UKTMN Methodology Bulletin
November 2021

Trial Methodology

What is trial methodology, and what does it mean to trial management?

The term 'methodology' is used heavily amongst the trial community, but what does it mean? And how does it affect your role within trial management?

Trials methodology research is focused on how trials are conducted. Methodological studies are carried out to find out if trial processes can be improved, for both efficiency of trial conduct and for patient benefit. Ultimately, trials methodology research aims to find out the best way to conduct trials to reduce research waste.

As trial management professionals are involved in all stages of trial conduct, their input into methodology research is invaluable.
As a trial management professional, you have a wealth of experience and ideas which can help guide methodological research studies. There are lots of opportunities to take part in research studies, which is an easy way to ensure the results of methodology research has taken into account the needs and experiences of trial managers.

Conducting, or being involved in, methodology research is a great way to develop as a professional. It increases your awareness of the best way to conduct trials, and helps to improve efficiency in the day to day management of your trials.
This bulletin has been written to give you more information about trials methodology research, and to hopefully inspire you to get involved!

Video: What is trials methodology?

in this issue

About the Trials Methodology Research Partnership

The MRC-NIHR Trials Methodology Research Partnership began in June 2019 following funding awarded by the MRC-NIHR Methodology Research Programme. The Partnership, led by Professor Paula Williamson, brings together a number of networks, institutions and partners working in trials and trials methodology research.

The TMRP partner networks are:

- The Global Health Network (TGHN)
- Health Research Board - Trials Methodology Research Network (HRB-TMRN)
- Health Data Research UK
- UKCRC Registered CTU Network
- UK Trial Managers' Network (UKTMN)

Eight working groups specialise in specific areas relevant to trial methodology. More about one of these groups, the Trial Conduct Group can be found below.

The TMRP offers an opportunity to explore new collaborations and avenues to make continued progress in advancing trial methodology, developing capacity and further reducing research waste.

https://www.methodologyhubs.mrc.ac.uk/about/tmrp/

The TMRP Trial Conduct Working Group

The overall aim of the Trial Conduct Working Group is to facilitate networking and collaborative research across the trials methodology community. Trial Conduct is considered to cover what happens from study set-up to reporting of results. Although this can be influenced by trial design, the group will consider the broader perspectives and influences (e.g. social and ethical) on trial conduct.

The group aims to:

- Develop research ideas/projects
- Identify need for practical guidance
- Develop applications for funding
- Support each other's research projects
- Propose activities for dissemination & awareness creation

The TCWG are targeting the following research areas:

- Recruitment to trials
- Retention to trials
- Qualitative research within trial conduct
- Site selection and training
- Communication with participants, sites, collaborators, funders, regulators etc.
- Data quality and monitoring
- Inclusivity

Why doing Studies Within A Trial (SWATs) is still important

Trial teams don't have a lot of evidence they can use to help them make decisions about how to do a trial. For example, trials need a retention strategy but evidence to help with putting together the actual strategy is very thin indeed. It remains thin for pretty much any trial process you can think of.

Studies Within A Trial, or SWATs, are one way to generate trial process evidence. Although the number of SWATs in the UK and Ireland was increasing just before the pandemic, anecdotal evidence suggests that this has fallen off, or at least they are not being included in trial grant applications in the numbers they once were. This is a shame because one thing the pandemic has shown us is that there are other ways to do trials but it would be good to know that these do more good than harm. High quality evidence to inform trial process decisions is always likely to be helpful and it could make the difference between a trial that answers its research question, and one that fails.

Trial managers are well-placed to spot where more evidence is needed and where a SWAT may be useful, as well as to lead the SWAT itself. SWATs can be included in a trial at any stage, from the very beginning (e.g. recruitment) to the very end (e.g. sharing results) and everything in between. Help is available too. The York Trial Forge Centre is happy to provide hands-on help, funders (especially NIHR) are still funding SWATs and Trial Forge is establishing a SWAT Network for groups doing SWATs that would like to link with others to swap ideas (https://www.trialforge.org/2021/06/swat_network/).

If you'd like to know more about SWAT priorities, get help or join the SWAT network email prometheus-group@york.ac.uk and info@trialforge.org.

ESP2

Estimating site performance

Multi-centre trials provide key evidence underpinning healthcare practice. However, they invariably take a lot of hard work and expense to complete, with some of this work and expense being devoted to sites that under-recruit. Developing practical methods to identify sites that will recruit to target would be helpful.
ESP2 aims to evaluate a guided site performance prediction tool for trial managers. The tool was developed during the initial ESP study using practical experience from trial managers.

ESP identified eight possible 'red flags' to predict recruitment failure at a site:
- previous poor site performance
- slow approvals process
- strong staff/patient preferences
- the site recruitment target
- the trial protocol and its implementation at the site
- lack of staff engagement
- lack of research experience among site staff; busy site staff.

We have used these identified flags to develop a site performance prediction tool. We hope that using this tool will improve the accuracy of trial managers' predictions about site recruitment performance, but this needs evaluation. To evaluate the tool, we need trial managers to make 1000 site performance predictions (will the site recruit to target yes or no?).

CLICK HERE TO REGISTER AND FIND OUT MORE

International Clinical Trials Methodology Conference 2022

ICTMC is the leading international platform for researchers and practitioners to present the very latest in trials methodology research. The meeting also offers valuable networking and training opportunities, with over 750 delegates from 22 countries attending in 2019.

A diverse programme will be prepared by the Scientific Committee and Education Committee, which promises to make this a highly rewarding and enjoyable meeting for all.

ICTMC will take place 3 - 6 October 2022 in Harrogate (UK)

CLICK HERE TO FIND OUT MORE

Webinars and resources

- TMRP - What is trials methodology?
- UKTMN webinars, online events and resources
- TMRP webinar recordings
- Information about TMRP Working Groups
- Trial Forge online resources
- HRB-TMRN (Health Research Board Trials Methodology Research Network, Ireland) - Online training and events