



Introduction to clinical trials: Methods and Design (Day 1-2) Trial Management (Day 3-4)

1st – 4th December 2009

A 4 day course covering an introduction to clinical trials methods, design and management.

COURSE FORMAT

This course combines two 2 day courses which encompass a complete introduction to clinical trials. There will be information sessions and interactive small group workshops throughout the 4 days. Participants will have the opportunity to learn from the NHMRC CTC presenters and also to gain insights into the conduct of clinical trials from the other participants in the practical workshops.

COURSE INCLUSIONS

Course fees include a course manual, morning and afternoon refreshments and lunch. A certificate of attendance will be provided to participants who complete a course.

WHO SHOULD ATTEND

This is an introductory course aimed at clinical trials staff that are new to the field. Course content delivery is aimed at attendees having minimal-intermediate clinical trials knowledge or experience.

For more information on whether this course is appropriate for you, please contact:

courses@ctc.usyd.edu.au

CONTENT FOR DAYS 1-2 ON TRIAL METHODS AND DESIGN

- Rationale and design
- Randomisation and Generalisability
- Sample size and Power
- Comparing groups
- Concepts of Multiplicity
- Interim analyses and stopping rules

CONTENT FOR DAYS 3-4 ON TRIAL MANAGEMENT

- Protocol development
- Ethics, regulatory approval and research governance
- Safety reporting
- CRF design and data management
- Clinical trial management principles
- Auditing and monitoring
- Biomarker and translational research

VENUE Law Building
Sydney University
Eastern Avenue
Camperdown, 2006

COST \$ 850 for 1 course (2 days)
\$ 1450 for full course (4 days)

Registrations close on the 20th November, 2009.