

| Degree programme | Type | Course |
|------------------|------|--------|
| Pharmacology     | OP   | 0      |

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## Group languages

You can consult this information at the [end](#) of the 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

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.

## Learning outcomes

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

## Contents

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 writing

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.

## Learning activities and methodology

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

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.

Use of Artificial Intelligence (AI): The use of AI technologies is permitted only for support tasks (such as information search, text correction, or translations) and in specific activities as indicated. Students must clearly identify the parts generated with AI, specify the tools used, and include a critical reflection on how these influenced the process and final outcome. Non-transparent use of AI will be considered a breach of academic integrity and may result in penalties.

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

### Continuous assessment activities

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

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.

Any irregularity in an assessment activity -academic misconduct, plagiarism, or improper use of AI, unless such use is expressly authorised in the course guide- that may lead to a significant change in the mark shall result in that assessment activity being awarded a mark of 0. If the course guide establishes that obtaining a minimum mark in that assessment activity is an essential requirement for passing the course, or if several irregularities occur in the assessment activities of the same course, the final mark for that course shall be 0. In addition, disciplinary proceedings may be initiated against any student who commits any of these irregularities.

## Bibliography

bibliographical and documentary resources:

- [www.pubmed.org](http://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](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.

### Course groups and languages

The information provided is provisional until November 30. After this date, you will be able to consult the language of each group through this [link](#). To access the information, you will need to enter the course CODE

| Type of teaching                        | Group | Language        | Semester       | Shift     |
|-----------------------------------------|-------|-----------------|----------------|-----------|
| (TEm) Theory (master)                   | 101   | Catalan/Spanish | first semester | afternoon |
| (PAULm) Classroom practices (master)    | 101   | Catalan/Spanish | first semester | afternoon |
| (PLABm) Practical laboratories (master) | 101   | Catalan/Spanish | first semester | afternoon |
| (SCCm) Clinical case seminars (master)  | 101   | Catalan/Spanish | first semester | afternoon |