



LUND UNIVERSITY
Faculty of Medicine

Approved by FUN 27 January 2015, valid from 1
January 2015

Research Programmed Board, FUN

Applied Statistics II – Clinical Research, METSKF2

3 credits

Third cycle

General information

The course provides students with general knowledge of commonly used statistical methods that are applicable in clinical research. The course is intended for all doctoral students at the Faculty of Medicine whose research is mainly in this area. *Applied Statistics I* or equivalent prior knowledge is required for admission to the course, along with basic skills in the statistical software the participant chooses to use during the course (see also *Teaching* below).

Language of instruction

The language of the course will alternate between Swedish and English.

Aim

The course will provide students with practical knowledge of the best ways to manage and analyse empirical data in clinical research projects. The course will also prepare the participants for understanding and critically examining other empirical research in medical science, including outside their own field of research.

Learning outcomes

On completion of the course, the student shall be able to

- propose, perform, interpret, and critically review basic statistical analyses within each of the four different themes of the course: binary outcomes, correlation and regression, advanced regression, and randomised clinical trials/diagnostic testing.

Course content

The course covers four themes:

- 1) Design and analysis of studies of binary outcomes
 - Cohort and case-control studies
 - Incidence and risk calculations
 - Association measurement. Odds ratios. Absolute and relative comparisons.
 - Simple problems of survival (time-to-event)
 - Power calculations

- 2) Introduction to correlation and regression analysis
 - Spearman's and Pearson's regression correlation coefficients
 - Simple linear regression
 - Simple logistical regression
- 3) Advanced regression analysis
 - Introduction to Cox regression
 - Multi-variable modelling
 - Interaction
- 4) Randomised clinical trials (RCT) and diagnostic studies
 - Design and analysis of randomised clinical trials
 - Diagnostic measuring: Sensitivity and specificity, predictive values
 - ROC analysis

This advanced course in applied statistics for clinical researchers focuses on regression methods. Major emphasis is placed on linear regression models with a continuous outcome variable and one or more explanatory variables: in what situations they may be used and how they are to be interpreted. The course will explain how regression methods can be used to take into account potential confounding factors, as well as more general models of mutual influence of two explanatory variables, so called interaction. The course also includes an introduction to other study designs and regression models adapted to these: more specifically, binary outcomes (logistic regression) and survival analysis (Cox regression).

Another theme of the course is statistical methods and measurements for diagnostic tests. This includes concepts such as sensitivity, specificity, positive and negative predictive values and the choice of cut-off through a ROC analysis.

Furthermore, the course will introduce students to theories and regulations concerning randomised clinical trials (RCTs).

Teaching

The course includes four and a half days of teaching, and five and a half days of independent study and project work. Days 1–4 are full days of lectures, group exercises and computer lab exercises. During the computer lab exercises, the students are to conduct analyses using a statistical software solution (SPSS, STATA, R, or SAS) in which they are well-versed from previous courses. The course requires that the student has access to a laptop with the selected software properly installed. Furthermore, on the basis of a set of data and predetermined research questions, the participants are to plan, perform, compile and present a statistical analysis in groups. Presentations will take place on the last day of teaching (half-day) in the form of a brief talk to the course management and other course participants.

Assessment

The assessment is based on a take-home exam. A Pass on the course requires a Pass on the take-home exam, as well as a completed group assignment, which involves active participation in the discussions about their own group's and other groups' work.

Grades

The grades awarded are Pass or Fail.

Reading list

Kirkwood B and Sterne J. *Essential Medical Statistics*. Blackwell Science, 2nd edition, 2003. Chapters: 10–16, 18–22, 26–27, 29, 34–38.

Available as an e-Book (see <http://www.lub.lu.se/>)