NIHR | National Institute for Health and Care Research

Clinical Trials Units

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What are Clinical Trials Units?

- Clinical Trials Units (CTUs) are specialist units with a specific remit to design, conduct, analyse and publish clinical trials & other well-designed studies
- They provide specialist statistical, epidemiological, methodological and coordination expert advice needed to undertake successful clinical trials
- The NIHR panel increasingly request CTU support even for feasibility studies. CTU collaboration reassures the panel that the design and delivery of the trial will be robust and optimise accrual.

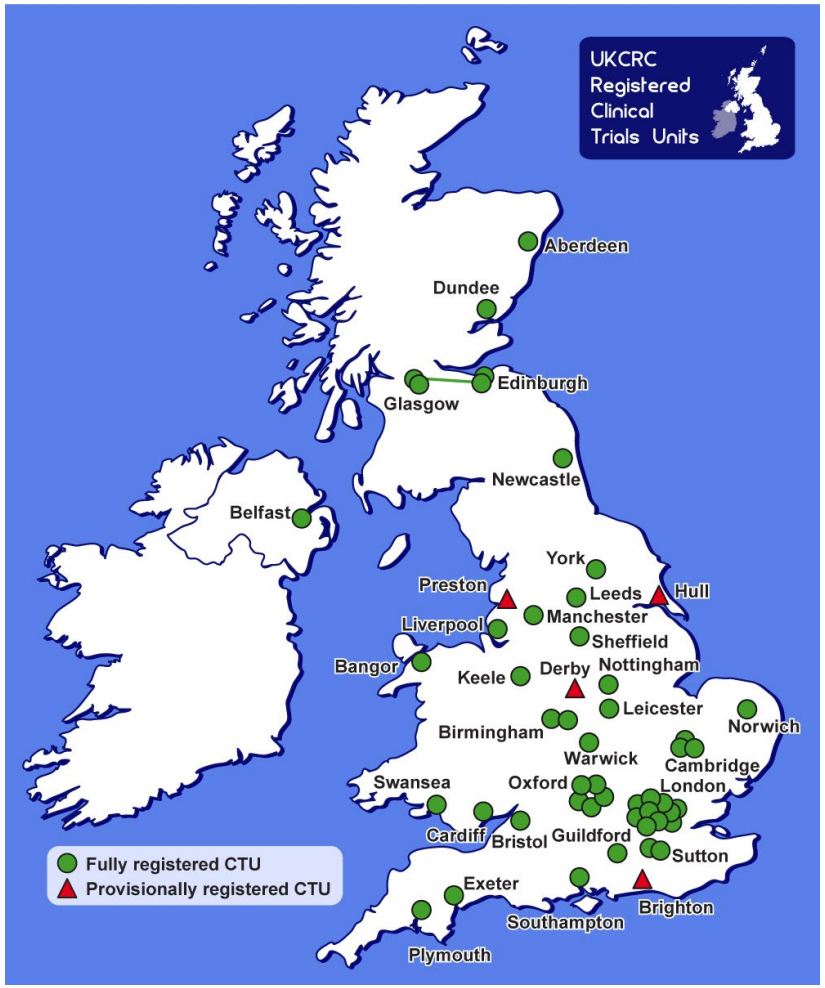
Roles within a Clinical Trials Unit

Trial management	• Responsible for day to day management of trials. Trial co-ordinators are the main contact for a trial and key to the successful trial delivery.
Statistics	• Statisticians involved in trial design, decisions on primary outcome, sample size calculations, complete interim and final analyses in accordance with the Statistical Analysis Plan. Input focuses on the planning phase, monitoring data quality, interim and final analyses.
Information Systems	• IS programmers develop bespoke applications for randomisation and data collection systems and also trial websites and mobile applications

Roles within a Clinical Trials Unit

Data Management	• Data Managers ensure that all necessary data is collected in a timely manner. They are involved in the trial from the planning stage and are involved in CRF Design, Data entry and Data Querying
Quality Assurance	• Ensure robust quality systems are in place inc. SOPs, audits and preparation for inspection
PPI	• To advise on patient facing documentation • Provide training for PPI contributors
Training	• Development and delivery of professional development for staff and fellows

UKCRC Registered Clinical Trials Units



- Registration applications Assessed by international review committee
- Evaluated against specific key competencies & evaluation criteria
- As of 2023: 52 registered CTUs (49 Full/3 provisional)
- Website includes a tool to search for CTUs

UKCRC (ukcrc-ctu.org.uk)

Roles of Clinical Trials Unit

CTUs can be involved in all stages of a clinical trials:

- Pre-funding
- Post award and set-up
- Recruitment and follow-up

Clinical Trials Unit Role: Pre-funding

- Statistics & Methodology
- Feasibility
- Budget
- Timely submission to Funder
- Advice on establishment and constitution of IDSMC & TSC
- Liaison with Sponsor
- Trial supplies
- Links to other expertise (e.g. Health Economics)
- Pre-application contribution not costed to grant
- Post award contribution costs included in award

Clinical Trials Unit Role: Post Award

- Protocol development
- Coordinate meetings of oversight committees
- Liaise with sponsor
- Management of trial supplies
- CRF and database development (Elsevier MACRO, other)
- Trial approvals – ethical, regulatory, institutional
- Establish/maintain Essential Documents centrally
- Site initiation and ongoing communication

Clinical Trials Unit Role: Recruitment and Follow-up

- Primary contact
- Safety monitoring/ reporting
- Progress reports, amendment notification
- Monitor accrual
- Ongoing database support, data query resolution
- Interim statistical analysis as per analysis plan
- Organise and prepare reports for oversight committees
- Notification of the end of the trial
- Archiving arrangements

When to Involve a Clinical Trials Unit

- As early as possible
- CTIMP (usually)
- Multi-centre RCT (CTIMP/non-CTIMP)
- Multi-centre pilot/ feasibility
- Methodology
- High risk
- Proposed funder
- Costs for CTU are included in grant applications

Summary

- Clinical Trials Units play an integral part in clinical trials and other well designed studies
- Not all trials require input from a Trials Unit
- CTIMP Trials, multicentre trials or high risk trials usually require Clinical Trials Unit input
- Chief Investigators should contact a Trials Unit as early as possible
- To accurately cost projects and work out resources required, Trials should be well designed and clear