VNIVERSITAT DE VALÈNCIA

Course Guide
43040 Research methodology on the rational use of medicinal products

COURSE DATA

Data Subject	
Code	43040
Name	Research methodology on the rational use of medicinal products
Cycle	Master's degree
ECTS Credits	4.0
Academic year	2024 - 2025

Study (s)

Degree	Center	Acad. year	Period
2138 - Master's Degree in Research in and Rational Use of Medicines	Faculty of Pharmacy and Food Sciences	1	Annual

Subject-matter

Degree	Subject-matter	Character
2138 - Master's Degree in Research in and Rational Use of Medicines	16 - Methodology for research on the rational use of medicines	Optional

Coordination

Name	Department
RECIO IGLESIAS, M. CARMEN	135 - Pharmacology

SUMMARY

Subject designed to meet such comparative research bases used to establish the level of evidence for the rational use of medicines. We compare the utility they provide different methods for clinical research with drugs you establish the rational use of it.

Be reviewed various methods of drug research and develop strategies for information about drugs that have an impact or can be used in rational drug use.

We will study the role of epidemiological methods to establish the consequences of drug use in humans, primarily from the population point of view.

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PREVIOUS KNOWLEDGE

Relationship to other subjects of the same degree

There are no specified enrollment restrictions with other subjects of the curriculum.

Other requirements

Knowledge of English reading level, user-level knowledge of the most common computer programs (word processor, spreadsheet and presentation of images), as to the databases facilitate learning general knowledge of the structure ; understanding of statistics.

COMPETENCES (RD 1393/2007) // LEARNING OUTCOMES (RD 822/2021)

2138 - Master's Degree in Research in and Rational Use of Medicines

- Manejar adecuadamente las fuentes de información biomédica y poseer la habilidad de hacer una valoración crítica de las mismas integrando la información para aportar conocimientos a grupos asistenciales multidisciplinares
- Know how to apply acquired knowledge and problem-solving skills in new or unfamiliar environments within broader (or multidisciplinary) contexts related to their area of study.
- To be able to integrate knowledge and face the complexity of formulating judgments from information that, being incomplete or limited, includes reflections on the social and ethical responsibilities linked to the application of their knowledge and judgments.
- Know how to communicate your conclusions (and the underlying knowledge and reasons) to both specialist and non-specialist audiences in a clear and unambiguous way.
- Possess the learning skills that will allow them to continue studying in a way that will be largely self-directed or autonomous.
- To acquire basic skills to develop laboratory work in biomedical research.
- Be able to make quick and effective decisions in professional or research practice.
- CG1 - Be able to access the information required (databases, scientific articles, etc.) and to interpret and use it sensibly.
- Students should possess and understand foundational knowledge that enables original thinking and research in the field.
- Be able to integrate new technologies in their professional and/or research work.
- Know how to write and prepare presentations to present and defend them later.
- Critically analyse one's own work and that of colleagues.
- CT2 - To be able to assess the need to complete the scientific, historical, language, informatics, literature, ethics, social and human background in general, attending conferences, courses or doing complementary activities, self-assessing the contribution of these activities towards a comprehensive development.

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- Be able to apply the research experience acquired to professional practice both in private companies and in public organisations.
- Dominar la comunicación científica. Poseer habilidades sociales y comunicativas en la práctica asistencial.
- Select and manage available resources (instrumental and human) to optimise research outcomes.
- Dominar el método científico, el planteamiento de protocolos experimentales y la interpretación de resultados en la búsqueda, desarrollo y evaluación de nuevos fármacos.

LEARNING OUTCOMES (RD 1393/2007) // NO CONTENT (RD 822/2021)

The student must have acquired skills and attitudes that enable:

1. To assess the effects of drugs in humans for a rational use of medicines, using information from pharmacoepidemiological studies.

2. File a critical attitude to make judgments argued about the role of drug therapy and it be able defending these judgments with rigorous and tolerance.

Adequately convey the information extracted from primary documents on pharmacoepidemiological and drug research studies.

The general objectives are:

• Become familiar with the methods of drug epidemiological research.

• Differentiate the characteristics of different types of pharmacoepidemiological study, as the interpretation, and application to specific problems.

• Interpret the results of clinical trials, pharmacovigilance, drug-use and other observational studies concerning the rational use of medicines.

DESCRIPTION OF CONTENTS

1. General principles in the investigation of drugs in humans

Relationship of pharmacology to epidemiology and the study of drugs in humans. Drug Research in humans. Clinical research with drugs. Post-market monitoring of drugs. Drug utilization studies.

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2. General characteristics and types of studies

Experimental studies: randomized clinical trials. Observational studies: case reports, case series, trend analysis, utilization studies, case-control and cohort studies. Most common errors and biases. Comparative analysis of different kind of studies.

3. Experimental and Observational studies

Safety and risk concepts. Types and risk calculations. Calculating risk from data obtained from published papers. Critical reading and comparative analysis of studies on adverse and efficacy effects of the drugs. Spontaneous reporting systems. Data monitoring drug safety. Other pharmacovigilance systems. Specific implications of pharmacovigilance in the rational use of medicines.

4. Other approach and methodological issues on drug research

Studies of drug utilization. The automated databases in pharmacoepidemiological studies. Studies of quality of life related to medications. The use of meta-analysis in pharmacoepidemiology.

WORKLOAD

ACTIVITY	Hours	% To be attended
Seminars	20,00	100
Theory classes	16,00	100
Tutorials	4,00	100
Attendance at events and external activities	5,00	0
Development of group work	10,00	0
Development of individual work	5,00	0
Study and independent work	10,00	0
Readings supplementary material	10,00	0
Preparation of evaluation activities	5,00	0
Resolution of case studies	15,00	0
TOTAL	**100,00**	

TEACHING METHODOLOGY

During the activities, both theoretical and practical, the applications of the subject contents in relation to the Sustainable Development Goals (SDG) will be indicated. This is intended to provide knowledge, skills and motivation to understand and address these SDGs, while promoting reflection and criticism.

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The methodology to be used is: Lectures, seminars and writing-works and problems solving cases. The face-to-face teaching will be completed in a non-face-to-face way through recorded presentations and videoconferences for the resolution of doubts and discussion of problems.

The first day will be a written exam consisting of answering a series of questions to assess the degree of prior knowledge on the subject.

In addition to the lectures (explanation of the topic by the teacher) will be held seminars that will focus on specific aspects of documents previously provided to students. At times, the students themselves will prepare the issues and they will make a brief description of them as the basis for discussion. Students work individually or in groups on the material previously delivered. After study the material, they have to present a summary of it in a limited time.

Students have to respond in a writing way to same questions and issues previously delivered. These materials will have been discussed during the session.

All documents and papers will be available in the Virtual Classroom

EVALUATION

Formative assessment is carried out by the answers to the questions and / or cases raised and work with your exposure developed by students.

There may also be a final evaluation consisting of a series of short questions (5 to 15) with limited space and one or two issues to respond in a systematic way on one side of a sheet, in order to determine the capacity to structure of orderly concepts according to their importance and their interconnection.

The work done during the course, significantly modulate the final grade.

Evidence of copying or plagiarism in any of the assessable tasks will result in failure to pass the subject and in appropriate disciplinary action being taken. Please note that, in accordance with article 13. d) of the Statute of the University Student (RD 1791/2010, of 30 December), it is the duty of students to refrain from using or participating in dishonest means in assessment tests, assignments or university official documents.

In the event of fraudulent practices, the "**Action Protocol for fraudulent practices at the University of Valencia**" will be applied (ACGUV 123/2020): https://www.uv.es/sgeneral/Protocols/C83sp.pdf

REFERENCES

Basic

- Baños JE, Farré M. Principios de Farmacología Clínica. Barcelona. Masson. 2002

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- Baños JE, Brotons C, Farré M. Glosario de Investigación Clínica y Epidemiológica. Barcelona. Monografías Fundación Dr. Antonio Esteve 23. 1998.
- Hernández-Aguado I, Gil A, Delgado M, Bolumar F. Manuel de epidemiología y salud pública. Buenos Aires. Panamericana. 2005
- Laporte JR, Tognoni G. Principios de epidemiología del medicamento. 2º e d Barcelona. Masson-Salvat. 1993
- Laporte JR. Principios básicos de investigación clínica. 2ª ed. Barcelona. Astra-Zeneca 2001.

Additional

- Strom BL. Pharmacoepidemiology. 4ª ed. Sussex: John Wiley, 2005
- Strom BL, Kimmel SE (eds). Textbook of Pharmacoepidemiology. Sussex: John Wiley, 2006

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