

30 April 2024 – Workshop Day 1

Venue: The Elwin Room, Bath Royal Literary and Scientific Institute, Bath, BA1 2HN



UNIVERSITY OF
BATH

09:00 – 09:05 Arrival & Welcome

09:05 – 10:20 Session: **Practical Implementation of Biomarker-driven Clinical Trials**

Juanita Lopez | Drug Development Unit, The Institute of Cancer Research, UK

Horses, Zebras and Unicorns

Nurulamin Noor | Department of Medicine, University of Cambridge, UK

PROFILE: a randomised, biomarker-stratified clinical trial of treatment strategies in newly-diagnosed Crohn's disease

Alexander Ooms | Centre for Statistics in Medicine, University of Oxford, UK

Some examples of innovative trial design in real world practice

10:20 – 10:50 Coffee break

10:50 – 12:30 Session: **The Quest for Precision Medicine**

Chris Hurt | Southampton Clinical Trials Unit, University of Southampton, UK

Sample size re-estimation in a precision medicine trial

Haiyan Zheng | Department of Mathematical Sciences, University of Bath, UK

Design and analysis of basket trials considering pairwise data commensurability

Luke Ouma | AstraZeneca, UK

Bayesian modelling strategies for borrowing of information in randomised basket trials

Michael Grayling | Johnson & Johnson, UK

Umbrella designs: Past, present and future implementations

12:30 – 13:30 Lunch

13:30 – 14:45 Session: **Dose-finding Trials Using Biomarker Information**

Pavel Mozgunov | MRC Biostatistics Unit, University of Cambridge, UK

Using ctDNA as a novel biomarker of efficacy for dose-finding designs in oncology

Peter F. Thall | MD Anderson Cancer Center, The University of Texas, US

Optimizing NK cell doses for heterogeneous cancer patients based on multiple event times

Ruitao Lin | MD Anderson Cancer Center, The University of Texas, US

DEMO: Dose Exploration, Monitoring, and Optimization using a biological mediator for toxicity, response, and survival

14:45 – 15:15 Coffee break

15:15 – 16:15 Keynote Speech

J. Jack Lee | MD Anderson Cancer Center, The University of Texas, US

Overview of augmenting randomized-controlled trials by incorporating information across multiple external sources of the control arm

16:15 – 16:30 Stretch break

16:30 – 17:00 Panel Discussion: **Borrowing of Information & Statistical Tools.**



01 May 2024 – Workshop Day 2

Venue: The Elwin Room, Bath Royal Literary and Scientific Institute, Bath, BA1 2HN



UNIVERSITY OF
BATH

09:00 – 09:05 Arrival & Welcome

09:05 – 10:20 Session: Statistical Analysis of Basket, Umbrella, and Platform Trials

Lucinda Billingham | CRUK Clinical Trials Unit, University of Birmingham, UK

Dealing with challenges emerging during recruitment in the umbrella-basket DETERMINE trial

Satoshi Hattori | Department of Biomedical Statistics, Osaka University, Japan

Frequentist analysis of basket trials with one-sample Mantel-Haenszel procedures

David Robertson | MRC Biostatistics Unit, University of Cambridge, UK

Online error rate control for platform trials

10:20 – 10:50 Coffee break

10:50 – 12:30 Session: Practice and Perspectives on Innovative Trial Designs

Philip Pallmann | Centre for Trials Research, Cardiff University, UK

Venturing into non-cancer territory: a tale of two baskets

Paola Berchialla | Department of Clinical and Biological Sciences, University of Torino, Italy

Enhancing Bayesian two-endpoints adaptive design with semiparametric priors

Tim Friede | Department of Medical Statistics, University Medical Center Göttingen, Germany

Use of short-term outcomes in adaptive seamless designs with treatment or subgroup selection

Julia Saperia | Medicines and Healthcare products Regulatory Agency, UK

Complex trial designs at the MHRA

12:30 – 13:30 Lunch

13:30 – 14:45 Session: Confirmatory Adaptive Designs with Multiple Comparisons

Chris Jennison | Department of Mathematical Sciences, University of Bath, UK

Designing a multi-test multi-stage clinical trial

Thomas Burnett | Department of Mathematical Sciences, University of Bath, UK

Optimising subgroup selection in two-stage adaptive enrichment and umbrella designs

Nigel Stallard | Division of Health Sciences, University of Warwick, UK

Confirmatory adaptive enrichment designs with a continuous biomarker

14:45 – 15:15 Coffee break

15:15 – 16:05 Session: Talks by Student Awardees

Lou E. Whitehead | Newcastle University, UK

Bayesian sample size determination using robust commensurate priors with interpretable discrepancy weights

Emily Alger | The Institute of Cancer Research, UK

U-PRO-CRM: Designing patient-centred dose-finding trials with patient-reported outcomes

16:05 – 16:30 Panel Discussion: Master Protocols for Precision Oncology and Beyond

16:30 – 17:00 Closing remarks & Collaboration opportunities.



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