

## Course guide

### 200627 - AC - Clinical Trials

**Last modified:** 13/06/2023

**Unit in charge:** School of Mathematics and Statistics  
**Teaching unit:** 715 - EIO - Department of Statistics and Operations Research.  
1004 - UB - (ENG)Universitat de Barcelona.

**Degree:** MASTER'S DEGREE IN STATISTICS AND OPERATIONS RESEARCH (Syllabus 2013). (Optional subject).

**Academic year:** 2023    **ECTS Credits:** 5.0    **Languages:** English

#### LECTURER

---

**Coordinating lecturer:** KONSTANTINA SKALTSA

**Others:** Primer quadrimestre:  
JOSEP LLUÍS CARRASCO JORDAN - A  
KONSTANTINA SKALTSA - A

#### PRIOR SKILLS

---

Students are expected to be familiar with descriptive and inferential statistics.

#### REQUIREMENTS

---

Descriptive and inferential basics, understanding of linear models

#### DEGREE COMPETENCES TO WHICH THE SUBJECT CONTRIBUTES

---

**Specific:**

5. CE-1. Ability to design and manage the collection of information and coding, handling, storing and processing it.
6. CE-2. Ability to master the proper terminology in a field that is necessary to apply statistical or operations research models and methods to solve real problems.
7. CE-3. Ability to formulate, analyze and validate models applicable to practical problems. Ability to select the method and / or statistical or operations research technique more appropriate to apply this model to the situation or problem.
8. CE-4. Ability to use different inference procedures to answer questions, identifying the properties of different estimation methods and their advantages and disadvantages, tailored to a specific situation and a specific context.
9. CE-5. Ability to formulate and solve real problems of decision-making in different application areas being able to choose the statistical method and the optimization algorithm more suitable in every occasion.  
Translate to english
10. CE-6. Ability to use appropriate software to perform the necessary calculations in solving a problem.
11. CE-7. Ability to understand statistical and operations research papers of an advanced level. Know the research procedures for both the production of new knowledge and its transmission.
12. CE-8. Ability to discuss the validity, scope and relevance of these solutions and be able to present and defend their conclusions.
13. CE-9. Ability to implement statistical and operations research algorithms.

**Transversal:**

1. ENTREPRENEURSHIP AND INNOVATION: Being aware of and understanding how companies are organised and the principles that govern their activity, and being able to understand employment regulations and the relationships between planning, industrial and commercial strategies, quality and profit.
2. SUSTAINABILITY AND SOCIAL COMMITMENT: Being aware of and understanding the complexity of the economic and social phenomena typical of a welfare society, and being able to relate social welfare to globalisation and sustainability and to use technique, technology, economics and sustainability in a balanced and compatible manner.
3. TEAMWORK: Being able to work in an interdisciplinary team, whether as a member or as a leader, with the aim of contributing to projects pragmatically and responsibly and making commitments in view of the resources that are available.
4. EFFECTIVE USE OF INFORMATION RESOURCES: Managing the acquisition, structuring, analysis and display of data and information in the chosen area of specialisation and critically assessing the results obtained.

**TEACHING METHODOLOGY**

---

The course is 100% practical. It will consist of:

- Lecture-type classes
- Hands-on classes where students are expected to work independently or in small groups on the proposed task
- Active learning classes, such as discussions
- Homework
- Presentation of selected topics by the students themselves

**LEARNING OBJECTIVES OF THE SUBJECT**

---

After completion of this course, students are expected to know:

- How drugs and other interventions are developed (i.e. clinical development process)
- What a clinical trial can and cannot answer
- The clinical trial's role in the growing body of scientific evidence on a specific intervention and disease indication
- The essential aspects of a clinical trial
- The statistician's role in clinical development
- How to properly report results from a clinical trial
- The recent and future trends in clinical development

**STUDY LOAD**

---

Type	Hours	Percentage
Hours small group	15,0	12.00
Hours large group	30,0	24.00
Self study	80,0	64.00

**Total learning time:** 125 h

## CONTENTS

---

### 1. Clinical development

**Description:**

- Stages of clinical development for drugs and other human interventions
- Clinical research
- Regulatory bodies
- The role of patient in drug development

**Full-or-part-time:** 7h

Theory classes: 3h

Self study : 4h

### 2. Introduction to clinical trials

**Description:**

- Definition of a clinical trial
- The role of clinical trials in the scientific evidence
- Protocol
- Good clinical practice
- Brief overview of phases of clinical trials

**Full-or-part-time:** 14h

Theory classes: 6h

Self study : 8h

### 3. Fundamental aspects of clinical trials

**Description:**

- Randomization
- Blinding
- Population
- Study interventions
- Endpoints

**Full-or-part-time:** 21h

Theory classes: 9h

Self study : 12h

### 4. Types of clinical trials

**Description:**

Types of clinical trials

**Full-or-part-time:** 15h

Theory classes: 6h

Self study : 9h

## 5. Other relevant topics

### Description:

- Regulatory bodies and processes
- Future trends in clinical trials

**Full-or-part-time:** 9h

Theory classes: 3h

Self study : 6h

## 6. Statistical aspects of clinical trials

### Description:

- Sample size estimation
- Common treatment effect estimates (continuous, binary, count and time-to-event endpoints)
- Meta-analysis

**Full-or-part-time:** 9h

Theory classes: 3h

Self study : 6h

## 7. Guidelines

### Description:

- SPIRIT
- CONSORT
- PRISMA

**Full-or-part-time:** 12h

Theory classes: 6h

Self study : 6h

## 8. Presentations

### Description:

Presentations

**Full-or-part-time:** 46h

Theory classes: 6h

Self study : 40h



## GRADING SYSTEM

---

Students will be graded based on:

- Classroom participation (C)
- Homework (H)
- A final presentation on a topic related to clinical trials design or analysis (P)

Classroom (C) participation consists in attending at least 75% of the planned classes.

Homework (H) will be rated 0-10 and the final grade for H will be the average of the tasks.

Presentation (P) will be rated 0-10. The aspects that will be assessed are: structure, content, format, accuracy of statements and related references, and finally, ability to convey the take-away messages to the audience.

The final grade will be calculated as:

$$\text{Grade} = 0.2C + 0.2H + 0.6P$$

There will be flexibility in the timing of the sessions for the presentations to allow everyone to find an appropriate slot.

Students that are still unable/do not wish to present, their final grade will be based on a brief report on a related topic only (i.e. C or H will not contribute to their grade), which should cover a broader topic to demonstrate that the student has acquired the knowledge from the entire course. This report will be in Word format, or other text editors.

## BIBLIOGRAPHY

---

### Basic:

- Friedman, L. M. [et al.]. Fundamentals of clinical trials [on line]. 5th. Springer, 2015 [Consultation: 15/06/2023]. Available on: <https://link-springer-com.recursos.biblioteca.upc.edu/book/10.1007/978-1-4419-1586-3>. ISBN 9783319185385.