MRC | Hubs for Trials Methodology Research

MRC | Biostatistics Unit

The MRC Hubs for Trials Methodology Research Network

www.methodologyhubs.mrc.ac.uk

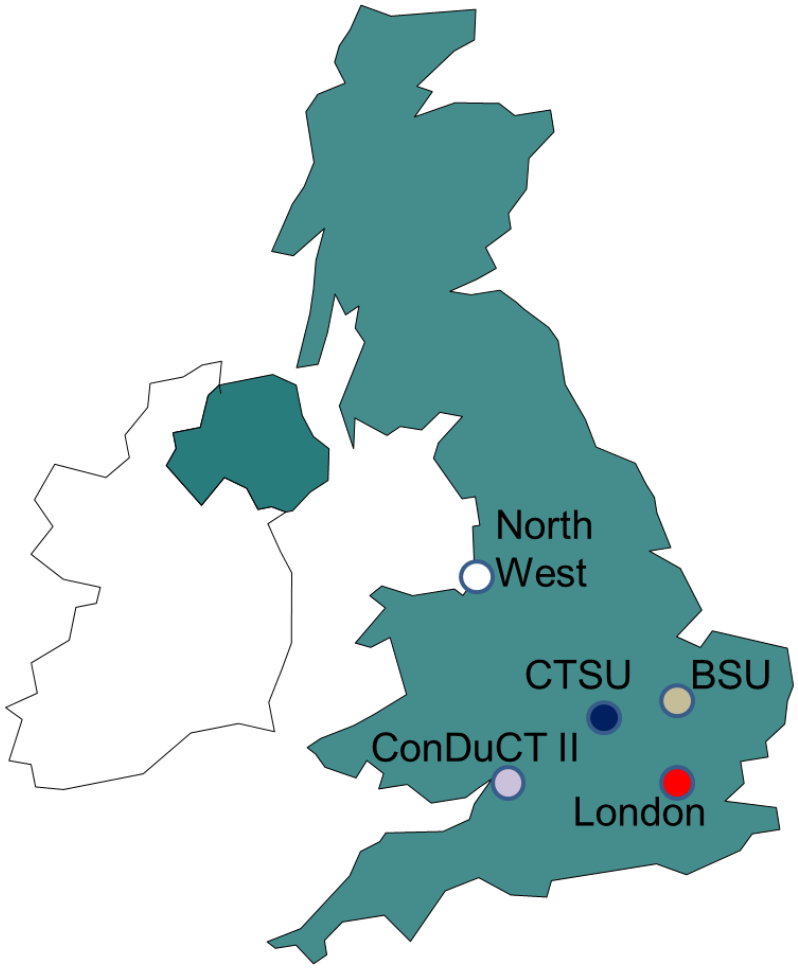
James Wason, MRC Biostatistics Unit

Overview

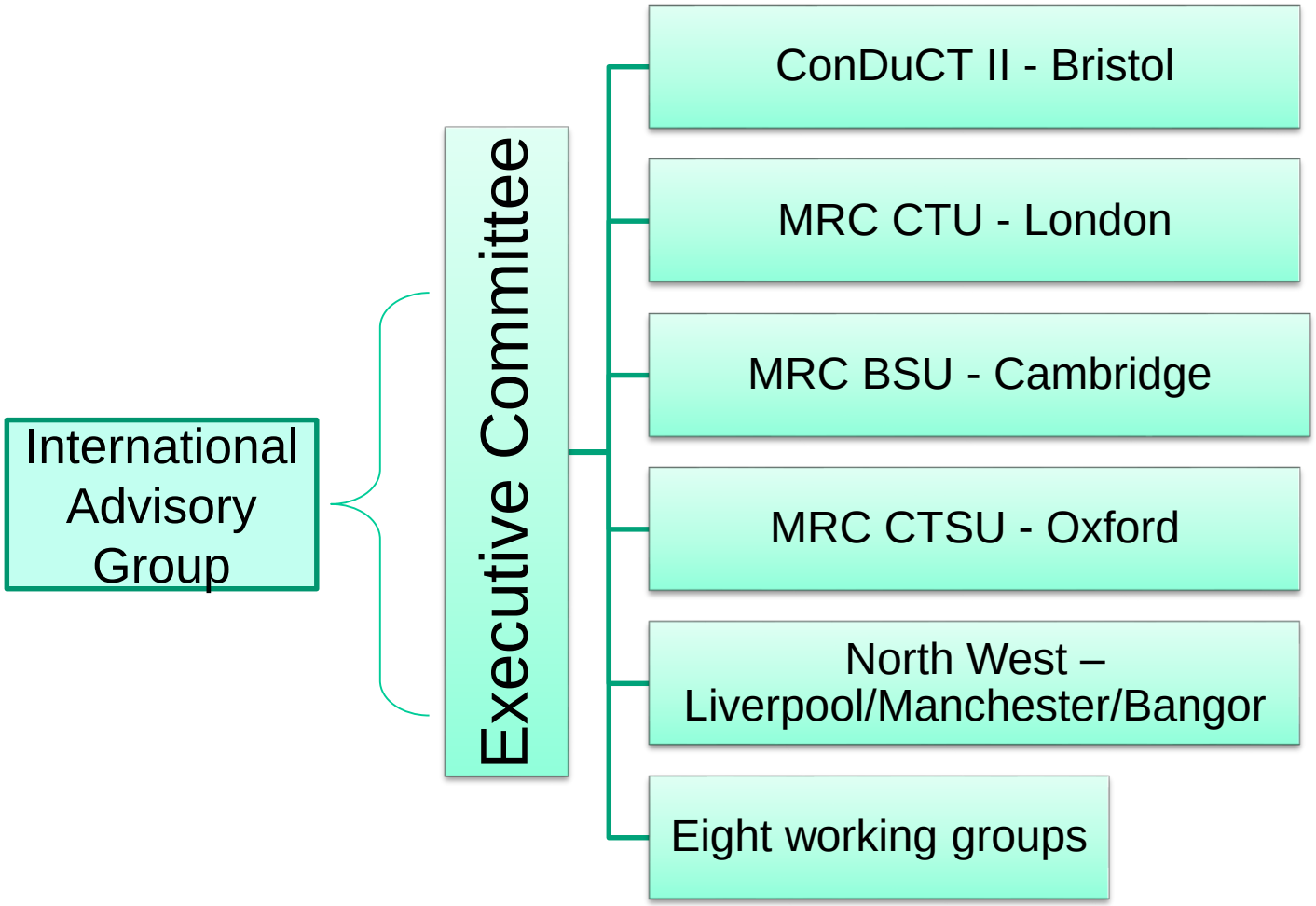
1. Background to the HTMR network.
2. Some example projects.
3. Current interactions with NIHR statistics group.
4. Ideas for the future (discussion).

History of the HTMR network

- Started as a MRC-NIHR partnership in 2008 to develop a national platform for trials methodology research.
- Eight regional hubs were funded through a £12 million investment from the MRC.
- The network itself was funded with a £1.25 million grant.
- In 2014 the network was renewed for an additional five years, with five hubs forming the network.



The HTMR Network today



Project funding

- Small investment projects
- Workshops
- Guidance
- Training

Some examples of funded projects

- Development of user-friendly web-based software for conducting Bayesian Phase I dose-escalation studies.
- Online tool for guidance on designing biomarker-guided randomised controlled trials.
- Clinical trials in small populations: methodological challenges and solutions.
- Development of guidance for statistical analysis plans for clinical trials.
- Full list on (together with final reports/publications): www.methodologyhubs.mrc.ac.uk/research/network-projects

Guidance on methodology

CONSORT PRO: Patient-Reported Outcomes

Monitoring trials efficiently: The role of central statistical monitoring

Sharing participant data:Good practice principles for sharing individual participant data from publicly funded clinical trials

CONNECT: Consent methods in paediatric emergency and urgent care trials

MAMS: Some recommendations for multi-arm multi-stage trials

NEW: Qualitative research: Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers

NEW: Surgical trials: Interventions in randomised controlled trials in surgery: issues to consider during trial design

NEW: SWATs:Online database for Studies Within A Trial (SWAT) and Studies Within A Review (SWAR)

NEW: Rheumatoid Arthritis: Consensus Decision Models for Biologics in Rheumatoid and Psoriatic Arthritis: Recommendations of a Multidisciplinary Working Party

NEW: Trial Steering Committees: Exploring the role and function of trial steering committees: results of an expert panel meeting.

NEW: Why not to use A+B design: A discussion of appropriate design for phase I dose escalation studies.

A list of some external resources of use to trialists can be found here.

Webinars

Home | Research | Workshops | Funding | Advice | Resources | About | Search

MRC Hubs for Trials Methodology Research

Resources

- Training Courses
- Workshops and events
- Webinars
  - Webinars 2014
  - Webinars 2015
- Guidance pack
- Publications
- Working Groups
- Jobs
- Studies Within a Trial
- Trials Change Lives
- External resource sites

Home / Resources / Webinars

Trial Conduct Webinars 2016

The Trials Conduct Working Group host regular webinar talks on topics pertinent to their research. You can access recordings of previous websites through the links below.

Next webinar

11 May 2016

"You have to keep your nerve on a DMC." Challenges for Data Monitoring Committees in neonatal intensive care trials: qualitative accounts from the BRACELET Study

Dr Claire Snowdon, Lecturer at the Department of Medical Statistics, London School of Hygiene & Tropical Medicine

Register to hear live. Or visit us later to listen to the recording.

Recordings 2016

11 February 2016 'Clinical trials safety and regulation: application of risk-based methodological approaches'. Christina Reith, Clinical Research Fellow, CTSU, University of Oxford

Older webinars

2015

2014


Guidance

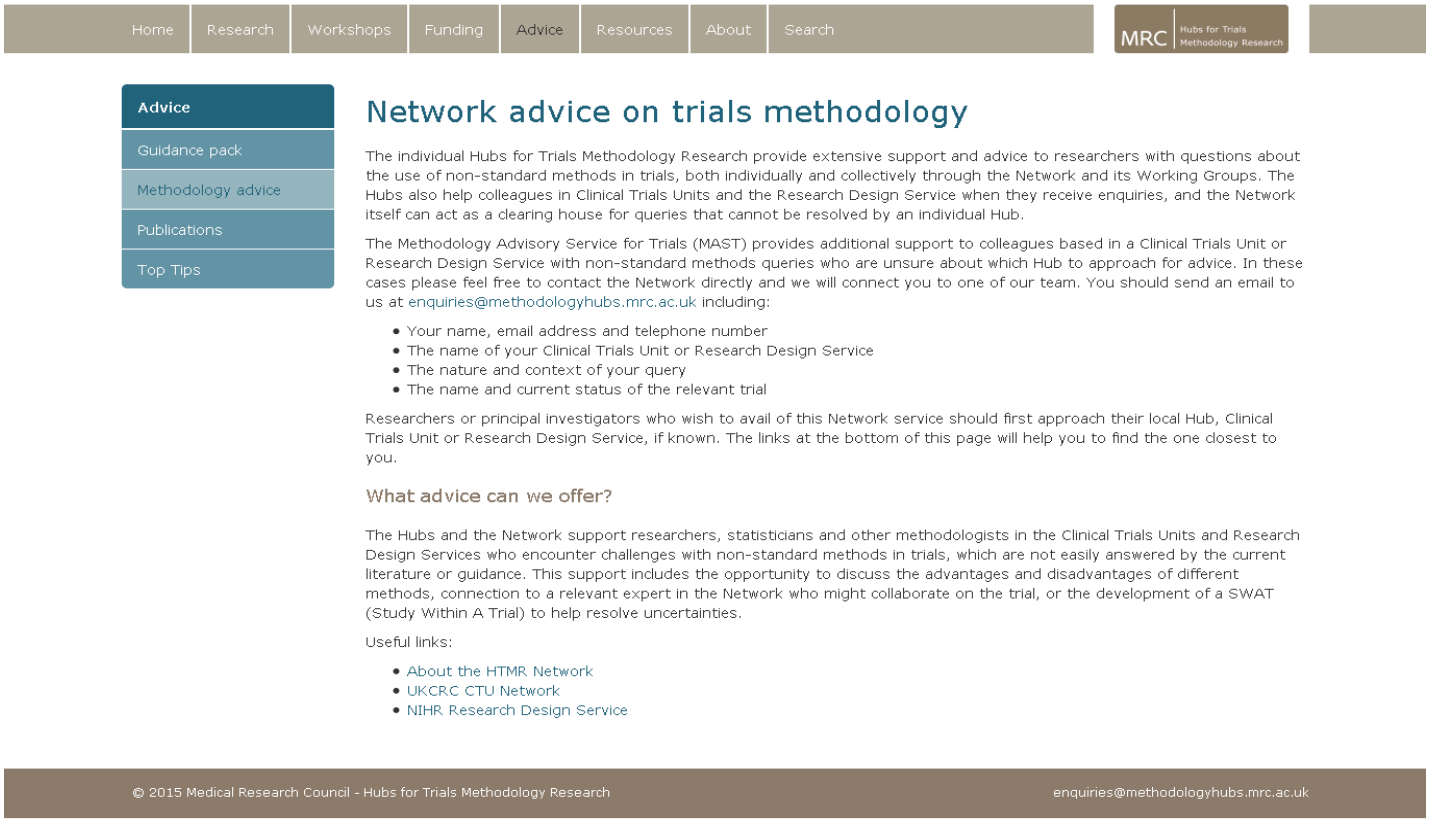

Workshops


Webinars


Working Groups


Publications

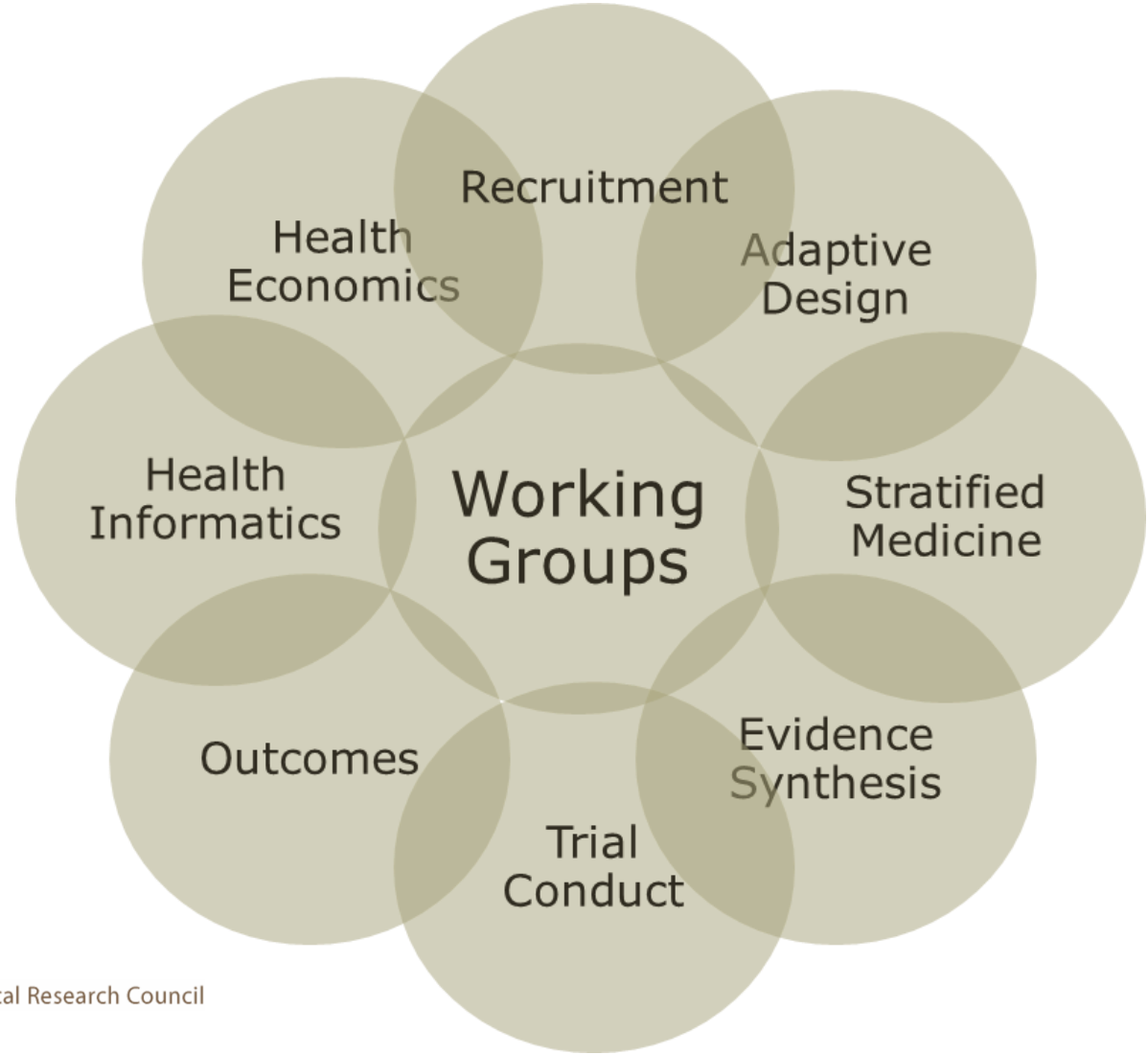
Methodology Advisory Service for trials (MAST)



Capacity Building

- Doctoral students
- Training workshops
- Conferences

Working Groups include HTMR members & others



Some current statistical focuses

- Stratified/personalised/precision medicine
- Platform trials
- Adaptive designs

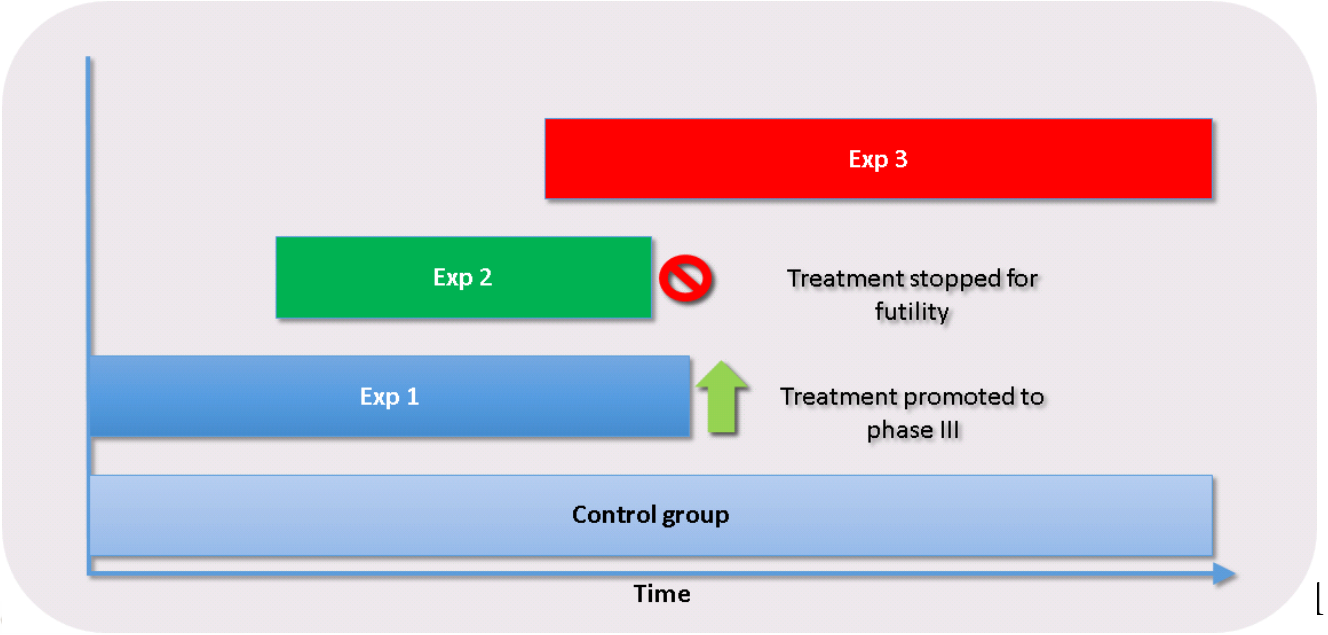
BiGTeD (**Bi**omarker **G**uided **T**rial **D**esigns) – www.bigted.org

- User-friendly online tool to inform on different trial designs.
- Easy to navigate graphical display to aid understanding and planning.
- Based on extensive literature reviews[1,2].
- Final version launch later this year.

1. Antoniou M, Jorgensen AL, Kolamunnage-Dona R. Biomarker-Guided Adaptive Trial Designs in Phase II and Phase III: A Methodological Review. PLoS ONE. 2016;11(2).
2. Antoniou M, Kolamunnage-Dona R, Jorgensen AL. Biomarker-Guided Non-Adaptive Trial Designs in Phase II and Phase III: A methodological Review. J.Pers.Med. 2017; 7(1), 1.

Perpetual platform trials

- Perpetual platform trials can continue adding in new treatments and biomarkers as they become available.
- Initial funding application can be done to test available treatments.
- New funding applications can be made to add new targeted treatments and linked biomarkers in.



Adaptive designs

- Adaptive designs have a lot of potential to improve efficiency of trials.
- However they are complicated and many more methodological approaches available than have actually been used in practice.
- The HTMR network has part-funded an ‘adaptive designs outreach officer’, Philip Pallmann (p.pallmann@lancaster.ac.uk).
- Aim of this role is to help encourage the use of suitable adaptive trial approaches.

Some current interactions

- In 2014 a meeting on early phase dose-finding trials was held, organised by Simon Bond.
- Since then considerable interaction between NIHR Statistics group early phase group and HTMR adaptive designs working group.
- Will hear more about this in Simon's talk later on.

Some current interactions

- ACE project to develop CONSORT extension for adaptive designs reporting.
- Led by Munya Dimairo (Sheffield).
- Funded by NIHR CTU support scheme and MRC HTMR.

Potential for more interactions with NIHR Statistics group?

- More contact between relevant subgroups?
- New groups to address challenges in trials?
- Joint events?

More general questions (to you)

- How can methodologists better work with NIHR statisticians?
  - to motivate new methodological work
  - to help support use of new methods in practice
- What about other (non-trials) methodology work?
- How to encourage applied statisticians to get involved in more methodology work?