Research Methods in Clinical Pharmacology

Code: 42360
ECTS Credits: 9

2024/2025

Degree	Type	Year
4311309 Pharmacology	OT	0

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Teachers

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Teaching groups languages

You can view this information at the end of this document.

Prerequisites

It is recommended to have passed the Module 2.
Basics in statistics and epidemiological methods can help to understand the material taught in this module.

Objectives and Contextualisation

Apply basic pharmacological and methodological knowledge to develop clinical drug research and interpret the results.

Apply basic pharmacological and methodological knowledge to carry out a critical analysis of clinical research.

Competences

- Design and conduct research on drugs.
- Generate innovative ideas.
- Interpret one's own and other results of research on drugs.

Learning Outcomes

1. Apply and interpret multivariate statistical techniques, the different regression models and the analysis of repeated-measure designs.
2. Generate innovative ideas.
3. Plan and design clinical and epidemiological studies. (pharmacovigilance and use of medicines).
4. Plan and design clinical trials with medicines.
5. Plan and design pharmacoeconomic studies.
6. Recognise and apply the ethical and quality requirements for conducting clinical research with drugs.
7. Use the results obtained in clinical research to justify decisions on pharmacological treatment.

Content

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a) Methodological aspects: the controlled clinical trial and elements in the design of a trial. Evaluation of results and economic evaluation. Clinical trials and clinical practice: meta-analysis, Cochrane collaboration. Medicine based on tests and applicability to clinical practice. Planning and development of a clinical trial. Clinical trial protocol. Researcher's manual. Information collection methods. Measurement quality Data collection notebook (CRD). Standard work procedures (PNTs). Clinical trial monitoring. Documentation of the study. Audits and inspections. Data management. Medical writting

b) Adverse effects of medications and pharmacovigilance: need for pharmacovigilance and methods of application. Adverse reaction notification systems: spontaneous notification data, national and international programs. Analytical observational studies in pharmacoepidemiology (cohorts, cases and controls, meta-analysis). Other strategies for assessing adverse effects. Evaluation of the benefit / risk ratio. Pharmacovigilance and agents involved (regulators). Definition and classification of drug use studies. Consumer studies Quantitative and qualitative evaluation of medications. Study of the process variables: indication, therapeutic scheme and factors that condition the use of medications. Intervention studies. Pharmaceutical policy (regulators, industry and international organizations).

c) Basic type of economic evaluation study: cost minimization, cost-benefit, cost-effectiveness and cost-utility. Basic methodological elements in the economic evaluation studies. Interpretation of studies of economic evaluation of medicines.

d) Limitations of the investigation in view of its clinical impact. Evidence-based medicine and critical evaluation of medical publications. Instruments that facilitate the clinical application of research results (meta-analysis, clinical practice guides, systematic reviews). The clinical practice guides: methodology and quality assessment. Critical evaluation of observational safety and efficacy research.

e) Protection of patient rights. International ethical codes. CEICs Legislation: regional, national and supranational. Regulatory Agencies Good clinical practice The national normative evolution: the new biomedical research law.

f) Reference population and sample. Hypothesis and error. Multivariate analysis. Regression Analysis Survival Analysis Linear and generalized models. Analysis of repeated measurements.

Activities and Methodology

Title	Hours	ECTS	Learning Outcomes
Type: Directed			
Classroom Practices (PAUL)	40	1.6	1, 2, 7, 4, 3, 5, 6
Seminars of case studies (SCC)	12	0.48	1, 2, 7, 4, 3, 5, 6
Theory (TE)	17.5	0.7	1, 2, 7, 4, 3, 5, 6
Type: Supervised			
Interactive case resolution	13	0.52	1, 2, 7, 4, 3, 5, 6
Unscheduled tutoring	3	0.12	1, 2, 7, 4, 3, 5, 6
review of written works	24	0.96	1, 2, 7, 4, 3, 5, 6
Type: Autonomous			
Study, writing papers ...	113	4.52	1, 2, 7, 4, 3, 5, 6

The teaching methodology used in the different training activities of Module 3 includes master classes, design of clinical studies and discussion in a group of them during practical seminars, as well as practices on critical reading of published studies and strengthening a critical attitude towards the information available in order to enhance the skills and willingness to research.

The module's note is the arithmetic mean of the notes of the matters that make up it.

Annotation: Within the schedule set by the centre or degree programme, 15 minutes of one class will be reserved for students to evaluate their lecturers and their courses or modules through questionnaires.

Assessment

Continous Assessment Activities

Title	Weighting	Hours	ECTS	Learning Outcomes
Attendance and participation	50%	0	0	1, 2, 7, 4, 3, 5, 6
Presentations	25 %	1.5	0.06	1, 2, 7, 4, 3, 5, 6
Written examination	25 %	1	0.04	1, 2, 7, 4, 3, 5, 6

The grade for the module is the arithmetic mean of the grades of the subjects that comprise it.

Students who do not take both the theoretical and practical assessment tests will be considered "Not Evaluable", exhausting their rights to enroll in the subject.
This module does not provide for the single assessment system.

Bibliography

bibliographical and documentary resources*:*

- *www.pubmed.org*

Textbooks:

- Laporte JR. Principios básicos de investigación clínica. Acceso on-line gratuito:

http://www.icf.uab.cat/ca/productes/publi/subllibres/pbic.html

- Laporte JR, Tognoni G. Principios de epidemiología del medicamento. Acceso gratuito:

http://www.icf.uab.cat/ca/productes/publi/subllibres/pem.html

- Figueras A, Narváez E, Vallano A. Estudios de utilización de medicamentos. Acceso gratuito:

http://www.icf.uab.cat/ca/productes/publi/subllibres/eum_man.html

- Diogène E. Guía de investigación clínica para la atención primaria. Ediciones Mayo, Barcelona 2005.

- The AGREE Research Group. Instrumento AGREE, 2009.

Software

No software is needed.

Language list

Name	Group	Language	Semester	Turn
(PAULm) Classroom practices (master)	101	Spanish	first semester	afternoon
(PLABm) Practical laboratories (master)	101	Spanish	first semester	afternoon
(SCCm) Clinical case seminars (master)	101	Spanish	first semester	afternoon
(TEm) Theory (master)	101	Catalan/Spanish	first semester	afternoon