

FREE STATISTICAL SEMINAR

Adaptive designs for clinical trials



PROFESSOR BRUCE TURNBULL*, CORNELL UNIVERSITY, USA, IS AN EXPERT IN CLINICAL TRIAL METHODOLOGY. THIS TWO-PART SEMINAR WILL PROVIDE AUSTRALIAN DOCTORS, RESEARCHERS AND STATISTICIANS INSIGHT INTO ADAPTIVE DESIGNS - THE NEW TREND IN RANDOMISED CONTROLLED TRIALS.

25 February 2010 | 3pm – 5pm (*Refreshments at 3.50pm*)

The George Institute, Level 7, 341 George Street, Sydney NSW

Please RSVP by 19 February to Leanne Clifford (lclifford@george.org.au)

ADAPTIVE DESIGNS FOR CLINICAL TRIALS: WHERE ARE WE NOW AND WHERE ARE WE GOING?

3pm – 3.50pm

Confirmatory (Phase III) clinical trials are extremely expensive and may last several years. Adaptive designs have been enthusiastically promoted as a way to introduce flexibility, and to reduce the cost and duration of the development process. There are, however, various ways that adaptive methods may be applied. These include sample size modification; switching endpoints; switching to a patient subpopulation (enrichment); joint planning of Phase II and Phase III trials. In this talk Professor Turnbull will review some of these topics and discuss practical aspects of their implementation.

ADAPTIVE CHANGE IN SAMPLE SIZE - A FREE LUNCH?

4.10pm – 5pm

There has been great interest in adaptive designs for clinical trials because of the flexibility they offer. However are they a panacea as they have been touted? This session will examine the efficiency of such designs and conclude that their flexibility can come at a price. Conventional group sequential tests with information monitoring, error spending boundaries and possibly unequally spaced looks may be preferable. However, it is still possible to fall back on flexible methods for re-design should study objectives change unexpectedly in mid-course. This session is particularly suited for statisticians and skilled researchers.

Questions regarding the seminar can be addressed to **Stephane Heritier (02 9657 0342)**

**Bruce Turnbull is Professor of Statistics at Cornell University in Ithaca, New York, USA. He is the author of over 130 journal articles, many in the area of clinical biostatistics. He is the co-author (with Chris Jennison) of a recent book on the monitoring of clinical trials. He has served on steering committees and on data monitoring boards for a number of large randomized clinical trials sponsored by government, academe and the pharmaceutical industry. He is a Fellow of the American Statistical Association and of the Royal Statistical Society.*