

## Statistical Issues in Drug Development

*A two-day course*

**Course presenter: Stephen Senn**

*1 & 2 September 2009*

*ENSAI, Campus de Kerlann, Rennes*

### Abstract

This course is based on the book by the same name (1<sup>st</sup> edition 1997, 2<sup>nd</sup> edition 2007). It has two objectives: first, to take a fresh look at statistical issues commonly encountered within drug development in a way that highlights controversies rather than trying to achieve false consensus and second to provide heuristic arguments to explain as simply as possible some difficult issues. The course will stress philosophical and inferential issues and will use very little algebra. It will be less about "how to" but more about "why" and "whether to".

### Course outline

#### Day 1

- Philosophy of clinical trials
- Frequentist and Bayesian approaches to inference
- Allocating patients to treatment (including sequential trials)
- Measurement of treatment effects

#### Day 2

- Use of baselines and covariate information
- Multi-centre trials
- Equivalence trials
- Subgroups and pharmacogenetics

### Suitable for

All those working or intending to work in drug development and with an interest in statistical issues, including, physicians and other life-scientists and regulatory and marketing personnel. It will also be suitable for statisticians in drug development who wish to find ways of presenting their subject to their colleagues.

### About the course presenter

Stephen Senn used to work in the pharmaceutical industry but is currently professor of statistics at the University of Glasgow and visiting ENSAI during 2009. He is the author of more than 200 scientific papers and the monographs *Cross-over Trials in Clinical Research*, *Statistical Issues in Drug Development* (on which the course is based), and *Dicing with Death*. In 2001 he was awarded the George C Challis prize for biostatistics of the University of Florida and in 2009 the Bradford Hill medal of the Royal Statistical Society.

### Course fee

Public sector 150€ , Private sector 500€

*Dossier suivi par :*

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