

An intermediate/advanced applied course in

(i) Methods for interim analysis of controlled studies;

(ii) Equivalence / Non-Inferiority Trials

12th & 13th October 2009

A Course in the Design and Analysis of

(i) Methods for interim analyses of controlled studies

(ii) Equivalence / Non-inferiority Trials

is an intensive course aimed at biostatisticians and health professionals with quantitative skills.

The course introduces participants to the methodological and practical issues facing researchers when designing and analysing interim analyses (i.e. boundaries and stopping rules) and Equivalence / Non-Inferiority trials.

Who should attend?

The course is ideally suited for biostatisticians working in clinical and health research areas. Health professional with strong quantitative skills may also find this course appropriate. Participants should be familiar with hypothesis testing, confidence intervals, and sample size calculations and power. Clinicians with a strong understanding of these concepts may also find this course of value.

Due to the nature of this course, only a limited number of people will be able to participate. We encourage early registrations so that you do not miss out!

Course emphasis

The course is designed to discuss both methodology and application of stopping rules to trials at interim analyses, and in the design and analysis of Equivalence / Non-Inferiority trials. There is emphasis on the practical experience of performing analyses with discussion about advantages and pitfalls for different approaches and the interpretation of results. The course will be presented at an intermediate/advanced level.

Proposed Topics

(i) Interim analyses; formal stopping rules and assessment of evidence

- Stopping rules including O'Brien-Fleming, Haybittle-Peto and Pocock
- Comparison of different approaches
- Alpha-spending methods
- Applications to different outcome measures; continuous, binary and time to event and regression models
- Stopping for futility – curtailment

(ii) Equivalence / Non-inferiority Trials

- Confidence interval approach
- Sample size considerations
- Non-compliance and intention to treat
- Validity and slippage
- Choice of margin
- Closed testing procedures
- Testing for non-inferiority in superiority designs

Dates

Full Course: Monday 12th - Tuesday 13th October 2009
(2 days)

Methods for interim analyses – Monday 12th October 2009
Equivalence / Non-inferiority - Tuesday 13th October 2009

Comprehensive notes and relevant software will be supplied.

Course fees (\$AUD, includes GST)

	Day 1 Interim Analysis	Day 2 Equivalence	Days 1&2
Early-bird rate	\$770	\$770	\$1,150
Standard rate	\$850	\$850	\$1,300

- Early-bird registrations must be received by close-of-business (5:00pm Sydney) on 28th August.
- Full payment must be received by close-of-business (5:00pm Sydney) by 25th September.
- Confirmation of registration will only occur with full payment.

Venue

The course will be held at the Citigate Central Sydney Hotel, 169-179 Thomas Street, Haymarket. This is ideally located in Sydney's CBD, with ready access to public transport & accommodation. Excellent restaurants and cafes are located at nearby Chinatown and Darling Harbour.

Morning tea, Lunch & Afternoon tea provided each day.

Laptops

Participants should bring their own laptop. User-friendly software will be provided as part of the course.

Note: If participants are unable to provide their own laptop, please contact us and we will try to make alternative arrangements.

Further Information

Tel: +61 2 9562 5000 ask for Kew Flood

E-mail: kew@ctc.usvd.edu.au