Designing & Conducting Clinical Trials

With Professor James Talcott from the Harvard Medical School

February 2008

***Designing & Conducting Clinical Trials* is a 3 to 5 day intensive course.**

The course introduces participants to the theoretical and practical issues facing clinical researchers who will learn how to conceptualise, plan, develop and execute effective clinical trials.

Who should attend?

The course is ideally suited to clinical investigators with an interest in clinical trials; suitably qualified individuals pursuing a career in clinical research and physicians with a serious interest in becoming more actively involved in clinical research. All participants will be expected to use the course syllabus to present a trial design in order to complete the course.

What should you bring?

Participants should bring a concept for a study or a protocol currently being written. This will be developed during the course leading to appraisal of an outline protocol on day 3 and presentation on day 5. Participants may attend the intermediate component alone or the full 5 day course (note there is a day off between days 3 and 4).

Advanced course

Participants with previous experience/skills in clinical trials or clinical epidemiology (such as a Masters Degree in Clinical Epidemiology or Biostatistics) may apply to attend only the advanced course starting on day 3. These participants will be required to submit a protocol outline (template to be provided) at the start of day 3.

About the Presenter

James A. Talcott, M.D., S.M., is an Associate Professor of Medicine at Harvard Medical School and Director of the Centre for Outcomes Research at the Massachusetts General Hospital Cancer Centre.
Dr Talcott received Bachelor's degrees from Stanford University (Biology) and the University of Oxford (Philosophy, Politics and Economics), his medical degree from Yale University and his Master of Science in Epidemiology from the Harvard School of Public Health. He received clinical training in Internal Medicine at the University of Washington in Seattle, including Chief Resident in Medicine at Harborview Hospital in Seattle.
His research activity focuses on clinical epidemiology, outcomes, technology assessment and racial and other socioeconomic disparities in cancer patients. Harvard is a world leader in clinical trials and for a number of years Professor Talcott has led a renowned practice-based intensive clinical trials training course for physicians already in the industry wishing to participate in clinical trials and students undertaking post-doctoral work at Harvard.

This course is convened by the NHMRC Clinical Trials Centre together with Professor James Talcott from The Harvard Medical School in collaboration with:

- Cancer Institute NSW
- The George Institute for International Health
- National Centre in HIV Epidemiology and Clinical Research
- St Vincent's Clinical Trials Centre
- Woolcock Institute of Medical Research

An initiative sponsored by the NSW Clinical Trials Business Development Centre and the NSW Office for Science and Medical Research.

Dates

Full Course: Thursday 7 February
to Tuesday 12 February 2008 (5 days)

Intermediate component (3 Days)
Thursday to Saturday, 7-9 February 2008

Advanced component (3 days)
Saturday, Monday & Tuesday
9, 11-12 February 2008

Note: The advanced course starts on Day 3 of the 5 day course. Saturday 9 February overlaps both courses.

Course fees

	Days 1-5 Full	Days 1-3 Intermediate	Days 3-5 Advanced
Early-bird rate	$2,000	$1,500	$1,800
After 8 January	$2,500	$1,800	$2,000

Full scholarships are offered and information will be available on the website. Scholarship applications must be lodged by Monday, 8 January 2008. Successful candidates will be notified in mid-January.

Venue

Day 1: Australian Graduate School of Management
1 O'Connell Street, Sydney
Days 2-5: NSW Trade and Investment Centre
Level 47, MLC Centre, Martin Place, Sydney

Further Information

Tel: +61 2 9562 5000
E-mail: clinicaltrialsprogram@ctc.usyd.edu.au
Website: www.ctc.usyd.edu.au

Designing & Conducting Clinical Trials

Our Hosts

Professor Anthony Keech, the course convenor, is Deputy Director of the NHMRC Clinical Trials Centre, Professor of Medicine, Cardiology and Epidemiology, Department of Medicine, University of Sydney and a practising Consultant Cardiologist at Royal Prince Alfred Hospital in Sydney.

John Simes is the Foundation Director of the NHMRC Clinical Trials Centre, Professor of Clinical Epidemiology in the School of Public Health at the University of Sydney, and a specialist medical oncologist at Royal Prince Alfred Hospital. He holds an MD from The University of Sydney.

The **NHMRC CTC**, at the University of Sydney is a clinical research organisation that runs large multi-centre clinical trials, takes part in trials of national and international collaborative trial groups and contributes expertise to trials run by others. It also undertakes research into trial methods, reviews evidence from completed trials and administers the Australian Clinical Trials Registry.

Our Speakers

Professor James Bishop is a former Fullbright Scholar and cancer specialist. Professor Bishop has a long history of participation in work on clinical trials for leukaemia, breast and lung cancer therapies and running major cancer centres.

The **Cancer Institute NSW** is Australia's first statewide, government supported cancer control agency. "We are driving innovation in cancer care in New South Wales by working in partnership with the leaders in our field to deliver the best cancer results for the people of New South Wales".

Sean Emery PhD is Head of the Therapeutic and Vaccine Research Program at the National Centre in HIV Epidemiology and Clinical Research. He is also Associate Professor, Faculty of Medicine, the University of New South Wales.

The **National Centre in HIV Epidemiololgy and Clinical Research** (NCHECR) at the University of New South Wales is a leading biomedical research centre focusing on HIV, viral hepatitis and sexually transmitted infections. The NCHECR leads and coordinates multicentre, multidisciplinary research throughout Australia, the SE Asian region and elsewhere in the world.

Stephen McMahon is Principal Director of The George Institute for International Health, Professor of Cardiovascular Medicine and Epidemiology at the University of Sydney and holds a number of honorary professorial and international appointments.

The George Institute for International Health seeks to improve global health through best practice research, knowledge sharing and collaboration. It has launched research, policy and training initiatives in more than 40 countries and has led landmark global clinical trials studies.

Ken Williams is Deputy Director, Department of Clinical Pharmacology and Toxicology, St Vincent's Hospital Sydney. He is the Executive Officer, Post Graduate Studies in Drug Development Programs, UNSW, and Manager, St Vincent's Clinical Trials Centre.

St Vincent's Clinical Trials Centre (CTC) supports Phase I (including first time in human studies) through Phase III studies. Established over 10 years ago, the CTC has supported over 100 trials across a range of disciplines.

Our Sponsors

The NSW Clinical Trials Business Development Centre was established in 2007 as the first point of contact for sponsors wishing to find out what Sydney offers for developing and conducting clinical trials. The centre has access to outstanding infrastructure for conducting trials and strategies tailored for product research and development for pharmaceutical, biotechnology and medical device companies.

Working closely with business, the higher education sector and research community, the **NSW Office for Science and Medical Research** promotes growth and innovation in science and medical research to achieve better economic, technological, health and environmental outcomes for the people of New South Wales.

Designing & Conducting Clinical Trials
Program Outline

Day 1 Thursday 7 February	Day 2 Friday 8 February	Day 3 Saturday 9 February		Day 4 Monday 11 February	Day 5 Tuesday 12 February
Asking the research question	**Developing the research programme and understanding obligations**	**Clinical trial management: the research tasks** *Submission of protocol outline*		**Finalising your protocol and getting funded**	**Further considerations**
Day 1 welcome Introduction to clinical research Rationale and design of clinical trials Randomisation **(PRACTICAL SESSION)**	Regulatory principles and requirements Ethical principles and protecting patients Full disclosure – protecting patients **(PRACTICAL SESSION)**	***Day 3 welcome*** Phase 1 and 2 studies Systematic reviews of existing evidence Ensuring that the research finishes before the money	***Sunday 10 February – Day Off***	Protocol outline 4 – fine tuning How to complete a successful grant application Getting into the game and playing the angles, funding Translation of lab to clinical research	International/multi-centre trial Reporting clinical research / CONSORT (group work) Protocol outlines 5 - development time Study modifications – special protocol design considerations
Lunch				***Lunch***	
Working with a statistician to plan your trial Sample Size **(PRACTICAL SESSION)** Protocol outline 1 – development	Recruiting patients and trial accrual strategies **(PRACTICAL SESSION)** Protocol outline 2 - development continued	Collecting and managing study data **(PRACTICAL SESSION)** Monitoring study progress Event reporting Protocol outline 3 - feedback		Measuring outcomes Interpreting time to event outcomes **(PRACTICAL SESSION)** Concerns with multiplicity **(PRACTICAL SESSION)**	Protocol outline 6 - presentations (in groups of 5) *Final remarks*
PM Welcome reception		***PM Networking reception***			

Please note: final program is subject to change.

Designing & Conducting Clinical Trials
Application Form / Tax Invoice

Enrolment is strictly limited. To ensure your place on the program, early registration is strongly recommended.
To register, fax this completed form to +61 2 9562 5094 / 9565 1863. One application form per participant is required.
This form becomes your tax invoice upon payment. OSMR. PO Box 5477 Sydney NSW 2001. ABN 16961 498 210

Organisation Information
Organisation Name
Postal Address

Personal Information	
Title (Mr/Mrs/Ms/Dr/Prof)	
First Name	Last Name
Position	Department
Email	Phone Number (w)
Qualifications	Phone Number (m)
	Phone Number (pager)
Outline areas of experience, area of qualification and duration	
Past & Present Research Experience	
Proposed Clinical Study	

Payment Options

Payment of course fees must be received prior to the commencement of the course. Payment can be made by credit card or cheque and should be made payable to the NSW Office for Science and Medical Research. Credit Card payments will show a debit by Central Corporate Services Unit (CCSU). All fees are in Australian Dollars. GST will be added to the cost.

Cancellations

Participants who cancel their enrolment more than 30 days prior to the commencement of the course will be refunded all fees less an administration charge of $100.00 per person. Participants who cancel their enrolment less than 30 days prior to the commencement of the course will forfeit their full fee. However, a suitable attendee may take their place.

Payment Information

Visa MasterCard

Credit Card Number _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ Expiration Date _ _ / _ _

Name on Card _____

Authorisation / Signature _____

Amount $ _____

OSMR NSW OFFICE FOR SCIENCE & MEDICAL RESEARCH NHMRC Clinical Trials Centre The University of Sydney

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NSW OFFICE FOR SCIENCE & MEDICAL RESEARCH

The NSW Office for Science and Medical Research

cordially invites you to a

Networking Evening on Sydney Harbour

3 hour private cruise on a catamaran

as part of the

Designing and Conducting Clinical Trials
Intensive Training Course – Feb 2008

Departing from Pier 26 Darling Harbour
(opp Sydney Aquarium), Sydney

All guests are required to be at the wharf 15 minutes prior to sailing

Saturday, 9 February 2008
7:00 pm to 10:00 pm

INVITATION

Please RSVP by Friday, 1 February 2008
Email andrea.ernudd@osmr.nsw.gov.au
or phone (02) 9338 6793

OSMR
NSW OFFICE FOR SCIENCE & MEDICAL RESEARCH

The NSW Office for Science and Medical Research

cordially invites you to a

Welcome Reception for Associate Professor James Talcott

Presenter of the *Designing and Conducting Clinical Trials* Intensive Training Course

Hamilton and Parkes Rooms
Level 47, MLC Centre
19 Martin Place, Sydney

Thursday, 7 February 2008
6:00 pm to 8:00 pm

INVITATION

Please RSVP by Thursday, 31 January 2008
Email andrea.ernudd@osmr.nsw.gov.au
or phone (02) 9338 6793