided by Registered CTUs

Registered CTUs will usually work with the Chief Investigator of a clinical study on the following:

- Development of new trials
- Identification of the right questions and appropriate design
- Systematic reviews (when appropriate)
- Discussions with different disciplines for different trial components e.g. quality of life, health economics, associated translational research
- Development of sub-studies
- Costing the trial and planning the staffing required to develop and manage the trial
- Communication with the Clinical Research Networks regarding feasibility and levels of interest
- Consideration of regulatory and governance issues
- Negotiations with international collaborators, if applicable
- Negotiations with industry, if applicable
- Coordinating protocol development and design of Case Report Forms (CRFs)
- Liaising with potential centres, identifying and initiating participating centres, and maintaining good communication with each centre
- Setting up the trial and obtaining relevant permissions (ethics approval, MHRA approval, etc)
- Recruiting clinical sites in order to identify and recruit eligible trial patients and allocating a trial entry number and treatment to trial patients
- Central coordination and management of essential trial documents and patient data collected from participating clinical sites
- Data monitoring
- Conducting interim and final analyses
- Preparation of reports (e.g. for funding bodies, NRES, MHRA, Data Monitoring Committees, Trial Steering Committees)
- CTU staff also have other roles such as representation on national and international advisory and review committees, and membership of Data Monitoring Committees and Trial Steering Committees for trials run by other CTUs.

