Universitat Autònoma de Barcelona

2019/2020

Clinical Trial Design

Code: 104880
ECTS Credits: 6

Degree	Type	Year	Semester
2503852 Applied Statistics	OT	4	0

Contact

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Use of Languages

Principal working language: catalan (cat)
Some groups entirely in English: No
Some groups entirely in Catalan: Yes
Some groups entirely in Spanish: No

Prerequisites

It is recommended to have completed the subject of Transversal Data Analysis and have basic knowledge of SAS.

Objectives and Contextualisation

Provide basic and applied knowledge about Clinical Trials in terms of organization, performance, supervision and analysis. The general objectives are:

1. Knowledge ot the basis of Clinical Trials in terms of historical, ethical and methodological aspects.
2. Knowledge of the different types of Clinical Trials and differentiate their specific characteristics.
3. To acquire knowledge about the basic aspects in the analysis and interpretation of the results of the Clinical Trials.
4. To acquire knowledge of advanced programming in SAS.

Competences

- Analyse data using statistical methods and techniques, working with data of different types.
- Correctly use a wide range of statistical software and programming languages, choosing the best one for each analysis, and adapting it to new necessities.
- Critically and rigorously assess one's own work as well as that of others.
- Identify the usefulness of statistics in different areas of knowledge and apply it correctly in order to obtain relevant conclusions.
- Interpret results, draw conclusions and write up technical reports in the field of statistics.
- Make efficient use of the literature and digital resources to obtain information.
- Students must be capable of applying their knowledge to their work or vocation in a professional way and they should have building arguments and problem resolution skills within their area of study.
- Students must be capable of collecting and interpreting relevant data (usually within their area of study) in order to make statements that reflect social, scientific or ethical relevant issues.
- Students must be capable of communicating information, ideas, problems and solutions to both specialised and non-specialised audiences.
- Use quality criteria to critically assess the work done.
- Work cooperatively in a multidisciplinary context, respecting the roles of the different members of the team.

Learning Outcomes

1. Analyse data corresponding to epidemiological studies or clinical trials.
2. Critically assess the work done on the basis of quality criteria.
3. Draw conclusions that are consistent with the experimental context specific to the discipline, based on the results obtained.
4. Draw up technical reports that clearly express the results and conclusions of the study using vocabulary specific to the field of application.
5. Interpret statistical results in applied contexts.
6. Justify the choice of method for each particular application context.
7. Make effective use of references and electronic resources to obtain information.
8. Reappraise one's own ideas and those of others through rigorous, critical reflection.
9. Recognize the importance of the statistical methods studied within each particular application.
10. Students must be capable of applying their knowledge to their work or vocation in a professional way and they should have building arguments and problem resolution skills within their area of study.
11. Students must be capable of collecting and interpreting relevant data (usually within their area of study) in order to make statements that reflect social, scientific or ethical relevant issues.
12. Students must be capable of communicating information, ideas, problems and solutions to both specialised and non-specialised audiences.
13. Use different programmes, both open-source and commercial, associated with the different applied branches.
14. Work cooperatively in a multidisciplinary context, accepting and respecting the roles of the different team members.

Content

I. Basic concepts in the design of a study

- Steps in research

- Types of epidemiological studies

- Statistical analyses

II. Introduction to the clinical trial Fase I

- Fase II

- Fase III

- Fase IV

III. Randomisation methods

- Simple

- Blocs

- Stratified

- Adaptative

IV. Masking and placebo

V. Analysis populations

- Intention-to-treat (ITT)

- As treated

- Por protocol (PP)

VI. Missing data

VII. Protocol of a Clinical Trial

VIII. Non inferiority and equivalenceIX. Sample size

X. Study design

- Parallel

- Crossover

- Factorial

Methodology

Presentation of theoretical sessions (1h).
Practical session in the computer room (2h).

Activities

Title	Hours	ECTS	Learning Outcomes
Type: Directed			
Session 12: Study designs	3	0.12	1, 3, 5, 6, 11, 9, 13
Session 13: Interim analysis	3	0.12	8, 3, 5, 6, 11, 13
Session 2: Introduction to clinical trials	3	0.12	1, 8, 4, 3, 5, 10, 13
Session 3: Randomization methods	3	0.12	8, 4, 3, 6, 12, 10, 13, 7
Session 4: Masking and placebo	3	0.12	1, 2, 4, 3, 5, 6, 12, 13
Session 5: Analysis population	3	0.12	1, 4, 3, 5, 12, 10, 11, 13
Session 6: Clinical trial protocol	3	0.12	2, 6, 12, 10, 14, 7
Session 9: Non inferiority and equivalence	3	0.12	1, 3, 5, 6, 10, 11, 13, 7
Session1: Basic concepts in the design of a study	4	0.16	1, 4, 5, 6, 10, 11, 9, 13
Sessions 10-11: Sample size calculation	6	0.24	4, 3, 6, 12, 14, 13, 7
Sessions 7-8: Missing data	6	0.24	4, 3, 5, 6, 12, 10, 13, 7

Assessment

The evaluation will consist of three parts:

- Each week a practical deliverable will be held the same day or before the next class.

- Drafting and presentation of a protocol.

- Exam of theory and practices.

Final note: 40% practices, 20% protocol, 20% theory exam, 20% practical exam (SAS).

Assessment Activities

Title	Weighting	Hours	ECTS	Learning Outcomes
Final exam	0.4	25	1	1, 8, 3, 5, 6, 10, 11, 13
Practice 10: Interim analysis	0.04	5	0.2	1, 8, 2, 5, 6, 13, 7
Practice 1: Introduction to SAS	0.04	6	0.24	4, 5, 6, 10, 9, 13
Practice 2: Baseline homogeneity analysis	0.04	5	0.2	1, 4, 3, 5, 6, 10, 11, 13
Practice 3: Randomization methods	0.04	6	0.24	1, 4, 3, 6, 13
Practice 4: Masking and placebo	0.04	6	0.24	1, 2, 4, 3, 5, 6, 12, 13
Practice 5: Population analysis	0.04	5	0.2	1, 2, 4, 3, 5, 6, 12, 10, 9, 13
Practice 6: Missing data	0.04	6	0.24	1, 8, 4, 3, 5, 6, 9, 14, 13, 7
Practice 7: Non inferiority and equivalence	0.04	4	0.16	1, 4, 3, 5, 6, 11, 9, 13, 7
Practice 8: Sample size calculation	0.04	6	0.24	2, 4, 3, 6, 10, 14, 13, 7
Practice 9: Crossover analysis	0.04	6	0.24	1, 3, 5, 6, 9, 13
Protocol presentation	0.2	30	1.2	8, 2, 6, 12, 10, 9, 14, 7

Bibliography

Basic

Stuart J. Pocock. Clinical Trials - A Practical Approach. John Wiley & Sons. 1983.

Shein-Chung Chow, Jen-Pei Liu. Design and Analysis of Clinical Trials: Concepts and Methodologies. Johon Wiley & Sons. 3rd Ed. 2014.

Geoff Der, Brian S. Everitt. A Handbook of Statistical Analyses using SAS. Chapman & Hall. 3rd Ed. 2009.

Complementary

Gordon Guyatt, Drummond Rennie. Guías para usuarios de la literatura médica. Jama & Archieves Journals. 2004.

Stephen Senn. Cross-over Trials in Clinical Research. John Wiley & Sons. 2nd Ed. 2002.