

## **MRC-NIHR TMRP Adaptive Designs Working Group Remit**

**Co-leads:** Thomas Jaki (Lancaster University) and Sofia Villar (University of Cambridge)

### **Objectives**

The Adaptive Designs Working Group (ADWG) works in partnership to undertake cutting edge research on the topic of adaptive designs for clinical trials, to increase uptake of adaptive methods and forge lasting collaborations. The working group links with key stakeholders, such as regulators and industry in this important area for improving the speed and efficiency of trials.

Besides undertaking research on methods for adaptive designs, our group aims to play a vital role in increasing the implementation of adaptive design methodology. The future plans for this group include continued annual meetings, strengthening the engagement with CTUs, industry and regulators and collaborative inter-partnership visits to develop novel adaptive designs.

Alongside fit for purpose research, the group is focusing its efforts on preparing tutorial papers for applied journals and mainstream medical journals; delivering presentations and lectures to raise awareness amongst patients, medical professionals and others and to increase uptake of methods amongst stakeholders; and the development of computer software to help researchers to undertake trials with adaptive designs. Moreover, it seeks to offer representation of innovative trial designs on advisory groups and within relevant stakeholder groups.

### **Research areas to target**

- Adaptive crossover designs
- Adaptive randomisation
- Bayesian adaptive designs
- Biomarker-adaptive designs
- Cluster-randomised / stepped-wedge designs
- Dose-finding and dose-ranging trials
- Group-sequential designs
- Multi-arm multi-stage designs
- Sample size re-estimation
- Trials for small populations
- Designs for trials that will run in challenging conditions

### **Membership**

Membership to the working group is open to all with an interest in research on or implementation of adaptive designs. Membership will be reviewed annually and is contingent on active participation in the group's activities.

The group is led by co-chairs Dr Sofia Villar and Prof Thomas Jaki, who together with Prof James Wason (liaison to Stratified Medicines Working Group), Dr Laura Flight (early stage researcher) and Chris Harbron (industry representative) form the steering group of the ADWG.

### **Collaborations**

The ADWG works in close collaboration with CTUs and the pharmaceutical industry and seeks to strengthen links with other important stakeholders such as regulators and patients. Moreover, it works in close collaboration with the Stratified Medicines Working Group.