UNIVERSITÀ
DEGLI STUDI DI MILANO-BICOCCA

COURSE SYLLABUS

Biostatistical Methods and Models For Clinical Research

2122-1-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 requires, however, knowledge of the content of the following courses: Statistical models I

Teaching methods

Lectures and computer lab classes

If COVID-19 emergency will continue the activities will take place remotely following the rules reported on the e-learning platform.

Assessment methods

Final test mode for attending students

Written exam with optional oral examination. The written exam is divided into two parts (laboratory test and term paper). In the laboratory test each student will have to analyze a small dataset of real data related to an observational or experimental study and report the main steps of the analysis and the results, commenting them according to the clinical question required in the exam theme. The software to be used is SAS. The analysis product (results report and comments) will be saved in a word file and printed to allow the teacher to exame the work. The laboratory test will last about 90 minutes. The vote attributed to the laboratory test will summarize the

organizational skills of a work of analysis in addition to the correctness of the statistical methodologies used and conclusions. In the term paper each student will deepen, from a theoretical point of view, a topic chosen from those presented in the course. The term paper will also produce a vote. The final vote will be an average of the vote of the laboratory test and the vote of term paper provided both are sufficient.

Final test mode for non-attending students

The final exam will be identical to that of the attending students.

If COVID-19 emergency will continue 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