

Keele Clinical Trials Unit (CTU) Collaboration Guide

Keele CTU holds full accreditation as a UK Clinical Research Collaboration (UKCRC) Clinical Trials Unit, and we provide extensive support for the design, planning, conduct, analysis and dissemination of randomised controlled trials and other well-designed studies. We welcome requests for collaboration. When assessing proposals for CTU adoption, we prioritise studies that meet the following criteria:

Study:

- The study addresses an important question and there is evidence of, or plans for, appropriate Patient and Public Involvement and Engagement (PPIE).
- There is convincing evidence demonstrating the need for the research.
- The study is well-designed, methodologically sound and feasible.
- There is appropriate expertise and experience in the study team to deliver the study.

Scope:

- The study requires the expertise and services of a CTU.
- The study data management and analysis will be overseen by Keele CTU.
- If the study is a trial, it is a phase III or IV study in design, or is a pilot/feasibility study that is preparing for a future phase III or IV study.
- If the study is a Clinical Trial of an Investigational Medicinal Product (CTIMP), then in line with Keele CTU's growing expertise in supporting CTIMPs:
 - Keele CTU is likely to agree in principle to collaborate on type A CTIMPs.
 - Keele CTU will consider type B CTIMPs on a case-by-case basis.
 - Keele CTU will currently not collaborate on type C CTIMPs.

Strategic fit:

- Priority will be given to studies that align with the research strategy of Keele CTU's key partners at Keele University and those supported by the NIHR Research Support Service (RSS).
- The study involves clear collaboration with one or more academic staff from Keele CTU and/or from Keele University.

Sponsorship:

- The study fits with Keele University's required arrangements for sponsorship, as detailed in Keele University's Health and Social Care (HSCR) Sponsorship, Regulatory Approvals and Green Light Standard Operating Procedure (SOP), HSCR-SOP-RM07.

Capacity:

- There is sufficient capacity and resource within the CTU to deliver the study.

Funding

- There is sufficient funding available to cover CTU services required.