

2021 Summer School

Join us online for two weeks of half-day workshops.

Week One: Multiple Imputation

Introduction to Multiple Imputation for missing data (15 & 16 February)

Sensitivity analyses to departures from the 'missing at random' assumption (17 February)

Multiple Imputation for longitudinal data (18 & 19 February)

Presented by: Dr Cattram Nguyen (Convenor), Prof Katherine Lee, Prof Julie Simpson, Prof John Carlin, Dr Margarita Moreno-Betancur, Dr Rheanna Mainzer, Dr Ghazaleh Dashti, Dr Anurika De Silva, Ms Rushani Wijesuriya, Ms Melissa Middleton and Ms Jiaxin Zhang.

Multiple imputation has become a de facto standard for handling missing data in epidemiological and clinical research. With a combination of lectures and computer practicals (Stata and R), this workshop will cover advanced topics in multiple imputation that are critical in modern research studies.

Week Two: Modern Concepts in Clinical Trials

Introduction to Adaptive Trial Designs (22 February)

Practical approaches to Adaptive Trial simulation (23 & 24 February)

Clarifying clinical trial aims and analysis using the estimands framework (25 February)

Presented by: Prof Katherine Lee (Convenor), Dr Julie Marsh, Prof Leonid Churilov, Dr Robert Mahar, Ms Sabine Braat, Dr Kaushala Jayawardana and Mr Michael Dymock.

Trialists are increasingly turning to designs that can adapt to internal evidence or emerging external factors as the study progresses. This series of workshops provides a comprehensive manual of "How to implement an adaptive trial"; initially using lectures for a nontechnical overview and later computer practicals in both R and Stata to design and implement a simple parallel group design. There will also be a half day workshop introducing the estimand framework (ICH E9 (R1), 2019), which links the estimates of the treatment effect to the trial's objectives, accounting for events that may occur during the trial.

Book Online Now

vicbiostat.org.au



Introduction to Multiple Imputation for Missing Data

Monday 16th and Tuesday 17th February, 1:30-5pm AEDT

Registration fee: Standard \$400 | Student \$280 | [Book online now](#)

This workshop is an introduction to multiple imputation and the practical issues faced by researchers wishing to apply this method. In particular, the course focuses on understanding when multiple imputation is likely to produce substantial gains over a standard complete case analysis, and on the decisions faced when developing an imputation model, once it has been decided that multiple imputation is appropriate.

We provide a detailed introduction, with practical computing exercises on how to perform analyses using multiple imputation in Stata and R. The application of multiple imputation is illustrated with two case studies, in which the decisions required for implementation of the method are examined, highlighting the potential benefits as well as limitations of multiple imputation.

Sensitivity analyses to departures from the ‘Missing at Random’ Assumption

Wednesday 18th February, 1:30-5pm AEDT

Registration fee: Standard \$200 | Student \$140 | [Book online now](#)

Standard implementations of multiple imputation are only guaranteed to provide unbiased results under the so-called “missing at random” (MAR) assumption. This roughly means that the chance of a value being missing does not depend on the value itself, given other observed data. It is therefore important to assess the plausibility of this assumption and, given that it is not testable, to perform sensitivity analyses considering scenarios where MAR does not hold (“missing not at random”—MNAR—scenarios). This workshop discusses approaches to examining the plausibility of the MAR assumption, and describes an extended multiple imputation strategy that can be used to conduct such sensitivity analyses.

Multiple Imputation for longitudinal data

Thursday 19th and Friday 20th February, 1:30-5pm AEDT

Registration fee: Standard \$400 | Student \$280 | [Book online now](#)

Longitudinal studies, collecting data from individuals over time, are central in modern health and medical research. However, the prolonged observation of individuals exacerbates the risk of missing data. While multiple imputation methods for handling missing data in multiple variables are widely available in mainstream statistical software, there are important considerations, both computational and conceptual, regarding their use in the longitudinal setting. Furthermore, specialised approaches have recently been developed. Over two days, we will review the concepts and methods available for multiple imputation of longitudinal data and provide guidance on good practice. Day 4 (Thursday 19th) will provide an overview of longitudinal data analysis and methods for imputing longitudinal data in “wide” format (Stata/R). Day 5 (Friday 20th) will focus on multiple imputation methods for longitudinal data in “long” format (available in R only).

Prerequisites: Participants will require a sound working familiarity with Stata or R, and with statistics to the level of multivariable logistic regression models for all three workshops.



Introduction to Adaptive Trial Designs

Monday 22nd February, 1:30-5pm AEDT

Registration fee: Standard \$200 | Student \$140 | [Book online now](#)

This workshop will provide an overview of adaptive designs for clinical trials with an emphasis on practical examples. Topics covered will include common adaptive trial designs, defining criteria for design adaptation, and an overview of conducting sample size calculations and interpreting trial operating characteristics for such studies. We teach these methods with a focus on simulation-based design.

This half-day workshop will cover why, how, who and when to run an adaptive trial while maintaining trial integrity. It is designed for participants with some knowledge of the design, analysis, or implementation of clinical trials within any discipline.

Practical approaches to Adaptive Trial Simulation

Tuesday 23rd and Wednesday 24th February, 1:30-5pm AEDT

Registration fee: Standard \$400 | Student \$280 | [Book online now](#)

Join us for an intensive workshop where you will take away the knowledge and practical skills for simulating simple adaptive trials using Monte Carlo methods. Topics include defining the inputs and outputs needed for trial simulation, and defining plausible trial scenarios for evaluation of decision quantities, thresholds and timing. Trial simulations will be generated and demonstrated using FACTS, a commercial software package, R and Stata, and graphical summaries will be used to aid communication of simulation outputs. We teach these methods focusing on a 2-arm parallel group study with adaptations based on frequentist and Bayesian methods.

This workshop will cover how to generate trial simulations to support the design of a simple adaptive trial.

Prerequisites: Participants will require a sound working familiarity with Stata or R and some knowledge of decision criteria in adaptive trials (e.g. content covered in the Overview of Adaptive Trial Designs workshop) for this workshop.

Clarifying clinical trial aims and analysis using the estimands framework

Thursday 25th February, 1:30-5pm AEDT

Registration fee: Standard \$200 | Student \$140 | [Book online now](#)

Clinical studies aim to quantify the treatment effect associated with the primary study question. Estimating this treatment effect in a randomised controlled trial can be challenging in the presence of post-randomisation events such as use of rescue medication, switching between treatment arms, or missing data. These issues may lead to difficulties in the interpretation of the treatment effect estimate and affect the validity of the study findings. The estimands framework, presented in the International Council for Harmonisation E9 (R1) Addendum, bridges the gap between the study objectives and the statistical analysis. It adds clarity to trial objectives, informs the study design and data collection, and determines the choice of statistical analysis methods. This half-day workshop will cover why, how, who and when to define and document estimands based on internationally agreed guidelines. It is designed for participants with some knowledge of implementing a clinical trial within any discipline. Participants will workshop estimands within cross-disciplinary breakout groups.

