



# DSBS Training Course in Estimating Sample Sizes in Clinical Trials

Presented by Professor Steven A. Julious

Medical Statistics Group, University of Sheffield

12-13 April 2018

The three most important aspects of a clinical trial are design, design and design. A sample size estimate is just one aspect of a clinical study design.

The course describes calculations for sample size estimation in the design of clinical trials. It will be highlighted how the objectives of a clinical trial will affect sample size calculations. The course is a practical course and all methods will be illustrated with examples and case studies.

The following topics will be covered:

- Introduction to Key Concepts
- Sample Sizes for Different Clinical Trial Objectives
- Sample Sizes for Different Types of Data
- Clinical Trial Designs
- How Design Considerations Impact on the Sample Size
- Other Considerations when Designing a Trial
- Considerations which Impact on the Sample Size
- Adaptive designs for efficacy
- Assessing futility
- Sample size re-estimation

Throughout the course, I will make use of worked examples and practicals.

*See next page for the full course structure.*

## REGISTRATION

Venue: LEO Pharma A/S  
Industriparken 55  
2750 Ballerup

The course fee is DKK 3000 for both days including lunch and Steven Julious' book "Sample Sizes for Clinical Trials"

**Deadline: 1 April 2018**

To register, please send a mail to  
Lea Helena Strother:

[OLNDK@leo-pharma.com](mailto:OLNDK@leo-pharma.com)

There is a limit on the number of attendees. The first come, first serve principle will be applied.

# Estimating Sample Sizes in Clinical Trials

Professor Steven A. Julious

## Course Structure

There will be 4 sessions per day, each between 1.30-2.00 hours. A session will consist of both lectures and practicals, involving calculators.

Day 1 - 12 April 2018		
8:30-9:00		Light breakfast
9:00-10:15	Session 1	Introductions Background to sample size calculations
10:15-10:30	Coffee	
10:30-12:15	Session 2	Sample sizes for Normal Data followed by a practical Software for sample size calculations
12:15-13:15	Lunch	
13:15-14:45	Session 3	Sample sizes for binary data followed by a practical
14:45-15:00	Coffee	
15:00-16:30	Session 4	Sample sizes for precision followed by a practical

Day 2 - 13 April 2018		
8:30-9:00		Light breakfast
9:00-10:15	Session 5	Sample sizes for cross-over trials followed by a practical Trials for non-inferiority followed by a practical
10:15-10:30	Coffee	
10:30-12:15	Session 6	Sample sizes for ordinal data followed by a practical Trials for survival followed by a practical
12:15-13:15	Lunch	
13:15-14:45	Session 7	Sample size for pilot trials Sample sizes for adaptive designs
14:45-15:00	Coffee	
15:00-16:30	Session 8	Trials for bioequivalence followed by a practical Other sample size issues



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