

DAY THREE: WEDNESDAY 25TH JULY 2018 – WORKSHOP FOUR

Time	Workshop Four: Clinical Trials
8:00 – 8:30 am	Registration and coffee
8:30 – 9:15 am	SESSION 1: Introduction to clinical trials <i>Chair: Professor Carmel Hawley</i> Developing a question Why trials are essential Feasibility and pilot studies
9:15 - 10:15 am	SESSION 2: Trial Designs <i>Chair: Ms Elaine Pascoe</i> Parallel group, cross-over, and multi-arm factorial designs Cluster designs; superiority and non-inferiority objectives
10:15 - 10:30 am	Morning tea
10:30 - 11:30 am	SESSION 3: Trial Outcomes <i>Chair: Dr Magid Fahim</i> Developing an outcome Surrogate and composite outcomes Types of outcome measures and statistical structures
11:30 – 12:30 pm	SESSION 4: Randomization <i>Chair: Associate Professor Mark Chatfield</i> The need for random assignment Methods of randomisation, minimisation, blinding and allocation concealment
12:30 – 1:00 pm	Lunch
1:00 – 2:00 pm	SESSION 5: Sample size determination <i>Chair: Ms Elaine Pascoe</i> Calculating study size for common outcomes and designs Assumptions, adjustments for loss to follow-up and non-compliance
2:00 – 3:00 pm	SESSION 6: Adaptive designs <i>Chair: Associate Professor Stephane Heritier</i> Inefficiencies in traditional designs, types of adaptations, multi-arm Bayesian adaptive designs
3:00 – 3:15 pm	Afternoon Tea
3:15 – 4:00 pm	SESSION 7: Data monitoring <i>Chair: Professor Carmel Hawley</i> Interim monitoring of safety and efficacy data Data and safety monitoring boards
4:00 – 4:30 pm	SESSION 8: Running a clinical trial <i>Chair: Dr Magid Fahim</i> Real life considerations in starting and running a clinical trial
4:30 pm	Workshop close