Why trial methodology research?

• As understanding of diseases/treatments have evolved, so has complexity of trial methodology
• Need to understand more about how trials should be designed, conducted, analysed, interpreted, reported
• Aim to improve quality of trials

Ultimately improving human health by improving how clinical trials are carried out
Hubs for Trial Methodology Research

Promoting high quality collaborative methodological research
Providing advice on development of innovative methods
Encouraging use of most effective/appropriate methods
Facilitating shared priorities for research and guidance
Strengthening research training & capacity in methodology

– 5 ‘hubs’ in academic trial units/groups
– 9 working groups (topics)
– 400+ colleagues
– 50+ funded/partially funded/supported projects
– 25 PhD students

www.methodologyhubs.mrc.ac.uk
Working Groups

The HTMR Network has identified a need for various Working Groups to focus on strategic areas of interest to the Network and its stakeholders.

Our Hub members are key participants in our Working Groups, and membership is also open to interested individuals who are active in trials methodology research. Follow the links for more on each Group, or contact us for more information.
Guidance

- COMET: Core Outcome Measures in Effectiveness Trials
- COS-STAR and COS-STAD: Core Outcome Set-STAndards for Reporting and Core Outcome Set-STAndards for Development
- CONSORT PRO: Patient-Reported Outcomes
- RoB 2.0: Revised Cochrane Risk of Bias tool 2.0 for randomised trials.
- ORBIT: Outcome Reporting Bias in Trials
- The role of central statistical monitoring
- Good practice principles for sharing IPD from publicly funded trials
- CONNECT: Consent methods in paediatric emergency/urgent care trials
- Maximising impact of qualitative research in feasibility studies for RCTs
- Interventions in surgery RCTs: issues to consider during trial design
- Database: Studies Within A Trial (SWAT), Studies Within A Review (SWAR)
- Exploring role/function of trial steering committees
• **Optimising Recruitment**: the Quintet Recruitment Intervention
• ORRCA: Online Resource for Recruitment Research in Clinical Trials
• SOS: Search for Oversight Statisticians
• Guidelines for the Content of **Statistical Analysis Plans** in Clinical Trials
• MAMS: **Recommendations for multi-arm multi-stage trials**
• Why not to use A+B design: **Appropriate design phase I dose escalation**
• BiGTeD: **Biomarker-guided trial designs**
• Informing efficient randomised controlled trials: exploration of challenges in developing progression criteria for internal pilot studies
• MODEsT Software: (**MOdel-based Dose-Escalation Trials**)
• ISRUM: Core Items for a **Standardised Resource Use Measure**
• DIRUM: Database of Instruments for Resource Use Measurement
• **Consensus Decision Models** for Biologics, Rheumatoid/Psoriatic Arthritis
Support, training, networking

- One-to-one support for UK researchers
- Esp. challenges with non-standard methods, not easily answered by current literature/guidance
- UK workshops through network
- Open access live/recorded webinars
- Annual conference
Phase 2: Trials Methodology Research Partnership (TMRP)

More and better, larger network within & outside of UK
What might a **Global Health Trials Methodology Research Agenda** look like?

- Previous UK project identified top priorities: **methods to boost recruitment, adaptive trial designs, sample size calculations**
- 2-round LMIC survey (412/314), through **the Global Health Network**
- Wide range of roles, 80 countries (50% Africa)
- 917/1620 topics categorised into 57 (27 primary – 4 or more participants)
- Over 50% scored critically important by > 80% participants involved trial conduct

**Top priority:** appropriate choice of outcomes (developing correct objectives, standardising outcome sets, identifying patient-focused endpoints)

**Second:** methods for staff training (e.g. cost-effective purposeful, use of blended learning incorporating new technologies)

Choice of appropriate outcomes to measure, methods for pragmatic trial conduct, calculating sample size all in top 10 most important items both LMIC and UK

An online science park for global health researchers; working space for groups, mechanism for knowledge exchange, training & access to tools, templates & guidance.
Providing applications to enable & speed-up research
Regional Faculties & Workshops

Over 1M visits, 100,000 members

Workshops: Ghana
Workshops & blended-learning West/Central African, Nigerian Groups
Workshop: Tunisia
EDCTP NoEs
Khyber University: webinars
Workshop: Honduras
Workshop: Instituto de Ciencias Neurologicas Lima
South African Faculty: Workshops & blended-learning pilot study
Workshop and study: Zambia
THE SOUTH AFRICAN FACULTY OF THE GLOBAL HEALTH NETWORK BRINGS YOU 3 EXCITING EVENTS

DATA MONITORING COMMITTEES, PHARMACOVOGILANCE & VACCINE DEVELOPMENT
1-day training for clinical trial investigators & statisticians

Presented by:
- The Multi-Regional Clinical Trials Center of the Brigham and Women’s Hospital & Harvard, Division of Global Health Equity, Cambridge, Massachusetts, USA

Topics
- DMC membership & responsibilities, monitoring for safety, efficacy & futility
- Important causality definitions, distinction between cause & correlation, case studies to assess causality
- Safety reporting processes
- Vaccine development

6th November 2015, 09:00 to 16:00
(registration from 08:30)
New Learning Centre, Anatomy Building, UCT Faculty of Health Sciences, Anzio Rd, Observatory

QUALITY & RISK IN CLINICAL RESEARCH AT INVESTIGATOR SITES: ENSURING SCIENCE IS VALID, PARTICIPANTS ARE SAFE
1-day training open to ALL involved in clinical research

Speakers from:
- The Biomedical Research Centre, NIHR CRF for Experimental Medicine, Guy’s & St Thomas’ NHS Foundation Trust, King’s College & the Evelina Children’s Hospital, London, UK
- The Global Health Network, Oxford University, Oxford, UK
- University of Cape Town

Morning talks
- Risk assessment by sites
- Quality: responsibility of the whole team
- Which SOPs do you actually need?
- Global core competencies for site staff
- Organising staff training
- Internal quality control: the onus on sites to produce accurate clinical trial data

7th November 2015, 09:00 to 16:00
(registration from 08:30)
New Learning Centre, Anatomy Building, UCT Faculty of Health Sciences, Anzio Rd, Observatory

Afternoon workshops
- Assessing a study’s potential for risk
- Data management: facilitated elearning
- Practical investigational product topics
- Health & safety matters for sites
- Handling non-compliance
- GCLP: facilitated elearning
- Community health worker meet & greet

DEVELOPING THE UK RESEARCH NURSE WORKFORCE: CHALLENGES & TRIUMPHS

Lunch for clinical research nurses & nurse researchers

Paula Darroch, Nurse Manager
The Biomedical Research Centre, NIHR CRF for Experimental Medicine, Guy’s & St Thomas’ NHS Foundation Trust, King’s College & the Evelina Children’s Hospital, London, UK

Paula will describe her experience of how career development of nurses within clinical research in the UK has changed over time, & been influenced by the UK Clinical Research Network & the National Institute for Health Research

6th November 2015, 13:00 to 16:00
(registration from 12:30)
Klein Schuur, Hospital Street, Groote Schuur Hospital (next to the café)

Submit a poster about an aspect of ensuring quality research at your site & WIN A PRIZE!
No experience? Be mentored in developing your poster from idea to design by staff from Global Health Trials & UCT’s Clinical Research Centre. Have your poster printed for free

Attendance is FREE for all events. For registration (essential) or information contact tamzin@globalhealthtrials.org, or visit https://globalhealthtrials.chn.org/get-involved/south-africa

Meetings organised by the UCT-MRC Collaborating Centre for Optimising Antimalarial Therapy, UCT Division of Clinical Pharmacology in collaboration with the UCT Faculty of Health Science’s Clinical Research Centre

Thank you to the following contributors and sponsors:

[Logos of various contributors and sponsors]
How will this impact LMICs?

- New TRMP webpage on TGHN
  - Dissemination of relevant information on collaborators/collaborative opportunities, studentships, webinars, training etc.
- Potential for networking online
- Pump-priming grants, small methods research
- South African faculty workshop
  - Scope of topic
  - Case studies
  - Skills (e.g. qualitative)
- International conference
- Competition

Please keep in touch if you would like to be involved