

Dear DSBS member,

As announced previously, a 2-day course in “Estimating Sample Size in Clinical Trials” for members of DSBS on **April 22 & 23 2009**.

The course will be held at Hilton, Copenhagen airport hotel where overnight stays are also possible. The course program is shown below.

The course starts Wednesday April 22. 08:30 with breakfast coffee/tea and ends Thursday April 23. at 16:30

Course fee is kr. 5.000 for the 2-day course, lunches, coffee/tea/ice water.

Due to the arrangements, please **sign up no later than April 8 2009**.

Sign up to [jlj@statcon.dk](mailto:jlj@statcon.dk). Thereafter an invoice will be sent to you.

BR

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