

**COURSE DATA****Data Subject**

Code	43018
Name	Fundamentals of research in clinical medicine
Cycle	Master's degree
ECTS Credits	15.0
Academic year	2023 - 2024

Study (s)

Degree	Center	Acad. year	Period
2137 - M.D. in Biomedical Research	Faculty of Medicine and Odontology	1	Second term

Subject-matter

Degree	Subject-matter	Character
2137 - M.D. in Biomedical Research	3 - Fundamentals of clinical research in biomedicine	Optional

Coordination

Name	Department
MARTINEZ HERVAS, SERGIO	260 - Medicine

SUMMARY**English version is not available**

Conocimientos generales sobre: Metodología de la investigación clínica. (diseño de trabajos clínicos. El laboratorio de investigación clínico en los servicios clínicos de los hospitales universitarios. Como diseñar un trabajo de investigación clínica. Como diseñar y escribir un artículo de investigación clínica...). La investigación en Cardiología, Dermatología, Endocrinología y Nutrición, Inmunología y Alergia, Medicina Interna, Nefrología, Neumología, Oncología, Psiquiatría y Radiología.

Una segunda parte del modulo se desarrollará en el Centro de Investigación Príncipe Felipe, cuyo objetivo principal será el desarrollo teórico-práctico de contenidos relacionados con las metodologías actualmente utilizadas en investigación biomédica de diferentes áreas: genética, biomarcadores, neurociencia, bioinformática, nanomedicina, terapia celular.



PREVIOUS KNOWLEDGE

Relationship to other subjects of the same degree

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

Other requirements

No se han especificado restricciones de matrícula con otras asignaturas del plan de estudios.

OUTCOMES

2137 - M.D. in Biomedical Research

- To have the ability to apply the foundations of the scientific methodology to the clinic investigation in human beings.
- To have the ability to design, perform and analyse clinical protocols and essays.
- Students should apply acquired knowledge to solve problems in unfamiliar contexts within their field of study, including multidisciplinary scenarios.
- Students should be able to integrate knowledge and address the complexity of making informed judgments based on incomplete or limited information, including reflections on the social and ethical responsibilities associated with the application of their knowledge and judgments.
- Students should communicate conclusions and underlying knowledge clearly and unambiguously to both specialized and non-specialized audiences.
- Students should demonstrate self-directed learning skills for continued academic growth.
- Students should possess and understand foundational knowledge that enables original thinking and research in the field.
- To have the ability to integrate and to teamwork within a group of consolidated biomedical research.
- To know how to make a suitable bibliographical and documentary search in order to know the state of the art of the issue.

LEARNING OUTCOMES

- To introduce students to the field of clinical research related to the diagnosis and treatment of diseases through the scientific method and the systematic process of research.
- To create a new climate favorable to research, trying to open the way to new scientific approaches.- Optimize research activity by facilitating access to the resources of the Clinical Departments and the University Hospitals assigned to them.



- To encourage the researcher with the establishment of a flexible and dynamic system to integrate into a consolidated group or emerging groups.

DESCRIPTION OF CONTENTS

1. General aspects of clinical research

- 1.1. Research in clinical medicine
- 1.2. The clinical research laboratory in the units of university hospitals.
- 1.3. Choice of a clinical research question. Hypothesis and objectives.
- 1.4. The sample size. Sample selection. Homogeneous groups. Inclusion and exclusion criteria.
- 1.5. Clinical variables. Variable types. Observation or measurement of the results in both groups. Accuracy and precision concept. Systematic and main causes of error.
- 1.6. The research work. How to write it and main errors.
- 1.7. Critical analysis of works in clinical research.

2. Research in medicine and medical specialties

2.1. Medicine Area

- Research in Cardiology
- Research in Endocrinology and Nutrition
- Research in Immunology and Allergy
- Research in Internal Medicine
- Research in Nephrology
- Research in Pneumology
- Research in Oncology

- Research methodology and main lines of research in the different clinical areas.
- Clinical applicability of research in each clinical area: translational research
- Clinical trials in each clinical area

2.2. Psychiatry and Clinical Psychology Area

- Introduction to Psychiatry
- Basic and clinical research

2.3. Dermatology Area

- Research methodology in dermatology and main lines of research

2.4. Radiology Area

- Clinical studies in radiology: comparison-validation of diagnostic techniques, evaluation of treatments carried out by interventional radiology.
- Application of artificial intelligence in Radiology: lung nodule and breast cancer screening.
- Imaging biomarkers.



3. CIPF. Diagnoses and treatment of rare diseases

Discovery of new genes associated with Mendelian diseases. Genealogy Workshop. Models and therapies for the study of hereditary retinal dystrophies.

4. CIPF. Bioinformatics

Introduction to transcriptomics and high-throughput technologies. Exploration and pre-processing of gene expression data. Differential expression analysis. Functional enrichment.

5. CIPF. Biostatistics.

Introduction to free software R and Rstudio. Univariate and multivariate descriptive statistics. Basic concepts of statistical inference. Parametric and non-parametric hypothesis tests. Analysis of variance. Regression models: linear and generalized linear.

6. CIPF. Cancer biology

Introduction to cancer: What is cancer. cancer properties. Cancer genetics: Oncogenes and tumor suppressors. Growth factors, receptors and cancer. Oncogenic signaling. Tumor stem cells or cancer stem cells (CSC). Cancer and placentation. Tumor and Stroma.

7. CIPF. Neuropsychiatric pathologies: hepatic encephalopathy and schizophrenia

Hepatic encephalopathy. animal models. Neuroinflammation and alterations in neurotransmission. therapeutic implications. Ex vivo and in vivo study. behavioral studies. Analysis of neurotransmission by cerebral microdialysis in vivo. Molecular psychiatry: pathophysiology of cortical circuits. The cortex, the most complex region of the brain. Pathologies of the neurological development of cortical circuits. What happens if something goes wrong?

The golden age of neurobiology: new tools to investigate cortical circuits.

8. CIPF. Cellular therapy

Pluripotent stem cells: fundamentals and types. iPS cells as a tool to study diseases. Cell Therapy in pathologies of the nervous system.

9. CIPF. Drugs and biomarkers

Nanomedicine in research and medical practice.

Cell models for biomedical research.

Animal experimentation models in drug development.

Intercellular communication by exosomes and their use as biomarkers.

Gut microbiota as functional food and biomarker of metabolic disease.

**WORKLOAD**

ACTIVITY	Hours	% To be attended
Theory classes	16,00	100
Other activities	6,00	100
Development of group work	25,00	0
Development of individual work	30,00	0
Study and independent work	60,00	0
Readings supplementary material	30,00	0
Preparing lectures	55,00	0
Resolution of case studies	20,00	0
TOTAL	242,00	

TEACHING METHODOLOGY

This course (Master) uses as teaching methodology the training:

A) Online teaching.

Research papers, bibliography.

B) Lectures.

A total of 15 sessions of 3 hours will be held at the Faculty of Medicine:

- 4 research sessions in clinical medicine.
- 1 research session in Cardiology
- 1 research session in Dermatology
- 1 research session in Endocrinology and Nutrition
- 1 research session in Immunology and Allergy
- 1 research session in Internal Medicine
- 1 research session in Nephrology
- 1 research session in Radiology

And 45 hours of classes from the month of March at the Principa Felipe Research Center.

C) Group and individual work.



EVALUATION

MEDICINE SESSIONS (50% GLOBAL MARK):

Participation and presentation in face-to-face sessions 50%

Final work individually (research project) 50%

CIPF SESSIONS (50% GLOBAL MARK):

Resolution of two questions chosen from a battery of practical questions.

REFERENCES

Basic

- Hulley SB, Cummings SR. Diseño de la investigación clínica. Barcelona, Doyma, 1993
- Laporte JR. Principios básicos de investigación clínica. ISBN 84-86754-22-4. Madrid, Ediciones Argo 1993.
- Argimon Payas JM, Jimenez Villa J. Métodos de investigación. ISBN 84-7592-387-9. Barcelona, Doyma, 1991.
- Hulley SB, Cummings SR. Diseño de la investigación clínica. ISBN 84-7592-549-9. Barcelona, Doyma, 1993.
- Sergi M, Hawkins C. Investigación médica. Barcelona, Medicine, 1990.
- Eco U. Como se hace una tesis: técnicas y procedimientos de estudio, investigación y escritura (6ª ed.). ISBN 9788474328967. Barcelona, Gedisa, 1989.
- Beidas RS, Koerner K, Weingardt KR, Kendall PC. Training Research: Practical Recommendations for Maximun Impact. AdmPolicyMentHealth. 2011 July; 38(4):223-23
- Gourevitch MN, Jay MR, Goldfrank LR, Mendelsohn AL, Dreyer BP, Foltin GL, et al. Training Physician Investigators in Medicine and Public Health Research. Am J Public Health. 2012; 102(7):e39-e45
- O'Cathain A, Nicholl J, Murphy E. Structural issues affecting mixed methods studies in health research qualitative study. BMC Med Res Methodol. 2009; 9: 82. Published online 2009 December 9 doi: 10.1186/1471-2288-9-82
- Knight KL. Study/Experimental/Research Design: Much More Than Statistics. J Athl Train. 2010; 45(1): 98-100.

Additional

- CIPF:
 - Strachan T, Read A. Human Molecular Genetics 3. Garland Publishing, 2004. ISBN-13: 978-0-81534182-6. ISBN-10: 0-81534182-2.
 - Weinberg RA. The biology of cancer. New York: Garland Science, Taylor & Francis Group, 2014. ISBN-13: 978-0815342205. ISBN-10: 0815342209.



-Benítez-Páez A, Hess AL, Krautbauer S, Liebisch G, Christensen L, Hjorth MF, Larsen TM, Sanz Y; MyNewGut consortium. Sex, Food, and the Gut Microbiota: Disparate Response to Caloric Restriction Diet with Fiber Supplementation in Women and Men. *Mol Nutr Food Res*. 2021 Apr;65(8):e2000996.

-Cabrera-Pastor A, Llansola M, Montoliu C, Malaguarnera M, Balzano T, Taoro-Gonzalez L, García-García R, Mangas-Losada A, Izquierdo-Altarejos P; Arenas YM, Leone P, Felipe V. (2019) Peripheral inflammation induces neuroinflammation that alters neurotransmission and cognitive and motor function in hepatic encephalopathy: Underlying mechanisms and therapeutic implications. *Acta Physiologica (Oxf)* :e13270

-Botto C, Rucli M, Tekinsoy MD, Pulman J, Sahel JA, Dalkara D. Early and late stage gene therapy interventions for inherited retinal degenerations. *Prog Retin Eye Res*. 2022; 86:100975.

-Patrick, G. (2017). *An introduction to medicinal chemistry* (6th ed.). Oxford University Press. ISBN 9780198749691.

-Ciferri MC et al. Extracellular Vesicles as Biomarkers and Therapeutic Tools: From Pre-Clinical to Clinical Applications. *Biology* (2021)