

MRC-NIHR TMRP Stratified Medicine Working Group Remit

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Objectives

Stratified (often referred to as personalized or precision) medicine has the goal of ensuring robust information is available for deciding which treatments should be given to which patients. High-quality clinical trials play a vital role in gathering this information.

The Stratified Medicine Working Group (SMWG) exists to encourage development and application of methodology for clinical trials to enable stratified medicine. Our objectives are to: encourage methodology development for stratified medicine trials through collaborative work, in particular focusing on the five areas above; increase UK capacity for methods research in stratified medicine clinical trials; disseminate novel methods to academic and industry stakeholders who may benefit from using them. In April 2019 a workshop was held to discuss methodology areas that would be a priority for the group to address.

Research areas to target

- Single-arm vs randomised studies for rare subgroups;
- More efficient use of continuous biomarker/subgroup information in trials;
- Improved stratified trial methods for chronic disease;
- Development of biomarker signatures from high-dimensional information;
- Using observational studies, registries and cohorts to design stratified trials.

Membership

We will have a steering committee consisting of up to six members including the two co-leads. This steering committee will be chosen to be diverse geographically and in expertise. The wider group will be open to any individuals who are interested in trials methodology for stratified medicine. We aim to have a membership that covers academic researchers, CTU staff, industry employees, patients with an interest in research and funders. Membership of early-career researchers and PhD students will be encouraged.

Where appropriate, subgroups will be informed to take forward particular projects or grant applications. Generally, such subgroups would have representation from one of the steering committee.

Collaborations

We are interested in developing collaborations with groups in the pharmaceutical industry and outside of the UK who are considering trials methodology in the era of stratified medicine. We are also exploring collaboration with Cancer Research UK on an agenda for methodology development for stratified cancer trials.