VNIVERSITAT DE VALÈNCIA

Course Guide
44785 Preclinical and clinical research. Design of experiments

COURSE DATA

Data Subject	
Code	44785
Name	Preclinical and clinical research. Design of experiments
Cycle	Master's degree
ECTS Credits	4.0
Academic year	2023 - 2024

Study (s)

Degree	Center	Acad. year	Period
2231 - Master's Degree in Biomedical Engineering	Faculty of Medicine and Odontology	1	First term

Subject-matter

Degree	Subject-matter	Character
2231 - Master's Degree in Biomedical Engineering	2 - Design and analysis of experiments	Obligatory

Coordination

Name	Department
GUILLEN DOMINGUEZ, MARIA LUISA	265 - Prev. Medicine, Public Health, Food Sc.,Toxic. and For. Med.
MUÑOZ COLLADO, CARLOS	275 - Microbiology and Ecology
SAEZ TORMO, GUILLERMO	30 - Biochemistry and Molecular Biology

SUMMARY

The subject “Preclinical and Clinical Research: Design of experiments”, is a compulsory subject, consists of 4.5 theoretical and practical ECTS credits and is taught in the Master in Biomedical Engineering.

It is a fundamental subject in which the basic concepts on clinical research developed in several areas of the basic sciences (microbiology, biochemistry and epidemiology) are provided. Issues related to the epidemiological evaluation of health technology will also be discussed; techniques for assessing the effectiveness, effectiveness and safety of sanitary processes and health technologies; security criteria; which are important for the professional development of a graduate in this master.

PREVIOUS KNOWLEDGE

Relationship to other subjects of the same degree

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

Other requirements

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

2231 - Master's Degree in Biomedical Engineering

- Students should apply acquired knowledge to solve problems in unfamiliar contexts within their field of study, including multidisciplinary scenarios.
- Students should possess and understand foundational knowledge that enables original thinking and research in the field.
- Ser capaz de analizar, proponer y construir soluciones a problemas complejos en entornos emergentes y multidisciplinares asociados a la ingeniería biomédica, con una visión global.
- Ser capaz de diseñar y llevar a cabo investigaciones basadas en el análisis, la modelización y la experimentación.
- Ser capaz de aportar ideas y soluciones de amplia originalidad, prácticas y aplicables, flexibles y complejas, que afecten tanto a las personas como a los procesos.
- Ser capaz de aplicar procesos innovadores a la resolución de problemas que conduzcan a la obtención de mejores resultados.
- Ser capaz de elaborar, dirigir y ejecutar proyectos en contextos poco estructurados que satisfagan las exigencias técnicas, de seguridad y medioambientales, ejerciendo liderazgo sobre el proyecto.
- Tener compromiso ético, medioambiental, profesional y social en el desarrollo de soluciones ingenieriles compatibles, sostenibles y en continua sintonía con la realidad del entorno humano y natural.
- Ser capaz de planificar las actividades a desarrollar en un proyecto complejo, definiendo los objetivos y prioridades a alcanzar por los diferentes miembros del equipo de trabajo.
- Saber emplear de forma efectiva la instrumentación y los métodos de observación del área biomédica para el estudio y análisis de los sistemas complejos del área.
- Ser capaz de diseñar, implementar y gestionar experimentos adecuados, analizar sus resultados y sacar conclusiones en el ámbito de la ingeniería biomédica.

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

- To know the level of scientific evidence of epidemiological, microbiological and biochemical studies that can be designed in clinical and preclinical research
- To calculate the main measures of frequency and association in epidemiological studies, as well as their integration through meta-analyzes and systematic reviews applied to clinical and preclinical research in epidemiology, microbiology and biochemistry
- To discuss the advantages, disadvantages, limitations and applications of the main study designs that are made to generate new data of interest in clinical research
- To know the basic operation and the characteristics of the experiments that are carried out in the clinical and pre-clinical research and clinical laboratories in the field of biomedical engineering

DESCRIPTION OF CONTENTS

1. Epidemiological Research

1.Basic concepts in research. The cientific method. Principles of causality
2.Design of epidemiological studies. Concept of level of evidence and its different classifications. Types of epidemiological studies and their contribution to the level of evidence.
3.Random errors and systematic errors in the investigation. Influence of errors in the investigation process. Examples and realization of practical cases.
4.Advantages and disadvantages of the different types of epidemiological designs applied to clinical and preclinical research. Experimental studies (clinical trials, field trials, community intervention trials); observational studies (ecological studies, cross-sectional studies, case-control studies, cohort studies).

2. Research in the Microbiological Laboratory

5.Conceptual bases of clinical microbiology and microbiological diagnosis. Methodology and biomedical instrumentation used in the clinical and research laboratory.
6.Connectivity and automation of the Microbiology laboratory. Advantages and limitations. Participation of the biomedical engineer.
7.Biosecurity in the microbiological laboratory. Systems of analysis and biological control

3. Research in Biochemical Laboratory

8.Basic aspects of clinical biochemistry and its biomedical applications. Phases in the development of the clinical analysis.
9.Methods of isolation and quantification of metabolites.
10.Biochemical-clinical exploration of the function of organs and systems

4. Practical approach to preclinical and clinical research

11.Basic knowledge of the teaching and assistance laboratory through practical activities.

WORKLOAD

ACTIVITY	Hours	% To be attended
Theory classes	30,00	100
Laboratory practices	10,00	100
Attendance at events and external activities	5,00	0
Development of group work	15,00	0
Development of individual work	10,00	0
Study and independent work	30,00	0
Readings supplementary material	7,50	0
TOTAL	**107,50**	

TEACHING METHODOLOGY

The theoretical contents will be taught through lectures in dialogue with the students encouraging the participation of them through questions. In the theoretical classes, the methodology based on learning will be used by solving problems that will allow them to acquire knowledge, attitudes and skills in a real situation. Group work will be encouraged, which will allow the development of coherent and logical communication and oral expression skills.

There will be several sessions that will be developed in teaching laboratories. In these the student will know the work that is done in these units and will face real problems created through the approach of practical cases that will be solved in the context of the laboratory

EVALUATION

The evaluation system is detailed below (the minimum and maximum percentage of the total that can be obtained in each section is indicated):

Assessment System	Mínimum	Máximum
Writting test	60	90
Mutiple choice test	60	90
Academical working	10	40

REFERENCES

Basic

- Introducción a la Microbiología, 12ª edición (2017) Tortora J. Gerard. Editorial Médica Panamericana. ISBN: 9
9500607407
Microbiología en Ciencias de la Salud: Conceptos y Aplicaciones, 3ª Edición (2011) Manuel de la Rosa. Elsev
España, S.L. ISBN: 9788480866927
http://jornades.uab.cat/workshopmrama/sites/jornades.uab.cat.workshopmrama/files/KIESTRA_lab_automation.
http://www.uib.cat/digitalAssets/195/195210_cdc_bmbl_4.pdf
Argimón JM, Jiménez J, Ed. Métodos de investigación clínica y epidemiológica. Barcelona. Harcourt 2004
Fletcher RH, Fletcher SW, Wagner EH. Epidemiología Clínica. 2ª ed. Elsevier Masson:Madrid:2007