200646 - MERC - Statistical Methods in Clinical Research

Coordinating unit: 200 - FME - School of Mathematics and Statistics
Teaching unit: 1004 - UB - (ENG)Universitat de Barcelona
Academic year: 2019
Degree: MASTER'S DEGREE IN STATISTICS AND OPERATIONS RESEARCH (Syllabus 2013). (Teaching unit Optional)
ECTS credits: 5
Teaching languages: Spanish

Teaching staff

Coordinator: JOSEP LLUIS CARRASCO JORDAN
Others: Segon quadrimestre:
MIQUEL CALVO LLORCA - A
JOSEP LLUIS CARRASCO JORDAN - A
ANTONIO MONLEON GETINO - A

Requirements

- It is necessary that students have basic knowledge of R. In the following link the materials from a course to introduction to R are available:
http://www.ub.edu/stat/docencia/EADB/Curso%20basico%20de%20R.htm
- It is recommended that students have taken a course in Design of Experiments or have basic knowledge on this subject. In particular it is recommended that students know the methodology outlined in chapters 12 and 13 included in Montgomery, DC (2001). Design and analysis of experiments, 5th edition. John Wiley & sons.

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
To face concrete situations, students must know how to identify the appropriate designs, properly conduct an experiment, and analyze the results.

- To obtain theoretical and practical knowledge of some critical designs in Biostatistics.
- To know the regulatory requirements for the approval of generic drugs and formulations.
- To differentiate between situations requiring analysis of differences and those requiring analysis of equivalence.
- To provide the concepts and approaches for carrying out analyses of bioequivalence and equivalence in general.
- To provide the concepts and approaches for carrying out analyses of concordance among measurements.
- To know how to differentiate an analysis of concordance from an analysis of association or parameter comparison.
- To identify the sources of disagreement.
- To develop the skill of discriminating among approaches depending on the type of data and objectives.

Teaching methodology

The in-person lessons consist of sessions in the classroom where theoretical concepts are introduced with practical examples using slides that will be available for students. Furthermore, the appropriate software for conducting analyses and procedures will be introduced by solving real data examples.

Learning objectives of the subject

The learning objectives include:

1. Understanding the complexity of economic and social phenomena typical of a welfare society, and the ability to relate social welfare to globalization and sustainability, and to use techniques, technology, economics, and sustainability in a balanced and compatible manner.

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 globalization and sustainability, and to use techniques, 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 specialization, and critically assessing the results obtained.

Study load

<table>
<thead>
<tr>
<th>Total learning time: 125h</th>
<th>Hours large group: 30h</th>
<th>24.00%</th>
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<tbody>
<tr>
<td></td>
<td>Hours medium group: 0h</td>
<td>0.00%</td>
</tr>
<tr>
<td></td>
<td>Hours small group: 15h</td>
<td>12.00%</td>
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<tr>
<td></td>
<td>Guided activities: 0h</td>
<td>0.00%</td>
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<tr>
<td></td>
<td>Self study: 80h</td>
<td>64.00%</td>
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## BLOCK 1. HIERARCHICAL FACTOR MODELS, REPEATED MEASURES AND CROSS-OVER DESIGNS

**Description:**
1.1.1. Factor designs with random effects. Mixed effects designs.
1.1.2. Hierarchical designs with two and three factors. Bennett-Franklin algorithm.
1.1.3. Repeated measures designs. Sphericity concept and ANOVA table corrections.
1.1.4. Crossover design concept. 2x2 crossover design (AB/BA). Crossover design of superior order and its analysis.

**Learning time:** 31h 15m  
- Practical classes: 12h  
- Guided activities: 8h  
- Self study: 11h 15m

## BLOCK 2. BIOEQUIVALENCE

**Description:**
2.1. Introduction  
2.1.1. Bioavailability. The concept of bioequivalence between drugs. Regulatory norms.  
2.1.2. TOST. The principle of confidence intervals inclusion. Confidence intervals for BE. Bayesian approach. Nonparametric approach.  
2.1.3. The problem of residual effects (carryover)

2.2. Individual and multivariate Bioequivalence  
2.2.1. Individual and populational bioequivalence  
2.2.2. Multivariate bioequivalence.

2.3. Equivalence tests.  
2.3.1. General concept of equivalence test  
2.3.2. Main applications: goodness of fit, homogeneity of variances, additivity in linear models, equivalence of proportions  
2.3.3. Accessories: No inferiority testing method based on statistics and distances; bioinformatics applications

**Learning time:** 31h 15m  
- Practical classes: 12h  
- Guided activities: 8h  
- Self study: 11h 15m
Students must solve some exercises at the end of each of the three blocks that make up the subject. These exercises must be delivered within a certain period to be announced during the course. The three exercises will be scored between 0 and 10, and the average of these three qualifications will be the exercise mark (NEJ).

Additionally, a test will be programmed with multiple choice questions at the end of the course that will include the complete syllabus of the subject. The qualification of this test (NPE) will be between 0 and 10. The attendance to this test will be optional and will be aimed at those students who wish to improve their qualification based on the NEJ.

The final grade of the subject will be calculated as:

1) For those students who do not attend the final test, the final grade of the subject will be the NEJ.
2) For those students who take the final test, the final grade of the subject will be the average of NPE and NEJ.

The subject is considered approved if the final grade is higher than 5.
Bibliography

Basic:


Complementary:


