

Degree	Type	Year
4311309 Pharmacology	OB	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

In order to correctly follow the module, students need to have previous knowledge of pharmacology, related to the mechanisms of action of drugs as well as the need to carry out specific studies during the development of a molecule as a drug. They are also supposed to have basic knowledge of simple statistical techniques. Most of this knowledge will have been acquired in module 1 of the master's degree itself, and some others should be of general knowledge before initiation of the master's degree. This knowledge is related to statistics, and, they are part of the knowledge gained in the majority of the diplomas, degrees, or bachelor's degrees that give access to the master's degree, .

## Objectives and Contextualisation

Apply basic pharmacological knowledge to drug development optimization (R+D) and clinical use, and expand knowledge to help understand their clinical use.

## Competences

- Apply pharmacological knowledge to clinical practice.
- Apply pharmacological knowledge to the development and optimisation (R&D) of drugs.
- Capacitat d'anàlisi i síntesi.
- Desenvolupar habilitats d'autoaprenentatge.
- Desenvolupar un pensament crític i autocrític.

## Learning Outcomes

1. Capacitat d'anàlisi i síntesi.
2. Describe the methodology used to critically assess studies on drug effectiveness and safety.
3. Desenvolupar habilitats d'autoaprenentatge.
4. Desenvolupar un pensament crític i autocrític.
5. Explain the regulatory framework in which medical trials must take place.
6. Identify how drugs are used in our society and the economic and medical factors that determine the choice of medicines.
7. Identify the phases of clinical and pre-clinical development of medicines and describe their characteristics.
8. Indicate the scientific and technical principles and the objectives that are formulated when applying the most common laboratory techniques for drug-testing.
9. Recognise basic statistical concepts and the main tests used that help to interpret pre-clinical and clinical studies with medicines.

## Content

a) Life cycle of a drug. Origin and obtaining of medicines: chemical synthesis, biotechnological processes and extraction from natural sources. Pharmaceutical and galvanic technology. Pre-clinical development: activity-structure, basic and safety pharmacology, basic and special toxicology. Clinical development: different phases of the clinical trial. Post-authorization and pharmacovigilance.

b) Legislation and registration of medicines in Spain, the European Union and other countries. Guides. Special medicines for rare diseases and/or special populations (paediatrics), medicines of biotechnological origin. The case of sanitary products. Agents involved in drug development: administration, industry, service companies (CRO), research centers and hospitals.

c) General introduction to classic and current pharmacology techniques. In vivo systems to evaluate the action and effect of drugs: induction of models, concepts of knockouts and GMOs. In vitro systems for drug evaluation: cell culture, FACS, MACS, organ bath, electrophysiology (patch clamp). Processing of histological samples and microscopy (optical, confocal, etc.). In vivo and in vitro techniques for the study of the release of neurotransmitters: indirect functional studies and others (synaptosomes, miniprisms, microdialysis). General methods of determination and quantification of molecules: colorimetry, spectrophotometry, fluorometry, chromatograph, mass spectrometry, etc. Protein determination: bioassays, immunoassays (ELISA/RIA), western blot, immunocyto(histo)chemical, flow cytometry. Determination of nucleotides: RT-PCR, northern blot, in situ hybridization / sequencing. Measurement of pharmacological receptors: radioligand fixation techniques, biochemical techniques of application in the study of receptors. Pharmacokinetic techniques: pharmacological treatment and sample collection, drug-protein binding, extraction, dose-response curve.

Biotechnological processes in the production of biopharmaceuticals: recombinant DNA, monoclonal antibodies, etc.

d) General concepts of epidemiology. Critical evaluation of clinical trials. Types of epidemiological studies. Evaluation of safety studies and pharmacovigilance. Meta-analysis. Drug use studies.

e) Descriptive statistics. Inferential statistics. Association - correlation. Imputation of causation. Bivariate analysis. Sample size. Sensitivity, specificity and ROC curves.

## Activities and Methodology

Title	Hours	ECTS	Learning Outcomes
Type: Directed			
Clinical cases seminars	5	0.2	1, 2, 4, 5, 6, 7, 8, 9
Practice in class	21	0.84	1, 2, 4, 5, 6, 7, 8, 9
Theory	66	2.64	1, 2, 4, 5, 6, 7, 8, 9
Type: Supervised			
Work supervision/evaluation	24	0.96	1, 2, 4, 5, 6, 7, 8, 9
scheduled tutoring	4	0.16	1, 2, 4, 5, 6, 7, 8, 9
unscheduled tutoring	4	0.16	1, 2, 4, 5, 6, 7, 8, 9
Type: Autonomous			
Study, tasks	172	6.88	1, 2, 3, 4, 5, 6, 7, 8, 9

Different methodologies will be used to encourage the interaction of students with each other, with professionals from different fields, as well as teamwork and personnel work.

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
Studying, performing tasks	35%	0	0	1, 2, 3, 4, 5, 7, 8
Test. Written questionnaire	15%	2	0.08	1, 2, 3, 4, 9
class follow-up	20%	0	0	1, 2, 3, 4, 5, 6, 7, 8, 9

works exhibition	30%	2	0.08	1, 2, 3, 4, 5, 7, 8
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The note of the module is the arithmetic mean of the notes 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

- Cell biology protocols - 2006 / Harris R et al / 978-0-470-84758-9
- Standards of mouse model phenotyping - 2006 / Hrabé de Angelis, Martin / 978-3-527-31031-9
- Fundamentos de las técnicas de biología molecular - 2006 / Tagu et al / 978-84-200-1067-0
- An introduction to molecular biotechnology: from molecular biological fundamentals to methods and applicaions in modern biotechnology - 2006 / Wink M. / 978-3-527-31412-6
- In vivo cellular and molecular imaging - 2005 / Ahrens E / 8978-0-12-153170-6
- Biología celular y molecular: conceptos y experimentos - 2005 / Karp G. et al / 978-970-10-5376-8
- The mouse in biomedical research - 2007 / Fox j. et al
- Cell Biology: a laboratory handbook - 2005 / Celis JE
- Medical methods handbook - 2005 / Walker JM et a
- A guide to methods in the biomedical sciences - 2005 / Corley R (Springer) / 0-387-22845-6
- Discovering Statistics Using IBM SPSS Statistics, 2013. By Andy Field
- Statistical Methods in Medical Research Hardcover - December 15, 2001 by Peter Armitage, Geoffrey Berry, J. N. S. Matthews
- Early Drug Development: Strategies and Routes to First-in-Human Trials. Aug 9, 2010 by Mitchell N. Caye
- Theory of Drug Development (Chapman & Hall/CRC Biostatistics Series)Oct 24, 2013 by Eric B. Holmgren
- A Comprehensive Guide to Toxicology in Preclinical Drug DevelopmentNov 16, 2012 by Ali S. Faqi
- Development of FDA-Regulated Medical Products: A Translational Approach, Second EditionFeb 22, 2012 by Elaine Whitmore
- Laporte J-R. La evaluación de los efectos de los medicamentos documento. Laporte J-R. Principios Básicos de investigación clínica. Barcelona: AstraZeneca; 2001: 1-7.

<http://www.icf.uab.cat/ca/pdf/publicacions/pbic/Cap-1.pdf>

- Laporte J-R, Tognoni G. Estudios de utilización de medicamentos y de farmacovigilancia. Principios de epidemiología del medicamento. Barcelona. Masson-Salvat; 1993: 1-24.

<http://www.icf.uab.cat/ca/pdf/publicacions/pem/cap1.pdf>

- Laporte J-R. Extrapolación de los resultados de ensayos clínicos a la práctica habitual. Laporte J-R. Principios Básicos de investigación clínica. Barcelona: AstraZeneca; 2001: 61-78.  
<http://www.icf.uab.cat/ca/pdf/publicacions/pbic/Cap-5.pdf>
- Coggon G, Rose G, Barker DJP. Epidemiology for Uninitiated (fourth edition). BMJ  
<http://www.bmj.com/about-bmj/resources-readers/publications/epidemiology-uninitiated>
- Principios básicos de investigación clínica. Glosario de términos utilizados  
<http://www.aulaterapeutica.net/moodle/mod/glossary/view.php?id=208>
- Grimes DA, Schultz KF. An overview of clinical research: the lay of the land. The Lancet 2002; 358: 57-61.
- Grimes DA, Schultz KF. Cohort studies: marching towards outcomes documento. The Lancet 2002; 359: 341-5.
- Schultz KF, Grimes DA. Case-control studies: research in reverse documento. The Lancet 2002; 359: 431-4.
- Abaira V. Medidas del efecto de un tratamiento (I). Notas estadísticas. SEMERGEN 2002; 26: 535-6.
- Abaira V. Medidas del efecto de un tratamiento (II). Notas estadísticas. SEMERGEN 2001; 27: 418-20.
- Evaluación de Tratamientos: <ftp://ftp.hrc.es/pub/programas/calcu/evaltrat/evaltrat.htm>
- Introducción al ensayo clínico. Documento. Bakke OM, Carné X, García F. Ensayos clínicos con medicamentos. Fundamentos básicos, metodología y práctica. Ediciones Doyma. Barcelona 1994.
- Características del estudio experimental. Documento. Bakke OM, Carné X, García F. Ensayos clínicos con medicamentos. Fundamentos básicos, metodología y práctica. Ediciones Doyma. Barcelona 1994.
- El ensayo clínico controlado: concepto y objetivos. Bakke OM, Carné X, García F. Ensayos clínicos con medicamentos. Fundamentos básicos, metodología y práctica. Ediciones Doyma. Barcelona 1994.
- Laporte J-R. El ensayo clínico controlado. Laporte J-R. Principios Básicos de investigación clínica. Barcelona: AstraZeneca; 2001: 27-54. <http://www.icf.uab.es/livre/pdf/CAP-3.PDF>
- Laporte J-R. Metaanálisis de ensayos clínicos. Laporte J-R. Principios Básicos de investigación clínica. Barcelona: AstraZeneca; 2001: 79-92. <http://www.icf.uab.es/livre/pdf/cap-6.pdf>
- Egger M, Smith GD, Phillips AN. Meta-analysis. Principles and procedures. BMJ 1997; 315: 1533-7.
- Egger M, Smith GD. Meta-analysis. Potentials and promise. BMJ 1997; 315: 1371-4.
- The Cochrane Collaboration archivo. <http://www.cochrane.org/>
- Critical Appraisal Skills Programme Español (CASPe) archivo. <http://www.redcaspe.org/>
- Cochrane Handbook for Systematic Reviews of Interventions. <http://www.cochrane.org/handbook>
- CONSORT, transparent reporting of trials. <http://www.consort-statement.org/resources>
- JR Laporte, D Capellà. Mecanismos de producción y diagnóstico clínico de los efectos indeseables producidos por medicamentos. Laporte J-R, Tognoni G. Principios de epidemiología del medicamento. Barcelona. Masson-Salvat; 1993: 95-109. <http://www.icf.uab.es/pem/docs/cap5.pdf>
- JR Laporte, X Carné. Metodología epidemiológica básica en farmacovigilancia. Laporte J-R, Tognoni G. Principios de epidemiología del medicamento. Barcelona. Masson-Salvat; 1993: 111-130. <http://www.icf.uab.es/pem/docs/cap6.pdf>

- D Capellà, JR Laporte. La notificación espontánea de reacciones adversas a medicamentos. Laporte J-R, Tognoni G. Principios de epidemiología del medicamento. Barcelona. Masson-Salvat; 1993: 147-169.  
<http://www.icf.uab.es/ca/pdf/publicacions/pem/cap8.pdf>
- JR Laporte, X Carné. Estudios de cohortes en farmacovigilancia. Laporte J-R, Tognoni G. Principios de epidemiología del medicamento. Barcelona. Masson-Salvat; 1993: 171-196.  
<http://www.icf.uab.es/pem/docs/cap9.pdf>
- S Shapiro, D Kaufman, JR Laporte. La estrategia de casos y controles en farmacovigilancia. Laporte J-R, Tognoni G. Principios de epidemiología del medicamento. Barcelona. Masson-Salvat; 1993: 199-217.  
<http://www.icf.uab.es/pem/docs/cap10.pdf>
- Schulz KF, Grimes D. Case-control studies: research in reverse. Lancet 2002; 359: 431-34.
- Grimes D, Schulz KF. Bias and causal associations in observational research. Lancet 2002; 359: 248-52.
- Greenhalgh T, Kostopoulou O, Harrie C. Making decisions about benefits and harms of medicines. BMJ 2004;329:47.
- Wood L, Martinez C. The General Practice Research Database. Drug safety 2004; 27; 871-81.
- E Ramirez, A J Carcas, A M Borobia, S H Lei, E Piñana, S Fudio and J Frias. A Pharmacovigilance Program From Laboratory Signals for the Detection and Reporting of Serious Adverse Drug Reactions in Hospitalized Patients. Clinical Pharmacology & Therapeutics 2010; 87:74-86.
- Hans-Georg Eichler, Francesco Pignatti, Bruno Flamion, Hubert Leufkens & Alasdair Breckenridge. Balancing early market access to new drugs with the need for benefit/risk data: a mounting dilemma. Nature Reviews Drug Discovery 2008; 7:818-26.
- Yannick Arimone, Ghada Miremont-Salamé, Françoise Haramburu, Mathieu Molimard, Nicholas Moore, Annie Fourrier-Réglat, and Bernard Bégaud. Inter-expert agreement of seven criteria in causality assessment of adverse drug reactions. Br J Clin Pharmacol. 2007; 64: 482-8.
- Introduction to Drug Utilization Research. 2003 WHO Pharmacological Services.  
[http://www.whocc.no/filearchive/publications/drug\\_utilization\\_research.pdf](http://www.whocc.no/filearchive/publications/drug_utilization_research.pdf)
- D. Rodríguez, J. Pujol Salud, A. Vallano Ferraz. Describir los resultados de las intervenciones en la práctica clínica. E. Diogène. Guía de investigación clínica para Atención Primaria.  
<http://w3.icf.uab.es/ficf/es/pub/IAP/GuiaInvestigacionClinicaAP/GICAPcapitulo-7.pdf>
- D Capellà, JR Laporte. Métodos aplicados en estudios descriptivos de utilización de medicamentos. Laporte J-R, Tognoni G. Principios de epidemiología del medicamento. Barcelona. Masson-Salvat; 1993: 67-92.
- Drug Utilization Research Group, Europa. <http://www.pharmacoepi.org/eurodrug/>
- Who Collaborating Centre for Drug Statistics Methodology. [http://www.whocc.no/atc\\_ddd\\_index/](http://www.whocc.no/atc_ddd_index/)

## Software

If needed (Teams)

## 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