

Behind every great application...are a bunch of great people: The power of collaboration

Sarah A Lawton, Stephanie Tooth & Louise Phillips-Darby on behalf of Keele Clinical Trials Unit
Keele CTU, Keele University, Staffordshire, ST5 5BG

Background:

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). At the heart of the CTU are strong collaborations which facilitate successful HRA applications.

Approach:

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 Adoption Group

Assess the design of the research, the expertise within the team, the funding and capacity to deliver the research.



HRA resources

HRA provides guidance and checklists which Keele CTU utilise to facilitate the application process ensuring compliance with the latest requirements.
Website: <http://www.hra.nhs.uk/>

HRA Top Tips

- Utilise IRAS guidance
- Clearly state IRAS reference number on all documents
- Submit ALL required documents on IRAS checklist
- Respond promptly to initial assessment letter
- Include copies of all contracts
- Be clear about access to data, location and storage

Clinical Trials Toolkit

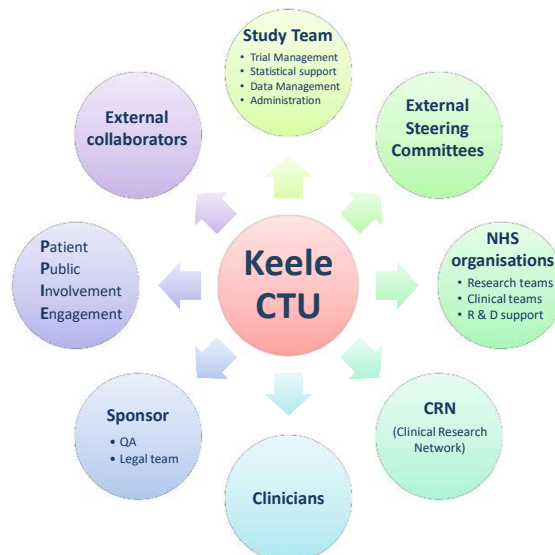


<http://www.ct-toolkit.ac.uk/>

CTU Collaborations

It is through strong collaborations within the research community that Keele CTU experiences a successful record of HRA applications

Employing this collaborative structure to support project management results in transparent and auditable processes within Keele CTU



Quality Management System
Keele CTU QMS ensures consistent working practices utilising standardised processes and adherence to regulatory obligations.

HRA application development

Conclusions

- ✓ The set-up stage for research, if conducted well, paves the way for the successful delivery of research. HRA research applications require a robust and supportive QMS to ensure success, together with strong collaborations, providing validation to the design of an application.
- ✓ The collaborations are essential in order to integrate all expertise required for a successful application adhering to HRA requirements. Following the introduction of the new HRA processes in April 2016, Keele CTU have achieved a number of successful HRA applications enabling the CTU start research to time and target.
- ✓ The HRA have advised us to share our application development process for others to learn from.