LTCC Proposed Course

* Title: **Adaptive Bayesian Clinical Trials**
* Basic Details:
  + Core Audience: stats
  + Course Format: advanced/optional (10 h)
* Course Description:

A clinical trial is a research study conducted to assess the utility of an intervention in volunteers and, in general, it provides the evidence to support regulatory approval of a new drug. This course will present the Bayesian adaptive approach to the design and analysis of clinical trials. We will first introduce the current state of clinical trial design and analysis. We will then present the main ideas behind the Bayesian alternative, and describe the potential benefits of such an alternative. At the end of the course, students will be able to design and analyse Bayesian clinical trials and interpret the results.

* + Keywords:

Hierarchical models, Prior and posterior probability, Predictive density, Phase II and III, Randomisation, Stopping criteria

* + Syllabus:

W1-2: Features and use of the Bayesian adaptive approach

Examples of the Bayesian approach to drug and medical device development

Bayesian inference

Hierarchical modelling and meta-analysis

Principles of Bayesian clinical trial design

Bayesian predictive probability methods

Prior determination

W3-4: Phase II studies

Standard designs

Limitations of traditional frequentist designs

Sequential stopping

Adaptive randomization

Hierarchical models for phase II designs

Case studies

W5: Phase III studies

Introduction to confirmatory studies

Bayesian adaptive confirmatory trials

Adaptive sample size using posterior probabilities

Arm dropping

Case studies

* + Recommended reading:

Good introductory books to clinical trials are:

Peace K.E. and Chen D. (2010) Clinical Trial Methodology (Chapman & Hall/CRC Biostatistics Series)

Chen D. and Peace K.E. (2010) Clinical Trial Data Analysis Using R (Chapman & Hall/CRC Biostatistics Series)

Cook D.T. and DeMets D.L. (2007) Introduction to Statistical Methods for Clinical Trials (Chapman & Hall/CRC Texts in Statistical Science)

* + Additional optional reading:

Yin G. (2012) Clinical Trial Design: Bayesian and Frequentist Adaptive Methods (Wiley Series in Probability and Statistics)

* + Prerequisites:

General knowledge about Bayesian statistics and basic knowledge in programming (e.g. R) will be needed to tackle the problem sheet

* Format:
  + No of problem sheets: 1 sheet containing all relevant problems. The problems will require the use of computer packages (e.g. R)
  + Electronic lecture notes: lecture material will be made available for download.
  + Proposed timing: autumn
  + Lecture/computer session/tutorial/discussion h split: 10/0 /0 /0 /0
* Lecturer Details:
  + Lecturer: Leonardo Bottolo
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