

Key Competencies for UKCRC Registered Clinical Trials Units

The following competencies should exist in Clinical Trials Units (CTUs)¹, responsible for the design, conduct and analysis of trials and other well-designed studies (referred to collectively in this document as studies). Clinical Trials Units in this context are defined as a single unit or as a collaborative group (i.e. it is not necessary for all of the expertise required to exist in the same geographical location) fulfilling or working towards all key competencies. New Clinical Trials Units, or epidemiology units extending their activities into clinical trials, should demonstrate that they have the capacity and ability to develop these competencies.

1. Key Competencies

Expertise, Continuity and Stability

- Knowledge, experience and a track record of coordinating multi-centre clinical research studies from design and initiation to publication in peer reviewed journals, with good multi-disciplinary working relationships with investigators, clinicians, academics and experts from other specialties.
- An established multi-disciplinary team of experienced staff including statisticians, trial/project managers and IT staff with clinical input at the strategic as well as the project level. Collaborative groups will need to explain/define how the multi-disciplinary team will be established, managed and monitored and in addition, to set out a formal approach to reviewing the individual core disciplines being provided from a different location, prior to the start of any project, to ensure quality from the outset.
- Capability and experience of identifying the need for and sourcing of the necessary expertise for component studies to clinical studies and/or associated research (e.g. systematic reviews, psychosocial issues, patient assessed outcomes, qualitative research, health economics, pharmacogenomics, pharmacokinetics etc).
- Resources to provide adequate and stable infrastructure and senior staff as well as an ability to ensure continuity of the core disciplines.
- Adequate infrastructure to support trials activity with a documented commitment to the Clinical Trials Unit from the host institution.
- Systems and processes in place for continuing professional development, including Good Clinical Practice (GCP) training for all relevant staff.

Quality

- Systems and processes in place to ensure that staff work to appropriate guidelines and standards.
- Systems and processes in place to meet appropriate regulations and legislation (e.g. the principles of GCP, the NHS Research Governance Framework, the Data Protection Act, the UK Regulations that implement the EU Directive for Clinical Trials).
- Systems and processes in place for risk assessment to guide appropriate monitoring of the whole study process, centrally and at clinical sites.

¹ The term Clinical Trials Unit has been used in this document but experience of designing other clinical research studies, especially large multi-centre epidemiological studies as well as Randomised Controlled Trials will be taken into consideration

- Systems and processes in place to archive study data at the end of a study and to retrieve it subsequently.

Information Systems

- Robust and secure information systems.
- Access to a secure randomisation system, as appropriate.

Best practice principles

Applicants will be required to sign up to the following three principles:

- A commitment to working with UKCRN to support clinical research, e.g. contribution to national CTU committees and working groups
- A commitment to providing study information and monthly accrual data to the UKCRN Portfolio Database for UKCRN portfolio studies
- An organisational commitment to patient/public involvement.