DEGREE CURRICULUM

CLINICAL TRIALS: DESIGN AND MANAGEMENT

Coordination: GOMEZ ARBONES, XAVIER

Academic year 2023-24

CLINICAL TRIALS: DESIGN AND MANAGEMENT 2023-24

Subject's general information

<table>
<tr><td>Subject name</td><td>CLINICAL TRIALS: DESIGN AND MANAGEMENT</td></tr>
<tr><td>Code</td><td>14702</td></tr>
<tr><td>Semester</td><td>1st Q(SEMESTER) CONTINUED EVALUATION</td></tr>
<tr><td>Typology</td><td>
<table>
<tr><th>Degree</th><th>Course</th><th>Character</th><th>Modality</th></tr>
<tr><td>Master's Degree in Biomedical Research</td><td>1</td><td>COMMON/CORE</td><td>Attendance-based</td></tr>
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<tr><td>Course number of credits (ECTS)</td><td>4</td></tr>
<tr><td>Type of activity, credits, and groups</td><td>
<table>
<tr><th>Activity type</th><th>PRALAB</th><th>PRAULA</th><th>TEORIA</th></tr>
<tr><td>Number of credits</td><td>0.6</td><td>2</td><td>1.4</td></tr>
<tr><td>Number of groups</td><td>1</td><td>1</td><td>1</td></tr>
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<tr><td>Coordination</td><td>GOMEZ ARBONES, XAVIER</td></tr>
<tr><td>Department</td><td>MEDICINE AND SURGERY</td></tr>
<tr><td>Teaching load distribution between lectures and independent student work</td><td>Each credit is calculated as 25 hours of work: 10 hours of lectures and 15 hours of independent study by the students.</td></tr>
<tr><td>Important information on data processing</td><td>Consult this link for more information.</td></tr>
<tr><td>Language</td><td>Catalan (70%), Spanish (10%) and English (20%; documentation).
The lessons are usually in Catalan or in Spanish, English is not the vehicular language, so students who do not understand Spanish will have difficulties to follow the subject.</td></tr>
<tr><td>Distribution of credits</td><td>Total: 4 ECTS
- Lectures: 1.2 ECTS
- Practices: 1.6 ECTS
- Seminars: 1.2 ECTS</td></tr>
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Teaching staff	E-mail addresses	Credits taught by teacher	Office and hour of attention
BERMUDEZ LOPEZ, MARCELINO	marcelino.bermudez@udl.cat	,2	
GOMEZ ARBONES, XAVIER	xavier.gomez@udl.cat	2,4	
MONTAL ROURA, ROBERT	robert.montal@udl.cat	,2	
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SANCHEZ DE LA TORRE, MANUEL	manuel.sanchez@udl.cat	,2	
SCHOENENBERGER ARNAIZ, JUAN ANTONIO	juanantonio.schoenenberger@udl.cat	,8	

Subject's extra information

The subject is presented as a very practical approach to the world of clinical, basic and translational research with people. It deals with the ethical, legal and methodological aspects of experimental studies (clinical trials), although not only these aspects, but also concepts related to the research of observational studies and other formats in health sciences, as well as as of the need for the favorable report of a research committee to be able to carry out any project with people.

This course aims to provide a global and integrated view of research, present the legal and ethical requirements in Spain, as well as work on how to prepare, present and evaluate a research project (methodology) in order to be carried out.

There are sessions with a more expository format (master classes) and others with an eminently practical format such as seminars or group dynamics. All of them with a practical and useful point of view for members of research teams and for people who need to audit or evaluate research projects.

During the course, exclusively in this subject, students also have the opportunity to attend sessions of the committee of ethics of research with drugs (CEIm) of Lleida, and to visit support facilities to research related to health projects of the Lleida Biomedical Research Institute (IRBLleida).

The sessions are taught by a good number of teachers, as we have sought people with maximum authority and expertise in the topics to be addressed.Tpocis all related to research with persons, and which try to cover as many relevant aspects as possible; preparation and evaluation of projects (legislation, ethical principles, methodological aspects of study design), and also we will discuss, among others, the importance of research in the advancement

of science, the roles of the CEIms in research, the point of view of researchers and the research industry, the monitoring of research studies, and we will hold seminars on specific aspects of project preparation and evaluation, informed consent, support services research and Biobanks, etc.

Students who approve this matter will:

Know the fundamental principles of bioethics and clinical research.
Know the rules on human research, especially related to clinical trials.
Be able to propose, design, analyze, monitor and evaluate clinical research studies.

Students will visit the Biobank of IRBLL

If it is possible, the studens could attend and participate in a meeting of the Ethics Committee of HUAV Lleida.

Students must sign a commitment to respect the confidentiality of the information that will have access in accordance with "Llei 15/1999, de protecció de dades de caràcter personal", and "Decret 406/2006, de 24 d'octubre, d'acreditació de comitès ètics d'investigació clínica".

The lessons are usually in Catalan or in Spanish, English is not the vehicular language, so students who do not understand Spanish will have difficulties to follow the subject.

Learning objectives

The objectives of the course are:

Learn the basic principles of bioethics and clinical research.
Know the legal regulations related to biomedical research.
Know the different types of research studies.
Be able to design and manage a clinical trial protocol and other projects.
Be able to evaluate clinical trial protocols (methodology, ethical and legal issues, informed consent, confidentiality)
Know the procedures for monitoring clinical trials.
Attend a meetings of the Ethics Committee of the Hospital Arnau de Vilanova of Lleida
Participate in clinical research projects of the Biomedical Research Institute of Lleida

Competences

Skills:

- CB1 Possess and understand knowledge that provides a basis or opportunity to be original in the development and / or application of ideas, often in a research context
- CB2 Know how to apply the knowledge acquired and have the ability to solve problems in new or unfamiliar environments within broader (or multidisciplinary) contexts related to their area of study
- CB3 Being able to integrate knowledge and face the complexity of formulating judgments based on information that, being incomplete or limited, includes reflections on the social and ethical responsibilities linked to the application of their knowledge and judgments
- CG1 Know how to choose and apply the different methodologies of molecular, biochemical, cellular, genetic and phenotypic analysis for the diagnosis and study of diseases.
- CG5 Ability to prepare, process and interpret the results obtained rigorously and applying the appropriate technologies
- CG3 Ability of team-working, leadership and decision making.
- CG4 Capacity for critical and creative thinking with their work and that of other researchers
- CG6 Know how to guide research to lines of medical and translational interest (diagnosis and therapy)
- CG7 Be able to present scientific reports and scientific articles that can be considered for publication in international journals
- CE6 Be able to design, monitor and evaluate clinical trial protocols.
- CT1 Have a correct oral and written expression

- CT4 Respect the fundamental rights of equality between men and women, the promotion of Human Rights and the values of a culture of peace and democratic values
- CT5 Apply the gender perspective in the tasks of the professional field

Subject contents

Contents (classroom sessions)

Introduction to different types of projects. Clinical trials.
Clinical and EBM. Role of research and clinical trials
Introduction to methodological and ethical aspects of clinical trials
Clinical trials. Results and importance in decision-making in health.
Regulations and legal issues in clinical trials.
CEIm
Methodological and statistical aspects of clinical trials
Units and structures for supporting research and clinical trials
Clinical trials and research projects. Perspective of the researcher I
Clinical trials and research projects. Perspective of industry
Product management research in the context of clinical trials
Monitoring research
Assays based on records.
Evaluation proojects I
Biobank (storage and custody of samples)
Project dessing and Informed consent
Quality Assurance
Final session.

Other sessions

Practice at the Biobank
Evaluation of projects for CEIC.
CEIC guest assistance (in small groups).

Methodology

The **methodology** of the course is based on the following activities:

Master classes about the program contents
Seminars and group work.
Attendance at scientific conferences of guest lecturers
Individual and group work (resolution of problems and activities)
Work on a clinical trial protocol.
Evaluation of clinical trial protocols
Attendance at meetings of the CEIm
Visit a biobank
Participation in research projects
Tutoring by teachers

Oral presentations

Development plan

The development of the subject is based on:

Theoretical classes.
Seminars and group work.
Conference attendance
Participation in projects
Assistance to a CEIC
Visit to a Biobank
Problem solving and activities.
Practical work.
Supervised activities
Autonomous work by the student

Evaluation

Detailed information in Spanish guide

Bibliography

Basic::

1. Hulley SB, Cummings SR. Diseño de la investigación clínica. Un enfoque epidemiológico. Ediciones Doyma. Barcelona, 1993.
2. Argimón Pallás JM, Jiménez Villa J. Métodos de investigación aplicados a la atención primaria. Mosby/Doyma. Barcelona, 1994.
3. Armitage P, Berry G. Estadística para la investigación biomédica. Ediciones Doyma. Barcelona, 1992.
4. Abella F, Fajó M, Gómez X, March J, Sorribas A. Metodología estadística en ciencias de la salud. Del diseño del estudio al análisis de los resultados. Edicions de la UdL y F.V. Libros Eines 26, 2001.
5. Evaluación de Ensayos Clínicos. Inés Galende. Fundación AstaZeneca. Madrid, 2006.
6. Evaluación de Protocolos de Investigación Biomédica. Inés Galende. Fundación AstaZeneca. Madrid, 2007.
7. Guía para los Miembros de los Comités de Ética de Investigación. El Comité Director de la Bioética. Consejo de Europa, enero 2012.
8. Aspectos éticos y jurídicos a tener en cuenta en los estudios clínicos en Fase II y III. Juan Canimas. Publicacions de la Càtedra de Promoció de la Salut. Documenta Universitària. 2013

Web resources:

1. Asociación Nacional de Miembros de Comités de ética de la Investigación: ancei.es
2. ClinicalTrials. Registre d'assaigs clínics de la Biblioteca Nacional de Medicina dels Estats Units: clinicaltrials.gov
3. EudraCT. Base de dades que registre tots els assaig clínics a la Unió Europea: eudract.ema.europa.eu
4. Web de Agencia Española de Medicamentos y Productos Sanitarios: www.aemps.gob.es