Network Support - Clinical Trials Units

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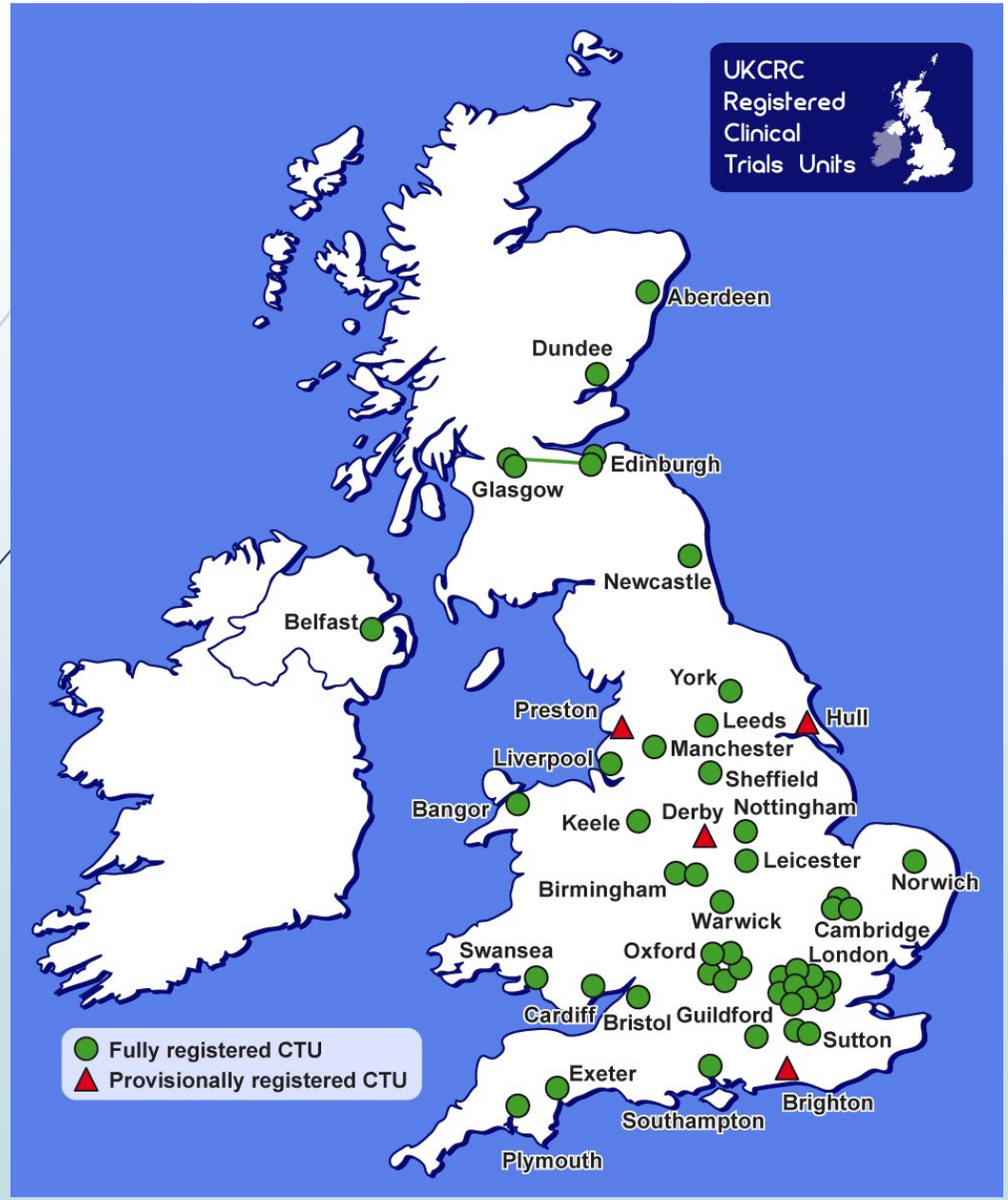
What are Clinical Trials Units

- The NIHR panel increasingly request CTU support even for feasibility studies. CTU collaboration reassures the panel that the design and delivery of the trial will be robust and optimise accrual.

- Specialist units with a specific remit to design, conduct, analyse and publish clinical trials & other well-designed studies

- **Provide specialist** statistical, epidemiological, methodological and coordination expert advice **needed to undertake successful clinical trials – we will look at some of these roles on the next slide**

UKCRC Registered CTUs



- Registration applications Assessed by international review committee
- Evaluated against specific key competencies & evaluation criteria
- As of 2022: 52 registered
- CTUs NETSCC Support funding for Registered CTUs
- Website includes a tool to search for CTUs

www.ukcrc-ctu.org.uk

When to involve a CTU

The NIHR panel increasingly request CTU support even for feasibility studies. CTU collaboration reassures the panel that the design and delivery of the trial will be robust and optimise accrual. RDS NW and CTU involvement assures the panel that the investigator has accessed the support available.

- As early as possible
- CTIMP (usually)
- Multi-centre RCT (CTIMP/ non-CTIMP)
- Multi-centre pilot/ feasibility
- Methodology
- High risk
- Proposed funder
- Costs for CTU are included in grant applications

CTU Role: Funding Application

- Statistics & Methodology
- Feasibility
- Budget
- Timely submission to Funder
- Advice on establishment and constitution of IDSMC & TSC
- Liaison with Sponsor
- Trial supplies
- Links to other expertise (e.g. Health Economics)
- Pre-application contribution not costed to grant
  - Post award contribution costs included in award

CTU Role: Post Funding

- Protocol development
- Coordinate meetings of oversight committees
- Liaise with sponsor
- Management of trial supplies
- CRF and database development (Elsevier MACRO, other)
- Trial approvals – ethical, regulatory, institutional
- Establish/maintain Essential Documents centrally
- Site initiation and ongoing primary communication
- Data collection and cleaning
- Data analysis
- Collaboration on publications

Links for further information

- https://www.ukcrc-ctu.org.uk/
- https://www.nihr.ac.uk/documents/clinical-trials-guide/20595#Clinical_trials_unit