

Good order is the foundation of all things:

A strong project management structure underpins successful research at Keele Clinical Trials Unit (CTU)

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Context

Keele Clinical Trials Unit (CTU) is a UKCRC registered CTU, specialising in the development and delivery of epidemiological studies, feasibility and main multicentre clinical trials, and an increasing portfolio of Clinical Trials of Investigational Medicinal Products (CTIMPs). An effective project management structure is essential for the delivery of high quality research.

Background

of Keele University's research was deemed to be world-leading, or of international importance in REF 2014 and Keele CTU, providing support for the design, delivery, analysis, reporting and dissemination of applied clinical research is contributing to this success!

Specialist expertise has been developed and deployed in the areas of;

(v) trial design (v) intervention development (v) biostatistic approaches (v) regulatory coordination

This expertise requires a strong project management structure to conduct and deliver clinical research to the highest quality standards.

Approach

A structural flow beginning at study conception through to successful dissemination of results, for each CTU supported research study, is employed.

Clinical Studies Think Tank

From conceptualisation, an early research idea is presented and discussed at a Clinical Studies Think Tank, attended by specialist and generalist clinicians, operational experts & methodologists to assist research design improvements.



CTU collaboration

Prior to grant application, studies seeking Keele CTU collaboration are considered against Keele CTU adoption criteria including;

- ✓ strategic fit
- ✓ sponsorship arrangements
- ✓ expertise
- ✓ capacity
- ✓ funding



Feasibility

Research partners, including the NIHR Clinical Research Network, review study feasibility and visualisation of study operationalisation within the NHS environment.

A CTU Operations Group reviews the finer various operational 🔽 🛴 infrastructure making up the operational delivery team e.g. IT, administration and health informatics.



Quality

*This structural process is underpinned by a Quality Management System (QMS). Strong internal and external communication links, together with our QMS, ensures consistent working practices utilising standardised processes and adherence to regulatory obligations.

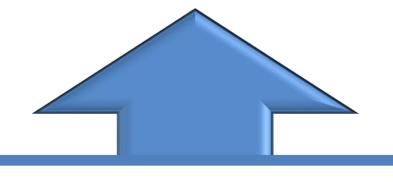
Results

- Studies managed efficiently and effectively within the resources available to secure delivery to time and target.
- Over **25** studies presented at Clinical Studies Think Tanks each year
- Keele CTU currently supports a portfolio of over 40 research studies



Dedicated coordination

Studies are allocated to CTU Trials Managers, and supported by Study Coordinators, the research is delivered.



Working groups

Working groups, such as the Lessons Learnt and Standard Documents working groups, provide invaluable support for study delivery. Within each working group, innovative and effective methodologies are developed, that include technological advances and standardised resources.

Conclusions

- Keele CTU is increasing its portfolio of research studies whilst making strides with innovative and effective operational improvements. This all needs to be carried out within a robust and supportive QMS to ensure successful study delivery.
- Good order is key to the foundations of any study. Our strong project management structure has allowed us to work collaboratively, integrating all specialties and expertise required, transparently, in order to achieve the successful delivery of research.