THIRD INTERNATIONAL CLINICAL TRIALS SYMPOSIUM

KEYNOTE SPEAKERS

Professor Doug Altman
Professor of Statistics in Medicine at the University of Oxford, and founding director of Oxford’s Centre for Statistics in Medicine

Professor Robert Califf
Vice Chancellor for Clinical Research, Director of the Duke Translational Medicine Institute, and Professor of Medicine in the Division of Cardiology at Duke University Medical Center in Durham, North Carolina

Professor Paul Glasziou
Director of the Centre for Evidence-Based Medicine, Professor of Evidence-Based Medicine in the Department of Primary Health Care at the University of Oxford, and part-time general practitioner

Dr Richard Horton
Editor, Lancet Publishing Group

Dr Joseph Pater
Former director of the National Cancer Institute of Canada Clinical Trials Group

Following the success of the international symposiums in Sydney in 1999 and 2002, the CTC again hosted the International Clinical Trials Symposium, in September 2007.

Internationally recognised experts in clinical trials research were invited from Australasia, America and Europe to speak. Presenters and delegates came from 15 countries, representing 185 organisations. A diverse and stimulating program on topical issues was delivered via workshops, plenary sessions, invited presentations, free papers, focus groups and panel sessions. A popular event was the now-traditional symposium debate, where the panelists paraded their erudition and life experience on a knife edge of good taste to offer a new slant on clinical trials.

Representatives from academia, regulatory bodies, the pharmaceutical industry and health care organisations exchanged ideas on the practical aspects of undertaking clinical trials research and translating these trials results into improvements in clinical practice.

Some of the themes for the third symposium had arisen from questions raised in the second symposium. Others were current topics warranting exploration and discussion. Themes were: partnerships among government, industry and academia; frontiers in statistical methods, including adaptive designs; biological and genetic therapies; nonpharmacological technologies; and translating trials research into practice.

At the symposium, the NSW Office for Science and Medical Research announced seed funding for the development of a national curriculum in training in clinical trials management. The first project will be a course for senior clinical researchers to be held by the CTC and other Sydney research groups, in conjunction with Harvard University, early in 2008.
PRESYMPOSIUM WORKSHOPS

160 people attended the four presymposium workshops organised by the CTC and presented by CTC staff and invited experts.

1: Biomarkers and surrogate evaluation

Topics included real-world experiences in cancer trials, ethical issues to do with tissue banks and international collaborations, biomarkers as surrogates for clinical endpoints and systematic evaluation of surrogacy evidence in cardiovascular disease, HIV medicine and oncology.

2: Updates for clinical trial managers

The workshop covered recruitment and retention strategies from the perspectives of the coordinating centre and the sites, performing well at an audit, interpreting trial results, and resources for phase I trials.

3: Publications: getting your research published

The presenters were dominant figures in publishing and leading researchers, who led discussion on CONSORT guidelines, preparing manuscripts and the practice and interpretation of statistics.

4: Health technology assessment: interpreting trial evidence for policy decisions

Nonpharmaceutical trials and assessments present challenges. This workshop had sessions on conducting trials of surgery and clinical devices, decision analysis and Australian regulatory policies.

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- Association of Regulatory and Clinical Scientists
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INTERPRETING AND REPORTING CLINICAL TRIALS

The CTC’s popular new textbook was published in 2007 and launched at the International Clinical Trials Symposium.

Interpreting and reporting clinical trials: a guide to the CONSORT statement and the principles of randomised controlled trials, edited by Tony Keech, Val Gebski and Rhana Pike, covers the fundamentals of clinical trials. CTC staff predominate among the chapter authors.

The book has been well received by its target readers — clinicians, trial coordinators, students and others — meeting their needs for a readable but comprehensive compilation of up-to-date knowledge.

It explains and expands on the items of the CONSORT statement, the international standard for reporting clinical trials. Its contents include randomisation, blinding, sample size calculation, basic statistical methods, how to deal with subgroups, and the interpretation and generalisability of results, supplemented by checklists and case studies.