LUXEMBOURG INSTITUTE OF HEALTH
RESEARCH DEDICATED TO LIFE

ESTIMATING SAMPLE SIZES IN CLINICAL TRIALS
16/17 October 2017

ABSTRACT

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 impact on sample size calculations. The course is a practical course and all methods will be illustrated with examples and interactive case studies.

SPEAKER

This two-day course will be given by Prof Steven Julious from the University of Sheffield (United Kingdom).He will cover the crucial task of deciding how much evidence is needed when planning your clinical study.

TOPICS 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 calculation
- bioequivalence
- pilot studies

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

Other considerations when designing a trial
- sensitivity analysis
- optimising variance estimates

Considerations which impact on the sample size
- adaptive designs for efficacy
- assessing futility
- sample size-re-estimation

META-ANALYSIS FOR EVIDENCE SYNTHESIS

18/19 October 2017

ABSTRACT

Meta-analysis is the application of statistical methods to summarising the evidence from independent studies investigating the same question. It has become a cornerstone of evidence-based medicine, yet remains controversial. The emphasis of this course will be on understanding basic principles rather than technical details, although some of these will be covered where necessary. Graphical representation will be covered in addition to statistical summaries. A thorough explanation of the difference in approach and purpose of fixed and random effects meta-analysis will be given. Frequentist and Bayesian methods will be covered. The increasingly important topic of network meta-analysis will also be explained.

SPEAKERS

This two-day course will be given jointly by Prof Stephen Senn and Dr Susanne Schmitz, both of whom have extensive experience of conducting meta-analysis and are well known for their contributions to the methodological literature.

TOPICS COVERED

Introduction
Technical background. Why do meta-analysis?

Some history
Early attempts. More modern approaches

Preparation
Data extraction. Outcome measures

Fixed effects approaches
Three kinds of meta-analysis
- Type 1. Analysis of original data: same outcome measure for all trials
- Type 2. Analysis of treatment estimates: same outcome measure for all trials
- Type 3. Analysis of treatment estimates: different outcome measure for different trials

Continuous data, binary data

Graphical methods
L'Abbe plots, bubble plots, forest plots, funnel plots, Galbraith plots

Random effect approaches
The philosophical difference to fixed effects approaches, method of moments (Der Simonian Laird), maximum likelihood (Hardy and Thompson), Bayesian methods

Software
SAS®, GenStat®, R®, WinBugs®

Case studies

Network meta-analysis
Generalised least squares, graphical representations, shade plots, mean-mean plots, consistency, heterogeneity, ranking analysis

Issues in performing meta-analysis