

MRC-NIHR TMRP Trial Conduct Working Group Remit

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Objectives

The overall aim of the Trial Conduct Working Group is to facilitate networking and collaborative research across the trials methodology community. The working group will aim to provide a forum to facilitate the development of improvements across key aspects of trial conduct and will seek to minimise duplication of effort within relevant areas.

Trial Conduct is considered to cover what happens from study set-up to reporting of results. Although this can be influenced by trial design, it is not about design per se, but will consider the broader perspectives and influences (e.g. social and ethical) on trial conduct. Specific objectives of the group will be to: encourage and promote maximising value of funded studies through the use of SWATs; generate evidence to support decisions about future trial conduct; develop approaches to get evidence into practice in trial conduct; build capacity in methods research within the area of trial conduct.

The new TMRP Trial Conduct Working Group, formed from and extending the previous MRC HTMR Trial Conduct and Recruitment Working Groups, will focus activities across areas which already have significant energy and traction behind them.

Research areas to target

- **Core Training Activities** - What are the barriers and enablers for clinicians/health care professionals in helping conduct randomised trials?
- **Inclusion of underrepresented/minority groups** - What are the best approaches to ensure inclusion and participation of under-represented groups in RCTs?
- **Core Information Sets** - What information should trialists communicate to members of the public who are being invited to take part in an RCT to improve informed consent to trials?
- **Adverse event reporting** – What is the best way to define, collect, monitor and report adverse events in RCTs (with particular focus on non-CTIMPs)?

Membership

The Trial Conduct Working Group will have a tiered approach to membership (with both full and associate members) allowing members to interact with the WG in ways appropriate for their interest. For example, full members will be actively involved in WG activities through the key areas or the core strategic group (made up of co-leads, target research area leads and PPI). Associate members may prefer to receive email updates and be invited to annual summary meetings.

The group should consider members that are included in (but not limited to) the groups outlined below:

- Members of the previous MRC Hubs for Trials Methodology Research Network Trial Conduct Working Group and Recruitment Working Group;
- Staff and research students from Institutes listed as Partners in the MRC Partnership Grant;
- Patient partners and patient representatives;
- International partners interested in trial conduct.

Collaborations

Collaborations for the Trial Conduct Working Group will be explored at several levels:

- Within the immediate working group – capitalize on the merger of the two existing groups and new partners and explore opportunities to maximise collaborative activities within the new Trial Conduct Group;
- Internally within the partnership – identify overlap with other working groups and reflect on contributions of trial conduct to add value (e.g. adaptive designs, global health)
- Externally – proactively engage with others out with the Partnership (both nationally and internationally) through activities such as webinars to scope potential for collaborative working. This will go beyond academic institutions and include opportunities with industry, regulatory bodies (e.g. MHRA, HRA), and others.