

## Evaluation Criteria for UKCRC Registration of Clinical Trials Units

(\* Denotes essential evaluation criteria that must be met to enable UKCRC Registration of Clinical Trials Units)

### Expertise, Continuity and Stability

Competency	Evaluation Criteria for Full Registration	Evaluation Criteria for Provisional Registration
<p>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 specialities.</p>	<p>* At least five open/in follow-up multi-centre randomised controlled trials (RCTs) or other well-designed studies, of which at least one has been funded by open national competition with full peer-review.</p> <p>* Evidence of being involved in the design, conduct and analysis of most of the unit's studies.</p> <p>* At least one trial publication from the Clinical Trials Unit (CTU) of an existing/closed study. If only one publication is available from the CTU, additional evidence of high quality trial conduct is also required e.g. reports to funders, MHRA inspection report.</p> <p>Evidence of having worked with at least one external clinical collaboration.</p>	<p>* Between one and four multi-centre RCTs or other well-designed studies, at least one of which must be an open multi-centre RCT or well-designed study.</p> <p>* Evidence of being involved in the design, conduct and analysis of most of the unit's studies.</p> <p>Have not worked with external clinical collaborations but willing to do so.</p>
<p>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.</p>	<p>* At least one statistician with at least five years' relevant experience, at least one trial/project manager with at least three years' relevant experience and at least one IT/IS person, ideally all core funded.</p>	<p>* At least one statistician with at least three years' relevant experience, evidence of access to senior statistical support, at least one trial/project manager with at least three years' relevant experience and at least one IT/IS person, ideally all core funded.</p>

	<p>*Evidence of clinical input at strategic level (need senior clinical input either as member of CTU or member of CTU advisory/executive committee).</p> <p>*Collaborative groups will need to explain/define how the multi-disciplinary team will be established, managed and monitored and 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.</p> <p>* Evidence of appropriate governance (as shown by a formal organisational chart of the staff in the CTU).</p>	<p>*Evidence of clinical input at strategic level (need senior clinical input either as member of CTU or member of CTU advisory/executive committee).</p> <p>*Collaborative groups will need to explain/define how the multi-disciplinary team will be established, managed and monitored and 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.</p> <p>* Evidence of appropriate governance (as shown by a formal organisational chart of the staff in the CTU).</p>
<p>Capability and experience of identifying the need for and sourcing of the necessary expertise for component studies to clinical studies and/or associated research.</p>	<p>Evidence of existing collaboration(s) with specialist group(s).e.g. health economics, primary care, prevention, screening, translational research, early phase trials, complex interventions.</p>	<p>Same as Full Registration.</p>
<p>Resources to provide adequate and stable infrastructure and senior staff as well as an ability to ensure continuity of the core disciplines.</p> <p>Adequate infrastructure, to support trials activity with a documented commitment to the Clinical Trials Unit from the host institution.</p>	<p>* Evidence of core funding or of a rolling programme of grants. Evidence of commitment from the host institution.</p> <p>* Evidence of capacity in terms of staffing, time and expertise to manage unexpected/unplanned circumstances (e.g. personnel changes or trial problems).</p>	<p>* Evidence of commitment from the host institution.</p>

Systems and processes in place for continuing professional development, including Good Clinical Practice (GCP) training for all relevant staff.	* Evidence of a functional process for staff training, including GCP training for all relevant staff.	* Same as Full Registration.
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## Quality

<b>Competency</b>	<b>Evaluation Criteria for Full Registration</b>	<b>Evaluation Criteria for Provisional Registration</b>
Systems and processes in place to ensure that staff work to appropriate guidelines and standards.	* Need to see list of Standard Operating Procedures (SOPs) with version numbers and dates. Need to have SOPs in areas identified by the National Cancer Research Institute CTUs (see below). Need to show evidence of how it is ensured that staff follow SOPs and who is responsible for managing SOPs.	* SOPs could be in development, but need to see planned list. Need to have SOPs in areas identified by the National Cancer Research Institute CTUs (see page 6). Need to show evidence of how it is ensured that staff follow SOPs and who is responsible for managing SOPs.
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 and the UK Regulations that implement the EU Directive for Clinical Trials).	* Evidence of systems for ensuring data quality, audit trails of data and data queries, ensuring patient confidentiality, adverse event reporting (pharmacovigilance for clinical trials of Investigational Medicinal Products (IMPs)), informed consent processes. Expect most studies to have Data Monitoring Committees (DMCs) and Trial Steering Committees (TSCs). Must show evidence of adherence to the principles of GCP.	* Same as Full Registration.
Systems and processes in place for risk assessment to guide appropriate monitoring of the whole study process centrally and at clinical sites.	Evidence of a functional system for risk assessment.	System could be in development, but need to be assured adequate.
Systems and processes in place to archive study data at the end	* Evidence of a system for this.	* System could be in development, but need to

of a study and to retrieve it subsequently.		be assured adequate.
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### Information Systems

Competency	Evaluation criteria for Full Registration	Evaluation Criteria for Provisional Registration
Robust and secure information systems.	* Evidence of an appropriate data management system. Evidence of a satisfactory validation process and infrastructure components for this system.	* Same as Full Registration.
Access to a secure randomisation system, as appropriate.	* Evidence of access to a randomisation system, if run RCTs and need to specify system used.	* System could be in development, but need to be assured adequate or else that access is available to a secure randomisation system.

### Areas to be covered by SOPs:

- Protocol development
- Monitoring
- Trials Master File
- Ethics approval
- Medicines and Healthcare products Regulatory Agency (MHRA) approval (if run clinical trials of IMPs)
- Initiation/site set up
- Data management
- Trials supplies/labelling (if run clinical trials of IMPs)
- Pharmacovigilance (if run clinical trials of IMPs)
- SOP on SOPs
- Internal audit of Quality Assurance system
- Audit
- Patient Information Sheet/Consent Form
- Training records
- Randomisation (if run randomised trials)
- Statistics
- IT/database issues
- Trial closure
- Clinical trial report
- Archiving