UNIVERSITÀ
DEGLI STUDI DI MILANO-BICOCCA

COURSE SYLLABUS

Biostatistical Methods and Models for Clinical Research

2324-1-F8203B034

Learning objectives

The course aims to provide the theoretical basis and the computer skills necessary for the analysis of experimental and observational data and the interpretation of results, with a focus on adaptive designs and predictive models. All subjects are complemented by practical exercises conducted with language SAS.

The course will allow the student to acquire solid foundations in the application of biostatistic model.

Knowledge and understanding

This course will provide knowledge and understanding in relation to:

- the rationale of different experimental designs and the principles of predictive studies
- the application of mixed models to experimental and observational studies

Ability to apply knowledge and understanding

At the end of the course the students will be able to:

- analyze data from an experimental or observational study with mixed models
- to interpret the obtained measurements
- evaluate a research protocol for an experimental study

Contents

Statistical methods for classical and adaptive experimental design

Statistical methods for predictive models

Detailed program

Theoretical and practical Introduction to statistical models for the analysis of the main designs of experiments (completely randomized, block, factorial, crossover (with language SAS)

Design and analysis of randomized intervention studies (cluster randomization)

Introduction to adaptive studies

Introduction to predictive models

Discrimination and calibration for predictive models

Prerequisites

No formal prerequisites. It is reccommended, however, the knowledge of the content of the following courses: Statistical models I

Teaching methods

Lectures and computer lab classes

Only in case of emergency periods the activities will take place also in videoconference streaming.

Assessment methods

Final test mode for attending students

Written exam with optional oral. The written test consists of two moments. In the first part the students, organised in groups, will analyze a small dataset of real data relating to an observational or experimental study and will draw up a scientific report with the main steps of the analysis and the resulte and the comment of the latter based on the clinical question required in the examination topic. The software to be used is SAS. The product of the analysis (results report and comments) will be sent to the teacher, before the exam date, who will verify the correctness of the analysis and the evaluation of the results obtained. At the time of the oral exam all the members of the group can describe and defend their actions. The vote awarded to the laboratory test will summarize the organizational skills of an analysis work in addition to the correctness of the statistical methodologies used and conclusions. The second apoart of the written test consists in the writing of a paper for each student in which he will deepen, from a theoretical point of view, a topic to be chosen from those presented in the course . The essay will also produce a vote. The final voto awarded to the student will be an average of the mark of the laboratory test and the thesis provided that both are sufficient.

Final test mode for non-attending students

The final test will be identical to that of the attending students except that the laboratory test will be individual and will take place during the examination session. The duration will be about an hour and a half.

Only in case of emergency periods the exam will take place remotely following the rules reported on the e-learning platform.

Textbooks and Reading Materials

Slides from http://elearning.unimib.it/. Other material will be provided by the teacher

Davies CS. Statistical Methods for the Analysis of Repeated Measurements. Springer, 2002

Chang M. Adaptive design theory and implementation using SAS and R. Chapman and Hall, 2008

Harrell F. Regression Modeling Strategies With Applications to Linear Models, Logistic and Ordinal Regression, and Survival Analysis. Springer, 2015

Semester

II semester, IV period (from May to June).

Teaching language

The language of the course is the Italian. Scientific articles needed to bibliographic research for essay are in English language. The essay can be written in English

Sustainable Development Goals

QUALITY EDUCATION