Course guide
200627 - AC - Clinical Trials

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: 2022 ECTS Credits: 5.0 Languages: English

LECTURER
Coordinating lecturer: JOSÉ ANTONIO GONZÁLEZ ALASTRUE

Others: Segon quadrimestre:
ERIK COBO VALERI - A
ALBERTO COBOS CARBO - A
JOSÉ ANTONIO GONZÁLEZ ALASTRUE - A

PRIOR SKILLS
The student is expected to know descriptive statistics and statistical inference (estimation and testing) and to be familiar with R.

REQUIREMENTS
Basics of experimental design, inference and R.

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.

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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 highly practical, PBL (problems based learning) oriented, and based on the flipped class-room methodology. Student presentations of problems, simulations, and paper reviews represent 40% of face-to-face time; and other active learning activities, such as discussions, 30%. Homework guided activities includes solving questionnaires, short data analyses and practical application of guidelines to selected cases.

LEARNING OBJECTIVES OF THE SUBJECT
After the course, the student will be aware than only a randomized study provides the rationale to confirm and to estimate the effects of an allocated cause. The student will be able to argument and to show that the CT provides a formal basis for evidence for any kind of health interventions; and will know how to write a transparent report with the help of reporting guidelines.

STUDY LOAD

<table>
<thead>
<tr>
<th>Type</th>
<th>Hours</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hours small group</td>
<td>15,0</td>
<td>12.00</td>
</tr>
<tr>
<td>Hours large group</td>
<td>30,0</td>
<td>24.00</td>
</tr>
<tr>
<td>Self study</td>
<td>80,0</td>
<td>64.00</td>
</tr>
</tbody>
</table>

Total learning time: 125 h

CONTENTS

A1: Introduction to Clinical Trials

Description:
drug development, fundamentals of clinical trials, and general issues in the design and analysis of clinical trials.

Full-or-part-time: 12h 30m
Theory classes: 3h
Practical classes: 1h 30m
Self study: 8h
<table>
<thead>
<tr>
<th>Course</th>
<th>Description</th>
<th>Full-or-part-time</th>
<th>Theory classes</th>
<th>Practical classes</th>
<th>Self study</th>
</tr>
</thead>
<tbody>
<tr>
<td>A2: Design of parallel trials</td>
<td>Analysis of parallel trials with and without baselines</td>
<td>12h 30m</td>
<td>3h</td>
<td>1h 30m</td>
<td>8h</td>
</tr>
<tr>
<td>A3: Design and analysis of crossover trials</td>
<td>crossover trials. The AB/BA design. Hills-Armitage analysis. The Grizzle model.</td>
<td>12h 30m</td>
<td>3h</td>
<td>1h 30m</td>
<td>8h</td>
</tr>
<tr>
<td>A4: Reporting clinical trial results.</td>
<td>Reporting clinical trial results. The CONSORT 2010 statement. ICH guidelines</td>
<td>12h 30m</td>
<td>3h</td>
<td>1h 30m</td>
<td>8h</td>
</tr>
<tr>
<td>A5: Review of part A</td>
<td>Review</td>
<td>12h 30m</td>
<td>3h</td>
<td>1h 30m</td>
<td>8h</td>
</tr>
<tr>
<td>B1: Confusion of effects.</td>
<td>Challenge of observational studies. Necessity of the experimental design.</td>
<td>12h 30m</td>
<td>3h</td>
<td>1h 30m</td>
<td>8h</td>
</tr>
</tbody>
</table>
### B2: Trials (Consort)
**Description:**
- Ethical aspects.
- Risks of bias.
- Random assignment of units and groups of units. Intra-class correlation.

**Full-or-part-time:** 12h 30m
- Theory classes: 3h
- Practical classes: 1h 30m
- Self study: 8h

### B3: Trials protocols (Spirit)
**Description:**
- Sample size under Neyman Pearson.
- Assignment of units and groups.

**Full-or-part-time:** 12h 30m
- Theory classes: 3h
- Practical classes: 1h 30m
- Self study: 8h

### B4: Meta-analysis of trials (Prisma)
**Description:**
- Systematic reviews versus meta-analysis. Estimation by interval of the effect by combining studies.
- Heterogeneity.

**Full-or-part-time:** 12h 30m
- Theory classes: 3h
- Practical classes: 1h 30m
- Self study: 8h

### B5: Drug regulation.
**Description:**
- Application of Neyman-Pearson to the pivotal trial.
- Necessary previous studies.
- Post-approval studies.
- Consort Extensions

**Full-or-part-time:** 12h 30m
- Theory classes: 3h
- Practical classes: 1h 30m
- Self study: 8h
GRADING SYSTEM

The student mark is the maximum of the final exam and the continuous (C) evaluation.  
Mark = Max (F, C)  
C is divided in blocks 1 and 2 and each one has 2 parts: Theoretical questions (T, 40%) and Homeworks (H, 60%).  
\[ C = 0.2T_1 + 0.3H_1 + 0.2T_2 + 0.3H_2 \]  
F has 3 parts: Theoretical (T) questions, Exercises (E) and Practices (P), with weights 30%, 40% and 30% respectively:  
\[ F = 0.3T + 0.4E + 0.3P \]

EXAMINATION RULES.

During on-line exams students have to activate the camera.

BIBLIOGRAPHY

Basic: