

INVITATION / COURSE

STATISTICAL ISSUES IN DRUG DEVELOPMENT

Our courses have been developed by people with years of hands-on experience, our presenters are all experienced both in their field of expertise and as trainers. All courses are subject to a rigorous quality approval process, so you can be assured they offer value for money.

Course Content

This two day event covers important issues and controversies with which statisticians working in drug development are confronted. It will be particularly useful for those who are interested in fruitful dialogue between medical statisticians and the life scientists with whom they collaborate. It should be of interest not only to statisticians but also to those who have to work with them.

COURSE AIMED AT

- > statisticians
- > regulatory scientists
- > clinical research associates
- > medical advisors
- > marketer working in the pharmaceutical industry

TOPICS COVERED

- > causality in clinical trials
- > approaches to inference
- > allocating patients to treatment
- > measuring treatment effects
- > the use of baseline and covariate information
- > determining sample size
- > personalised medicine

DATE

10-11 May 2016

VENUE

Hôtel Parc Belair

111, av. du X Septembre
L-2551 Luxembourg
Bus Stop "Parc Merl"

PRESENTER

Stephen SENN

Stephen Senn has held chairs in statistics at Glasgow University and University College London but has also worked in the NHS and the pharmaceutical industry. He is head of the Competence Center for Methodology and Statistics at LIH. He is the recipient of the Bradford Hill medal of the Royal Statistical Society (2009) and the George C Challis prize for biostatistics of the University of Florida (2001).

REGISTRATION

laura.star@lih.lu

Registration fees	Single Day	Full Course
Private Companies	460€	810€
Hospital, Researchers	230€	405€
Students	115€	230€
LIH Staff	130€	160€
LIH Students	100€	130€

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Agenda

DAY 1

Four Views of Statistics in Drug Development:
Depth of Understanding through Different
Perspectives

- 09:30 Introduction
- 09:45 History
- 10:45 Quiz
- 11:00 Coffee
- 11:30 Philosophy
- 12:30 Questions and Discussion
- 12:45 Lunch
- 14:00 Methodology
- 15:00 Quiz
- 15:15 Coffee
- 15:45 Professional
- 16:45 Questions and Discussion
- 17:00 Cocktail

DAY 2

Some common and one advanced topic
in drug development

- 09:00 Introduction
- 09:15 Allocating Treatment to Patients
- 10:15 Questions and Discussion
- 10:30 Coffee
- 11:00 Baseline and Covariate Information
- 12:00 Questions and Discussion
- 12:15 Lunch
- 13:30 Measuring Treatment Effects
- 14:30 Questions and Discussion
- 14:45 Coffee
- 15:15 Perspectives on and issues in personalized medicine
- 16:15 Questions and Discussion
- 16:30 Discussion of Issues and Problems Provided by Course Delegates

This course is based on Stephen's book "Statistical Issues in Drug Development" (Wiley, 1997, Second edition 2007). The quotes below are taken from reviews of the book.

"This excellent book should serve to inspire both statisticians and life scientists" / "It is ideal for readers ... who want to get to the bottom of statistical approaches and their interpretations in medical settings" / "Statisticians with limited experience in drug development will greatly benefit from seeing the careful layout of controversies that are unique to this arena" / "This should be required reading for anyone considering or starting out on a career in clinical drug development"

