Course guide
270247 - MEACAS - Statistical Methods in Controlled Trials and Survival Analysis

Last modified: 10/07/2026

Unit in charge: Barcelona School of Informatics
Teaching unit: 723 - CS - Department of Computer Science.

Degree: BACHELOR'S DEGREE IN DATA SCIENCE AND ENGINEERING (Syllabus 2017). (Optional subject).

Academic year: 2026 **ECTS Credits:** 6.0 **Languages:** Catalan

LECTURER

Coordinating lecturer: MARTA BOFILL ROIG

Others: Primer quadrimestre:
MARTA BOFILL ROIG - 10

PRIOR SKILLS

Recommended prior knowledge:

Fundamental statistics: Basic concepts of parameter estimation, hypothesis testing, and regression models.

Data management and analysis: Ability to perform basic data manipulation (cleaning, filtering, transforming variables) and apply descriptive statistics techniques (calculation of frequencies, means, deviations, and graphical representations).

TEACHING METHODOLOGY

Lectures: Magisterial sessions where the faculty will introduce the theoretical concepts, methodological foundations, and the statistical and design tools of the subject. Interactivity will be encouraged through the resolution of doubts and brief discussions on key concepts.

Application sessions: Practical classroom sessions aimed at problem-solving, case study discussion, or the critical analysis of medical articles. The objective is to apply the learned theory to practical situations and debate the results in groups.

Laboratory sessions: Practical sessions where students will learn to use the statistical software (R). Work will focus on data manipulation, analysis programming (such as survival analysis or sample size calculation), and the interpretation of computer output.

LEARNING OBJECTIVES OF THE SUBJECT

1.Objective 1 (Methodological Evaluation & Problem Solving): To critically analyze, model, and solve complex technical problems in medical and clinical research by applying fundamental statistical principles, causal inference, and advanced experimental or observational designs.
2.Objective 2 (Data Management & Survival Analysis): To efficiently manage, structure, analyze, and visualize complex biomedical data, specifically implementing advanced survival analysis techniques and modeling time-to-event outcomes using statistical software.
3.Objective 3 (Clinical Decision Making & Application): To design and implement advanced statistical (such as group sequential methods and adaptive designs) to optimize decision-making processes in clinical trials, including early termination for efficacy or futility.
4.Objective 4 (Ethical Judgements & Uncertainty): To integrate incomplete or limited clinical data to make reasoned, critical judgments, taking into full account the social, ethical, and safety responsibilities associated with human clinical trials and medical research.
5.Objective 5 (Scientific Communication & Argumentation): To reason, argue, and clearly communicate scientific-technical conclusions, study rationales, and statistical reports to both specialized (medical/statistical) and non-specialized audiences without ambiguity.
6.Objective 6 (Autonomous Learning & Professional Drive): To develop self-directed learning skills and a continuous improvement mindset, enabling the student to autonomously master new advanced methodologies and face future professional challenges in the fast-evolving field of medical statistics.

STUDY LOAD

Type	Hours	Percentage
Hours large group	30,0	20.00
Hours small group	30,0	20.00
Self study	90,0	60.00

Total learning time: 150 h

CONTENTS

Introduction and Statistical Foundations

Description:
Description of the different types of medical studies and conceptualization of the challenges in the field and the scope of the subject. The concepts of bias, confounding, and causal inference are introduced, along with a review of the statistical tools necessary for evidence-based inference. In particular, data types and descriptive statistics, probability and distributions, hypothesis testing, p-values and confidence intervals, and sample size and statistical power.

1. Observational study designs (cohort, case-control, cross-sectional)
2. Experimental study designs (non-randomized trial, randomized controlled trial)

Clinical Trial Design

Description:
This part focuses on clinical trials as a central tool in experimental medical research. The phases and objectives of trials, the main randomization methods, and the statistical techniques that allow for the decision of early trial termination due to signs of efficacy or futility are examined.

1. Phases and objectives of clinical trials
2. Randomization methods
3. Group sequential methods for early termination

Survival Analysis

Description:
Many medical studies evaluate the time until an event (death, relapse, recovery) instead of simple presence or absence. Survival analysis is the branch of statistics designed for this context, with applications that go beyond medicine: engineering (time-to-failure) or economics (unemployment duration).

1. Observation schemes and censoring
2. Basic concepts in survival analysis
3. Estimation of the survival function and cumulative hazard
4. Comparison of survival curves between treatment groups
5. Design and sample size in survival clinical trials
6. Regression models in survival analysis

ACTIVITIES

A. Introduction and Statistical Foundations

Specific objectives:
1, 5

Full-or-part-time: 13h
Theory classes: 4h
Practical classes: 2h
Laboratory classes: 1h
Self study: 6h

B. Clinical Trial Design

Description:
Progress in B. Clinical Trial Design

Specific objectives:
1, 3, 4, 5

Full-or-part-time: 50h 30m
Theory classes: 10h
Practical classes: 5h 30m
Laboratory classes: 5h
Self study: 30h

C. Survival Analysis

Description:
Progress in C. Survival Analysis

Specific objectives:
2, 5, 6

Full-or-part-time: 50h 30m
Theory classes: 10h
Practical classes: 5h 30m
Laboratory classes: 5h
Self study: 30h

Exam 1

Description:
Exam 1

Specific objectives:
1, 3, 4, 5, 6

Full-or-part-time: 11h
Guided activities: 1h
Self study: 10h

Exam 2

Description:
Exam 2

Specific objectives:
1, 2, 3, 5, 6

Full-or-part-time: 11h
Guided activities: 1h
Self study: 10h

Test 1

Description:
Test 1

Specific objectives:
1, 3, 4, 6

Full-or-part-time: 7h
Guided activities: 1h
Self study: 6h

Test 2

Description:
Test 2

Specific objectives:
2, 4, 5, 6

Full-or-part-time: 7h
Guided activities: 1h
Self study: 6h

GRADING SYSTEM

The assessment of the subject is continuous and consists of the following elements:

2 Midterm exams, EP1 and EP2 (Theoretical-practical): Written tests that will assess both the understanding of theoretical concepts and the ability to apply them in solving problems and practical cases.

2 Quizzes, T1 and T2: Short tests aimed at verifying regular progress in the subject and the achievement of key concepts.

The final mark will be computed using the following formula: 0.35(EP1+EP2)+0.15(T1+T2)

BIBLIOGRAPHY

Basic:

- Wassmer, G., & Brannath, W.. Group Sequential and Confirmatory Adaptive Designs in Clinical Trials.. Springer Cham., 2016. ISBN 978-3-319-32062-5.
- Kleinbaum, David G; Klein, Mitchel. Survival analysis : a self-learning text. 3th ed. Springer, cop. 2012. ISBN 978-1-4419-6645-2.
- Friedman, Lawrence M; Furberg, Curt; DeMets, David L; Reboussin, David M; Granger, Christopher B. Fundamentals of clinical trials. Fifth edition. Springer International Publishing, [2015]. ISBN 978-3-319-18538-5.
- Senn, S. (2021).. Statistical Issues in Drug Development. 3rd ed.. John Wiley & Sons., 2021. ISBN 978-1-119-56554-3.
- Lawless, Jerald F. Statistical models and methods for lifetime data. 2nd ed. Wiley-Interscience, c2003. ISBN 9781118033005.