Introduction to Clinical Trials:  
Methods and Design (Days 1-2)  
Trial Management (Days 3-4)  
Monday 22nd - Thursday 25th November 2010

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

Workshop Faculty, Venue & Times
The workshop faculty based at the NHMRC Clinical Trials Centre has extensive experience and expertise in the development and management of clinical trials, teaching clinical trials methods, statistical design and analyses.

Law Building, Room 107, University of Sydney  
Eastern Avenue, Camperdown, 2006

The registration desk will be open from 8:30am, with a prompt start time of 8:50am. Each day approximately finishing time of 5pm.

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

COST
$ 900 for 1 course (2 days)  
$ 1500 for full course (4 days)

A copy of Interpreting and Reporting Clinical Trials, A guide to the CONSORT statement and the principles of randomised controlled trials. Authors Anthony Keech, Val Gebski and Rhana Pike will be included in course fee.

Registrations close on the Friday 12th November, 2010.

Further Information
NHMRC Clinical Trials Centre  
courses@ctc.usyd.edu.au  
http://ctc.usyd.edu.au