The UKCRC Statistics Operational Group:

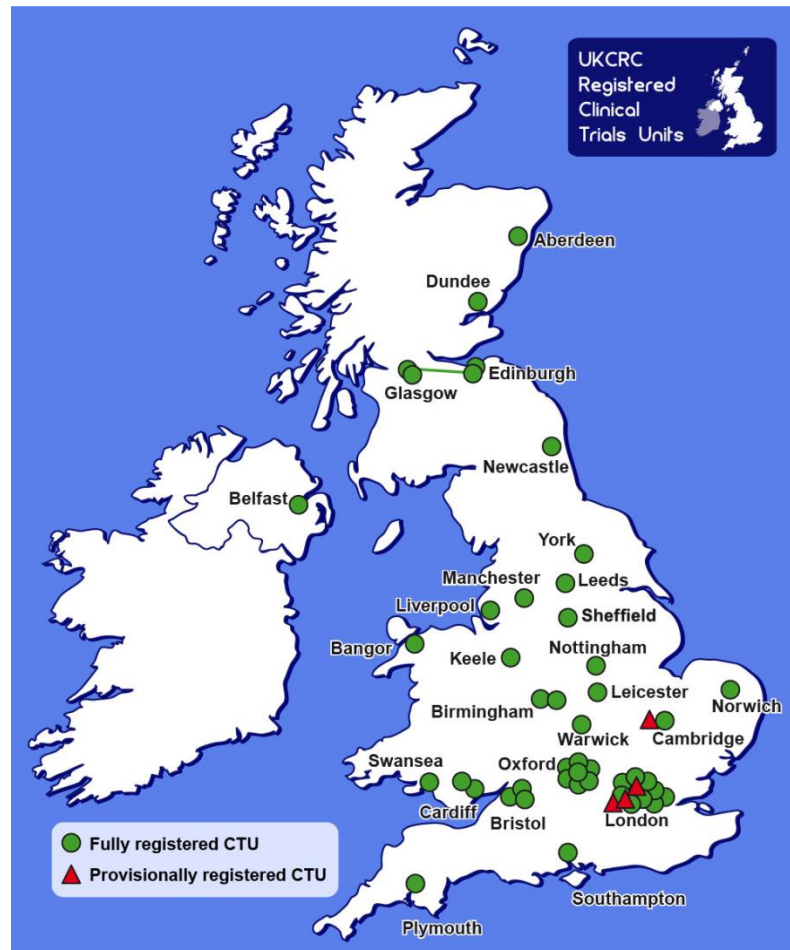# An overview of activities and opportunities for joint initiatives

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What is the UKCRC?

- **UK Clinical Research Collaboration (UKCRC)**

- An infrastructure to help clinical research centres to work together more efficiently

- http://www.ukcrc.org/

What is the UKCRC CTU network?

UKCRC Registered Clinical Trials Units

- **Network of "registered" clinical trials units (CTUs)**

- Currently 49 registered CTUs

- Most recent registration call April 2017

- http://www.ukcrc-ctu.org.uk/

What is "registration"?

- **Registered CTUs must demonstrate :**

- A track record and experience of coordinating multi-centre randomised controlled trials (phase II-IV) or other well-designed trials
- A core team of expert staff to develop studies
- Presence of robust quality assurance systems and processes (Good Clinical Practice, the NHS Research Governance Framework, Data Protection Act, MHRA…)
- Evidence of longer-term viability of capacity for trials coordination … [and] commitment from the host institution.
- Provisional registration / Re-registration

What are the advantages of registration?

- NIHR infrastructure funding

- Platform to share working practice
  - Directors
  - IT systems
  - Quality assurance
  - Statisticians
  - …

UKCRC Subgroups and Operational Groups

- Core Infrastructure & Resources
- Efficient Trial Conduct
- Industry
- Information Systems
- Insurance
- Participant Data Sharing
- Patient and Public Involvement & Engagement
- Quality Assurance
- Statistics

What do we talk about?

- Past meetings have included
  - Contents of a statistical analysis plan
  - SOPs/GCP for statisticians
  - MHRA-compliant data processing/analysis
  - The good & bad of routine data

  As well as more statistical presentations: missing data, adaptive designs, instrumental variable regression…

How does this link to the NIHR statistics group?

- At present not much

1) Restricted to clinical trials units

- So not of direct benefit to e.g. epidemiologists

2) ..and to 1-2 statisticians per CTU

- "CTU statistics lead" would feed back to CTU/stats team

3) …and to registered CTUs

- Like MRC methods hub, there is selectivity.

Barriers

- Network is primarily for its members operational benefit

- Limited funding and infrastructure

- Formal collaborative events unlikely – not in remit nor funding to offer wider outreach

- There are options, even if UKCRC doesn't lead them

Benefits

- NIHR wants methodology that improves clinical practice

- CTU involvement is two-way: can benefit project and CTU

We've been there

- How many patients does a pilot need?

- Clusters: surgeons, married couples… how should we analyse these?

- What happens when a DMEC wants to stop a trial

- Use of routine data in trials

- Issues around recruitment

- Logic models in complex interventions

- ………………………

What next?

- Make use of your local CTU (if your institution has one)

- Think about what would help a researcher improve the conduct of an RCT, and how your work might contribute

- As a network, our statisticians can share our experiences

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