



## Design of Early Phase Clinical Trials

### A one-day course for scientists and statisticians working in clinical research

**Location:** Postgraduate Statistics Centre, Lancaster University

**Presenters:** John Whitehead and Anne Whitehead

**Date:** 19 May 2010, 9.30 – 17.30

The importance of exploratory clinical research prior to the launch of a large-scale definitive “phase III” clinical trial is becoming increasingly recognised, both in the pharmaceutical industry and in public sector medical research. Early phase trials include first-in-human studies intended to determine a safe dose or range of doses, studies to identify the most effective dose and trials on which a decision whether or not to launch a phase III study will depend. Advances in the identification of medical biomarkers of therapeutic effect and in statistical techniques based on adaptive designs and Bayesian inference now allow such studies to be designed efficiently, to take account of information from a variety of sources and to combine objectives such as establishing safety and seeking evidence of potential benefit.

This course will present some of the new methods that are now available. The presentation will concern statistical concepts but is intended to allow non-statisticians to appreciate what is now available, what information is needed for the designs to be set up and what inferences can be drawn from the study results. Illustrative examples, demonstrations of appropriate software and class discussions about strategy will be included. Although the focus of the course will be on trials of new drugs, the methodology has potential for application in evaluations of other medical interventions such as surgical techniques.

This course is presented on behalf of the North West Hub for Trial Methodology Research based at the Universities of Liverpool, Lancaster and Bangor.

#### Programme

- Dose-escalation studies
- Simultaneously searching for a safe and effective dose (phase I/II designs)
- Seeking safe and effective dose combinations
- Sample size considerations for phase II
- Phase II selection trials
- Phase II/III studies

**Cost:** £75, to include course materials, lunch and refreshments

**Booking:** online at <http://www.maths.lancs.ac.uk/psc>

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