

Kære DSBS medlem,

Som tidligere annonceret vil der blive afholdt et 2-dages kursus i "Estimating Sample Size in Clinical Trials" for DSBS medlemmer **den 22-23 april 2009**.

Kurset holdes på Hilton, Copenhagen airport hotel hvor der er mulighed for overnatning. Kursusprogram er vis nedenfor.

Kurset starter onsdag den 22. april kl. 08:30 med morgenkaffe/te og slutter torsdag den 23. april ca. kl. 16.

Kursusafgiften er kr. 5.000 for kursus, frokost, kaffe/te/isvand.

Af hensyn til arrangementet bedes du venligst **tilmelde dig senest den 8. april 2009**.

Tilmelding til [jlj@statcon.dk](mailto:jlj@statcon.dk)

Derefter vil du blive tilsendt en faktura af selskabets kasserer.

Pbv

Judith L. Jacobsen

## **Estimating Sample size in clinical trials – 2 days**

Presenter:

Steven A. Julious, Senior Lecturer in Medical Statistics, University of Sheffield

This course will describe calculations for sample size estimation in the design of clinical trials. Different clinical trial objectives and types of data will be discussed pertinent to how these impacts on sample size calculations. The methods will be illustrated through the use of worked examples and practicals.

**The following topics will be covered:**

### **Introduction to Key Concepts**

- Type I error
- Type II error
- Power

### **Sample Sizes for Different Clinical Trial Objectives**

- Superiority
- Equivalence
- Non-inferiority
- Precision based
- Bioequivalence

### **Sample Sizes for Different Types of Data**

- Normal
- Binary
- Ordinal
- Survival

### **Clinical Trial Designs**

- Cross-over
- Parallel Group

### **How Design Considerations Impact on the Sample Size**

- Baselines/covariates
- Multiple endpoints
- Interim analyses

### **Other Considerations when Designing a Trial**

- Sensitivity analysis
- Optimising variance estimates

### **Sample Size Worked Examples**

- Worked examples and practicals throughout the course