Universitat Autònoma de Barcelona

2021/2022

Research Methods in Clinical Pharmacology

Code: 42360
ECTS Credits: 9

Degree	Type	Year	Semester
4311309 Pharmacology	OT	0	1

The proposed teaching and assessment methodology that appear in the guide may be subject to changes as a result of the restrictions to face-to-face class attendance imposed by the health authorities.

Contact

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Use of Languages

Principal working language: spanish (spa)

Teachers

Maria Antonieta Agustí Escasany
Jordi Alberola Domingo
Magí Farré Albaladejo
Xavier Vidal Guitart
Maria Dolors Romero Cereijo
Caridad Pontes García
Immaculada Danés Carreras
Clara Perez Maña
Maria Gloria Cereza García
Mónica Sabaté Gallego

External teachers

D. Capellà
S. Grau

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

2733/5000
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.

Methodology

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.

Activities

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

Assessment

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

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

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/sublllibres/pbic.html

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

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

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

http://www.icf.uab.cat/ca/productes/publi/sublllibres/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.