Research into Clinical Pharmacology

Code: 42151
ECTS Credits: 10

2024/2025

Degree	Type	Year
4312326 Applied Clinical Research in Health Sciences	OT	0

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Teachers

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(External) M. Sabaté
(External) S. Grau

Teaching groups languages

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

Prerequisites

Basic knowledge of statistics and pharmacological methods can help to understand the subject taught in this module

Objectives and Contextualisation

To apply the basic pharmacologic and methodological knowledge to develop clinical research of drugs and interpret the results.

To apply the basic pharmacological and methodological knowledge to carry out a critical analysis of clinical research.

Competences

- Act respecting the Independent Ethics and legal aspects of the research and of the professional activities.
- Covering demonstrate the importance and limitations of scientific and translational research in health sciences.
- Development of habilidades autoaprendizaje y su formación Motivación to continue to postgraduate level.
- Development scientific knowledge, creativity and Critical Thinking.
- Participate in the development of a protocol for basic, clinical or experimental research, based on scientific methodology.
- Prove that the methodologies covering estadísticas básicas utilizadas in the biomedical and clinical estudios y análisis use the tools of the modern computational technology.
- Recognize and explain the ethical, regulatory and financial context in which biomedical research must be conducted

Learning Outcomes

1. Act respecting the ethical and legal aspects of research and professional activities.
2. Apply and interpret multivariate statistical techniques, different regression models and analysis of repeated measures designs.
3. Develop scientific knowledge, critical thinking and creativity.
4. Develop self-learning skills and motivation to continue their education at the graduate level.
5. Plan, design and interpret studies of drug-economy.
6. Planning, designing and interpreting clinical drug trials.
7. Planning, designing and interpreting clinical-epidemiological studies: pharmacovigilance and drug use,
8. Recognize and apply ethical and quality requirements to conduct clinical research with drugs.
9. Transferring the results of clinical research in decision-making to the drug therapy.

Content

A) methodological aspects: The controlled clinical trial and elements in the design of an essay. Evaluation of results and economic evaluation. Clinical trials and Clinical practice: meta-analysis, Cochrane collaboration. Medicine based on tests and applicability in clinical practice. Planning and development of a clinical trial. Clinical trial Protocol. Researcher's Handbook. Methods of gathering information. Quality of measurement. Data collection notebook (CRF). Standardised working procedures (NWPs). Clinical trial monitoring. Study documentation. Audits and inspections. Data management. Medical writting.

b) The adverse effects of medicines and pharmacovigilance: the need for pharmacovigilance and application methods. Systems of notification of adverse reactions: data of spontaneous notification, national and international programs. Observational analytical studies in pharmacoepidemiology (cohorts, cases and controls, metaanalysis). Other strategies for evaluating adverse effects. Evaluation of the benefit/risk ratio. Pharmacovigilance and agents involved (regulators). Definition and classification of studies on drug use. Consumption studies. Quantitative and qualitative evaluation of medicines. Study of process variables: indications, therapeutic schema and factors that condition the use of medicines. Intervention studies. Pharmaceutical policy (regulators, industry and international organizations).

c) Basic type of study of economic evaluation: minimization of costs, cost-benefit, cost-effectiveness and cost-usefulness. Methodological Elements In the study of economic evaluation. Interpretation of studies of economic evaluation of medicines.

d) Research limitations on the clinical impact. Medicine based on evidence and critical evaluation of medical publications. Instruments that facilitate the clinical application of research results (meta-analysis, clinical practice guidelines, systematic reviews). Clinical Practice guidelines: Methodology and qualityassessment. Critical evaluation of the observational research on safety and efficacy.

e) Protection of the rights of the patient. International ethical Codes. Ceics. Legislation: autonomic, national and supranational. Regulatory agencies. Good clinical practice. The National normative Evolution: The new law of biomedical investigation.

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

Activities and Methodology

Title	Hours	ECTS	Learning Outcomes
Type: Directed			
Practice in class	40	1.6	1, 2, 3, 4, 5, 6, 7, 8, 9
Theory	17.5	0.7	1, 2, 3, 4, 5, 6, 7, 8, 9
clinical cases seminars	12	0.48	1, 2, 3, 4, 5, 6, 7, 8, 9
Type: Supervised			
Tasks review	24	0.96	1, 2, 3, 4, 5, 6, 7, 8, 9
interactive resolution of clinical cases	13	0.52	1, 2, 3, 4, 5, 6, 7, 8, 9
unescheduled tutoring	3	0.12	1, 2, 3, 4, 5, 6, 7, 8, 9
Type: Autonomous			
study, realization of tasks	138	5.52	1, 2, 3, 4, 5, 6, 7, 8, 9

The teaching methodology used in the different training activities of the module includes master classes, design of clinical studies and group discussion of the same 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 skills and willingness to research.
The grade of the module is the arithmetic mean of the notes of the materials that compose 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
Test. Written questionaire	25%	1	0.04	1, 2, 3, 4, 5, 6, 7, 8, 9
Work presentation	40%	1.5	0.06	1, 2, 3, 4, 5, 6, 7, 8, 9
attendancy and participation	35%	0	0	1, 2, 3, 4, 5, 6, 7, 8, 9

The qualification of the module is the arithmetic mean of the marks of the materials that compose 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 subject/module does not provide for the single assessment system

Bibliography

Bibliographic searchs:
- www.pubmed.org

- www.sietes.org

Text books:
- 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

Teams

Language list

Name	Group	Language	Semester	Turn
(PAULm) Classroom practices (master)	101	Spanish	first semester	morning-mixed

(PLABm) Practical laboratories (master)	101	Spanish	first semester	morning-mixed
(SCCm) Clinical case seminars (master)	101	Spanish	first semester	morning-mixed
(TEm) Theory (master)	101	Catalan/Spanish	first semester	morning-mixed