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Workshop 3.1 Overview

W3.1: Statistical and practical aspects of the design and analysis of Multi-Arm Multi-Stage (MAMS) Platform Trials

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This workshop consists of three main sessions. The first session of the workshop provides an overview of the design issues involved in MAMS platform protocols. The second session explores the issue of adding new research arms and the control the operating characteristics in this case. The final session explores MAMS designs in which research arms are ranked and selectively chosen to continue. Examples of past and ongoing MAMS trials will be used throughout to motivate and discuss the relevant design issues in the MAMS platform trials.

Typically, in these protocols, randomisation is stopped to insufficiently active treatment arms at interim stages and new research arms can be added during the course of the trial. MRC Clinical Trials Unit at UCL is a leader not only in the design, but also in implementation and analysis of such trials. The MAMS approach is one of the few adaptive designs being deployed in a number of trials and across a range of disease in the phase III setting, including STAMPEDE (prostate cancer), TRUNCATE-TB (TB), RAMPART (renal cancer), and ROSSINI-II (wound surgery).

This workshop is aimed at trial statisticians, regulators and clinicians who want to understand more about the design and analysis of multi-arm multi-stage (MAMS) platform trials, or those who are new to the area.

The workshop aims to help participants:

- understand the motivation behind these designs
- learn how to choose the design parameters and stopping boundaries, both for lack-of-benefit and efficacy
- learn how to deal with overwhelming efficacy
- learn how to add a new research arm, and how to control Type I and II error rates in both pre-planned and unplanned addition of a new research arm
- learn about MAMS designs in which arms are ranked and selectively chosen to continue