

UKCRC
Registered
Clinical
Trials Units



The 2019–2024 UKCRC Registered CTU Network Strategy

‘Quality, Excellence, Integrity’



igniting our potential

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Contact us

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Introduction

Clinical trials research is essential in shaping modern medicine. In order to find the treatments and therapies of tomorrow we must ensure we have good quality clinical research today. Clinical research studies are highly complex; involving multiple disciplines often across multiple centres, and must comply with strict approvals and regulations to ensure safety to the highest standards. Clinical Trials Units (CTUs) are multi-disciplinary specialist units that offer expertise across all required disciplines to ensure quality, robust, and effective clinical research from design to reporting.

CTUs provide experience and expertise in trial design, development and delivery. They offer extensive methodological knowledge and skills, as well as the infrastructure, regulatory understanding, and experience in practical management of clinical trials research. These Units are seen as leading the way in clinical research. The involvement of a CTU in a clinical study is advocated by funding agencies such as the NIHR and MRC. Indeed, the NIHR encourages researchers to contact a CTU early in the research development process and the preparation of funding bids.

The UK Clinical Research Collaboration (UKCRC) has established a process to register non-commercial CTUs involved in multi-centre trials. Registration is a hallmark of CTU quality and excellence. The UKCRC Clinical Trials Unit Network, which administers the registration process, also supports Registered CTUs through sharing best practice, providing information and guidance, and promoting the work of registered Trial Units across the UK.

“In the 10 years since the Network was established, the number of Trials Units registered has risen to over 50, with a demonstrable improvement in the quality of clinical trials provision across the UKCTU landscape. We aim to continue to see Registered CTUs increase their quality and efficiency in trials research. We want to give them a unified voice to ensure that the key decision-makers in clinical research in the UK understand the important role CTUs play in delivering research excellence.

This strategy outlines our commitment to continuing to support member CTUs, and outlines where we will focus our efforts over the next five years”

(UKCRC Registered CTU Network Executive Group Chair, Sarah Rudkin)

Our Purpose

Our vision

Our vision is for Registered Clinical Trials Units to be world leaders in high-quality clinical trial design and conduct.

Our mission

The UKCRC Registered CTU Network promotes academic trials units and, through its activities, provides its members with information, guidance, and representation in support of the conduct of high-quality, effective, efficient, and sustainable clinical trials research.

How we work

The UKCRC Registered CTU Network is a network of Clinical Trials Units that have been assessed against key criteria by an independent international panel of experts in clinical trials research. The Network consists of CTU members from across the UK.

UKCRC CTU Registration

Registration is a process involving the independent review of applicants by an international committee of experts against a range of key criteria.

- Full registration is awarded for a period of five years. Following this, units are subjected to a Quinquennial Review of registration status supported by interim annual review where Registered Units have been the subject of significant changes. The next scheduled Quinquennial Review will take place in 2022
- Provisional registration is awarded where units have not yet completely satisfied the criteria for full registration status. Provisionally Registered Units are expected to reach the criteria for full registration within three years.
- The Network promote ad hoc open calls for new applicants at regular intervals.

Our Set-up

Executive Group

The Executive Group provides oversight, governance, and accountability to the Network and consists of representatives from regulatory and funder agencies, CTU Directors, Government Research bodies, and a range of stakeholders including:

- National Institute for Health Research (NIHR)
- Cancer Research UK
- Health & Social Care Research Wales
- Versus Arthritis
- UK Trial Manager's Network
- MRC-NIHR Trials Methodology Research Partnership
- Chief Scientist Office, Scotland
- NIHR Clinical Research Network

Operations Groups

The Operations Groups represent individual professional disciplines within non-commercial CTUs. They provide opportunities for professional development through peer-to-peer support, networking events, the creation of training and guidance materials and sharing learning and best practice. These Groups are:

- Statistics
- Information Systems
- Quality Assurance
- Trial Management

Each Operations Group leads a programme of work with the aims of:

- Identifying challenges and developing solutions together;
- Highlighting challenges which require a policy response;
- Identifying opportunities to improve efficient trial conduct;
- Sharing best practice and developing practical guidance on good research practice and quality standards for non-commercial trials;
- Contributing to national and internationally led new initiatives within the clinical research community; and

- Representing the views of Registered CTUs.

The Operations Groups develop an annual programme of individual and cross-Group deliverables to support these aims. These deliverables are agreed with the UKCRC CTU Executive Group.

Task and Finish Groups

Our Task and Finish Groups are time-limited and lead topical work programmes relating to efficient trial conduct, good research practice, quality standards, and the capacity and sustainability of non-commercial CTUs. Current Task & Finish Groups include:

Participant Data Sharing

Sharing data from publically funded research ensures valuable research outputs can be used more widely for the benefit of patients and the public. The UKCRC Registered CTU Network supports the sharing of clinical trials data with trusted partners for further ethical research purposes. This group will facilitate the development and implementation of good practice in relation to the sharing of research data through the provision of peer-to-peer support, written guidance, and training events

Patient and Public Involvement and Engagement

Patient and public involvement and engagement in the design and planning of research improves the quality and relevance of clinical research. CTUs must work collaboratively to develop and share best practice and make the best use of the limited resources available. This group will identify and develop resources to help member CTUs to effectively involve and engage patients and the public in their work.

Staff Development and Sustainability

Clinical Trials Units have demonstrated their effectiveness as centres of trials excellence. Building the strength, stability, and sustainability of member units is important in ensuring that they are able to continue to deliver high-quality non-commercial clinical trials research in the UK both now, and in the future. Well-trained and appropriately developed staff are key to this endeavour. This group will identify recommendations around staff training, development and retention to ensure registered CTUs have, and keep the best staff. This group will also focus activities on promoting careers in clinical trials to ensure that registered CTUs are recruiting and developing the excellent trialists of the future.

Our aims

1. Develop and share best practice across our members
2. Improve the promotion of Registered Clinical Trials Units
3. Be a strong voice for Registered Clinical Trials Units

Aim 1: Develop and share best practice across our members

We want to enhance high standards within clinical trials through the development and sharing of best practice across the Network. We want to develop Network values and processes to support members with host institutions, funder, publisher and regulatory expectations and quality standards. We recognise the wide range of experience, knowledge, and skills across Clinical Trials Units; the Network will continue to harness this expertise through networking, knowledge development, and the work of our Operations and Task and Finish Groups.

We will:

- Develop shared policies/procedures and statements on trial transparency, data sharing, and GCP compliance;
- Create a programme of annual meetings, events, and webinars on topics of interest to our members;
- Support Operations Groups in the areas of Statistics, Quality Assurance, Trial Management, and Information Systems to identify and share good practice and highlight challenges and opportunities;
- Invest in and support Task & Finish Groups to identify challenges and solutions, and deliver activities to improve quality across the Network;
- Develop a new Group on Strength & Sustainability to identify activities to improve resource sustainability including recruitment, retention, career development, and staff management;
- Develop activities and share learning on using new technologies to support high-quality, efficient, and effective trials; and
- Review our current registration criteria to ensure emerging and new practice, case law, points of compliance, and best practice are reflected.

Aim 2: Improve the promotion of Registered Clinical Trials Units

The research carried out by Registered CTUs is of high quality and impact. The Network will work to ensure that funders, regulators, and publications understand the valuable work of non-commercial CTUs in clinical research. We want our member CTU to be recognised as world leading centres of excellence in clinical trials. We will expand our horizons over the next five years and develop international links across Europe, Australia, Canada and America to promote the varied and valuable innovative research of Registered CTU members, and explore ways of collaborating and sharing learning.

We will:

- Review and improve the Network website to communicate more clearly with our key stakeholders;
- Improve communication with, and to, our members through developing a clear communication plan and creating a more user-friendly member area on the website;
- Develop publicity materials to highlight the important role and high-quality impact of CTUs in the research environment;
- Improve engagement and communication links with industry networks and bodies;
- Cultivate relationships with the international clinical trials research community to promote the quality and expertise of UK Registered Clinical Trials Units; and
- Undertake activities and develop materials to promote and highlight careers within Registered Clinical Trials Units.

Aim 3: Be a strong voice for Registered Clinical Trials Units

The Network represents a broad range of Clinical Trials Units across the UK. We are uniquely positioned to represent our members and collate, amplify, and communicate their views on strategic issues. The Network will work to ensure that the voice of our member CTUs is heard, and understood by regulators and decision-makers both in the UK and internationally.

We will:

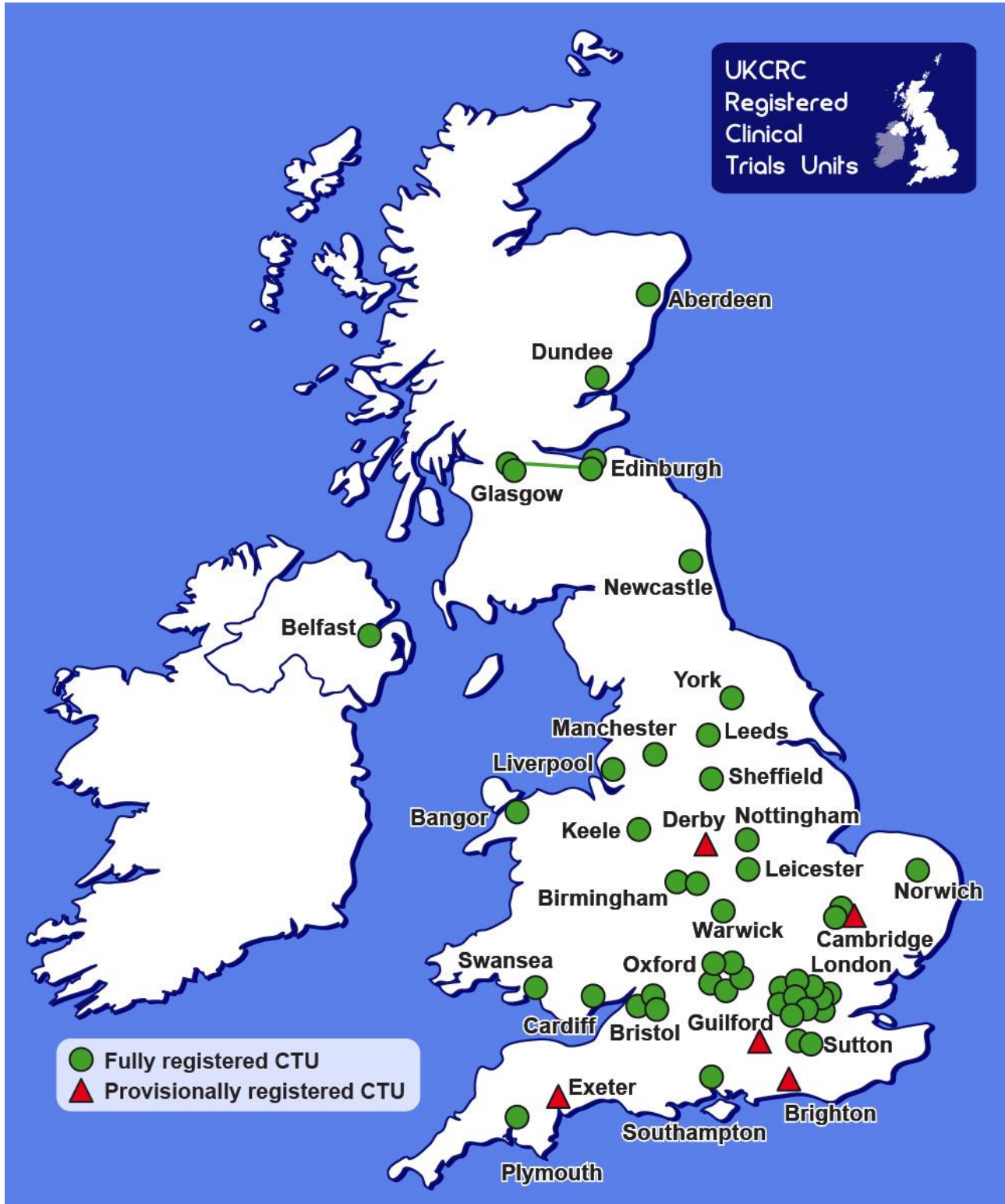
- Develop a strong social media presence to share Network activities and promote best practice;

- Develop a strong policy function so the views of Registered CTUs are represented, and communicated to key decision makers during consultations, evidence calls and policy development;
- Develop closer relationships with key regulatory, funder and Governmental bodies to ensure Registered CTU views and issues are considered; and
- Increase representation of member CTUs in positions of influence with key stakeholders nationally and internationally:

How we will measure success

It is important that we measure our performance to ensure that we achieve the aims we have set out in this strategy. We will develop SMART (Specific, Measurable, Achievable, Realistic, Time bound) actions and milestones in a work plan that will be refreshed annually. Our performance will be monitored regularly by the UKCRC Registered CTU Network Executive Group. We will publish an annual summary report of our key successes and achievements.

Sites of Currently Registered CTUs*



* An up to date list of all Registered CTUs can be found at: www.ukcrc-ctu.org.uk.