

Monday 22 July 2024

15:30-17:00 Invited Session 3 (Main Room)

Innovative Complex Adaptive Designs for Confirmatory Clinical Trials with Multiple Primary Research Questions (Chairs: Babak Choodari-Oskooei and Ian White)

Graph Based Adaptive MAMS Designs for Trials with Multiple Endpoints

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The graph-based approach is an extremely powerful and intuitive tool for designing trials that have multiple endpoints. This method enables a study team to represent clearly its priorities for hierarchical testing of the endpoints, and for propagating the available type-1 error from rejected hypotheses to hypotheses yet to be tested. While originally developed for single stage non-adaptive designs it has recently been extended to two-stage designs that permit adaptive sample size re-estimation, dropping of hypotheses, and changes in the hierarchical testing strategy at the end of stage one. Two approaches are available for preserving the family wise error rate (FWER) in the presence of these adaptive changes; the p-value combination (PV) method, and the conditional error rate (CER) method. In this session we will present the statistical methodology underlying each approach and will compare the operating characteristics of the two methods in a large simulation experiment.