UKCRC Registered Clinical Trials Units

UKCRC Registered CTU Network

Key Competencies and Evaluation Criteria 2023

This document is for use by:

- New applicants
- CTUs seeking transfer from provisional to full status

UK Clinical Research Collaboration

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Appendix 1

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 or 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 merger or 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.

Key Competencies

1. Expertise, Continuity and Stability

a) Knowledge, experience and a track record of coordinating (NIHR CRN Portfolio eligible)[2] multi-centre clinical research trials (phase II – IV) or other well designed 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.

b) An established multi-disciplinary team of experienced staff including statisticians, trial/project managers and IT staff. Collaborative groups or merged unit will need to explain/define how the multi-disciplinary team has been 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.

c) 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).

d) To demonstrate robust leadership and future planning indicative of clear research, operational and succession planning strategies.

2. Infrastructure

a) Resources to provide adequate and stable infrastructure and senior staff as well as an ability to ensure continuity of the core disciplines.
b) Adequate infrastructure to support trials activity with a documented commitment to the Clinical Trials Unit from the host institution and clinical input at a strategic level.
c) Systems and processes in place for continuing professional development, including Good Clinical Practice (GCP) training for all relevant staff.

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[1] The term Clinical Trials Unit has been used in this document but experience of *leading* the design, the *central/national* coordination and the *overall* analysis of other clinical research studies; especially large multi-centre epidemiological studies as well as Randomised Controlled Trials will be taken into consideration.

[2] NIHR and Devolved Nations Portfolio eligibility see http://www.crn.nihr.ac.uk/can-help/funders-academics/nihrcrn-portfolio/which-studies-are-eligible-for-clinical-research-network-support/ (NIHR) http://www.cso.scot.nhs.uk/wp-content/uploads/Scottish-studies-and-the-UKCRN-Portfolio.pdf (Scotland) https://www.healthandcareresearch.gov.wales/get-your-study-on-the-clinical-research-portfolio/ (Wales) http://www.nicrn.hscni.net/nicrn-study-adoption/nicrn-adoption-process/ (Northern Ireland)

* Must run one Randomised Controlled Trial (RCT)

3. Quality

a) Systems and processes in place to ensure that staff work to appropriate guidelines and standards.

b) Systems and processes in place to meet appropriate regulations and legislation (e.g. the principles of GCP, the UK Policy Framework for Health and Social Care Research, the Data Protection Act, and any other regulations and legislation relating to Clinical Trials

c) Systems and processes in place for risk assessment to guide appropriate monitoring of the whole study process, centrally and at clinical sites.

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

4. Information Systems

a) Robust and secure information systems.

b) Evidence of satisfactory validation process.

c) Evidence of adequate staffing to support Information system(s).

5. Statistical Input

a) Robust statistical input.

b) Access to a secure randomisation system, as appropriate.

Appendix 2

Evaluation Criteria for UKCRC Registration of Clinical Trials Units

Expertise, Continuity and Stability

Competency	1. Evaluation Criteria for Full Registration	2. Evaluation Criteria for Provisional Registration
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.	**1.1** Five open to recruitment/in follow-up/ in analysis (at least two open) multi-centre randomised controlled trials (phase II-IV) or other well-designed studies, of which at least one has been funded by open national competition with full peer-review[3] and at least one must be a randomised controlled trial (RCT).	**2.1** Three either in setup/open to recruitment/ in follow-up/in analysis (at least one open) multi-centre randomised controlled trials (phase II-IV) or other well-designed studies, at least one of which must be funded by open national competition with full peer-review[3] and at least one of which must be a randomised controlled trial (RCT).
	1.2 Evidence of being involved in the design, conduct and analysis of the unit's studies.	**2.2** Evidence of being involved in the design, conduct and analysis of the unit's studies.
	1.3 At least three peer reviewed trial publications from the Clinical Trials Unit (CTU) of a recent existing/closed study. (Can be protocol publications from different studies but must include one final analysis).	**2.3** At least one peer reviewed trial publication from the Clinical Trials Unit of a recent existing/closed study. (Can be a protocol publication).

[3] As judged by NIHR and Devolved Nations Portfolio eligibility.

An established multi-disciplinary team of experienced staff including statisticians, trial/ project managers and IT staff.	**1.4** At least two statisticians (with one that has at least five years' relevant experience). At least two trial/project managers (one with at least five years' relevant experience). An appropriate level (for internally hosted systems this would usually be at least 2 persons, for externally hosted systems this would usually be a minimum of 1 person) of IT/IS persons (with at least three years' experience). A named person who is responsible for the QA function with at least three years' relevant experience. A named PPI&E lead with at least three years' relevant experience, Ideally all funded independently of specific research grants. **1.5** 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.	**2.4** 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. At least one IT/IS person with at least one years' relevant experience. A named person who is responsible for the QA function with at least one years' relevant experience A named PPI&E lead with at least one year's relevant experience, Ideally all funded independently of specific research grants. **2.5** 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.

Infrastructure

Competency	1. Evaluation Criteria for Full Registration	2. Evaluation Criteria for Provisional Registration
Resources to provide adequate and stable infrastructure and senior staff as well as an ability to ensure continuity of the core disciplines.	**1.6** Evidence of core funding or of a rolling programme of grants. Evidence of commitment from the host institution.	**2.6** Evidence of commitment from the host institution.
Adequate infrastructure, to support trials activity with a documented commitment to the Clinical Trials Unit from the host institution and clinical input at the strategic as well as the project level.	**1.7** Evidence of capacity in terms of staffing, time and expertise to manage unexpected/unplanned circumstances (e.g. personnel changes or trial problems).	**2.7** Evidence of capacity in terms of staffing, time and expertise to manage unexpected/unplanned circumstances (e.g. personnel changes or trial problems).
Robust leadership and future planning indicative of clear research, operational and succession planning strategies.	**1.8** Evidence of clinical input at strategic level **1.9** Evidence of robust research, operational and succession planning strategies.	**2.8** Evidence of clinical input at strategic level **2.9** Evidence of robust research, operational and succession planning strategies.

Quality Assurance

Competency	1. Evaluation Criteria for Full Registration	2. Evaluation Criteria for Provisional Registration
Systems and processes in place to meet appropriate regulations and legislation (e.g. the principles of GCP, the UK Policy Framework for Health and Social Care Research, the Data Protection Act and any other UK regulations and legislation relating to Clinical Trials).	**1.10** List of Standard Operating Procedures (SOPs) with version numbers and dates. SOPs in areas identified by the UKCRC-Registered CTUs (see page 6) and evidence of how it is ensured that staff follow SOPs and who is responsible for managing SOPs.	**2.10** SOPs could be in development but need to see planned list. SOPs in areas identified by the UKCRC-Registered CTUs (see page 6) and evidence of how it is ensured that staff follow SOPs and who is responsible for managing SOPs.
Systems and processes in place for risk assessment to guide appropriate monitoring of the whole study process centrally and at clinical sites.	**1.11** Evidence of a functional system for risk assessment.	**2.11** System could be in development.

Information Systems

Competency	1. Evaluation criteria for Full Registration	2. Evaluation Criteria for Provisional Registration
Robust and secure information systems.	**1.12** Evidence of an appropriate data management system. Evidence of a satisfactory validation process and infrastructure components for this system.	**2.12** Evidence of an appropriate data management system. Evidence of a satisfactory validation process and infrastructure components for this system.
Evidence of satisfactory validation process	**1.13** Evidence of robust validation process for trial specific database systems and treatment allocation systems.	**2.13** Evidence of robust validation process for trial specific database systems and treatment allocation systems.
Evidence of adequate staffing to support Information system(s).	**1.14** Evidence that the numbers and experience of systems staff are sufficient to support information system development, management, and validation'.	**2.14** Evidence that the numbers and experience of systems staff are sufficient to support information system development, management, and validation'.

Statistical Input

Competency	1. Evaluation criteria for Full Registration	2. Evaluation Criteria for Provisional Registration
Robust statistical input.	**1.15** Evidence of statistical involvement throughout the trial process.	**2.15** Evidence of statistical involvement throughout the trial process.
Access to systems and processes to manage a secure randomisation system.	**1.16** Evidence of systems and processes to manage a secure randomisation system when running RCTs and need to specify system used.	**2.16** System could be in development, but need to be assured adequate or else that access is available to a secure randomisation system.

Essential areas to be covered by SOPs:

Quality Management Systems

1. Quality Management Systems
2. Non-conformance
3. SOPs creation and update

4. Training and Induction
5. Dealing with Non-Conformance
6. Good Documentation Practices
7. Change Control

All Trials

8. Sponsorship, contracts/agreements and indemnity
9. Business Continuity
10. Protocol development
11. Patient Information
12. Ethical Approvals
13. Regulatory approvals
14. Sit set up
15. Statistics
16. Registration/Randomisation (if running randomised trials)
17. Data management
18. Data Sharing
19. Monitoring and Independent oversight
20. Trial Master File/Site File (Investigator & Pharmacy)
21. IT Systems
22. Data protection and confidentiality (GDPR)
23. Trial closure
24. End of trial reporting and publication
25. Archiving
26. Deviations, Misconduct and serious breaches of GCP and/or the Protocol
27. Data protection and confidentiality
28. Document control
29. Trials supplies
30. Safety Reporting/Pharmacovigilance
31. Urgent safety measures