DEGREE CURRICULUM

CLINICAL TRIALS: DESIGN AND MANAGEMENT

Coordination: GOMEZ ARBONES, XAVIER

Academic year 2017-18

CLINICAL TRIALS: DESIGN AND MANAGEMENT 2017-18

Subject's general information

Subject name	CLINICAL TRIALS: DESIGN AND MANAGEMENT
Code	14702
Semester	1st Q(SEMESTER) CONTINUED EVALUATION
Typology	<table><tr><th>Degree</th><th>Course</th><th>Typology</th><th>Modality</th></tr><tr><td>Master's Degree in Biomedical Research</td><td>1</td><td>COMMON</td><td>Attendance-based</td></tr></table>
ECTS credits	4
Groups	1GG
Theoretical credits	2.4
Practical credits	1.6
Coordination	GOMEZ ARBONES, XAVIER
Department	CIENCIES MEDIQUES BASIQUES,INFERMERIA I FISIOTERÀPIA,MEDICINA,MEDICINA EXPERIMENTAL
Teaching load distribution between lectures and independent student work	Each credit is calculated as 25 hours of work: 10 hours of lectures and 15 hours of independent study by the students.
Important information on data processing	Consult this link for more information.
Language	Catalan (70%), Spanish (10%) and English (20%; documentation)
Distribution of credits	Total: 4 ECTS - Lectures: 1.2 ECTS - Practices: 1.6 ECTS - Seminars: 1.2 ECTS
Office and hour of attention	Telèfon: 973702208 Correu: xga@medicina.udl.cat Ubicació del Despatx: 1.04. Unitat Docent Facultat de Medicina. Hospital Universitari Arnau de Vilanova

CLINICAL TRIALS: DESIGN AND MANAGEMENT 2017-18

Teaching staff	E-mail addresses	Credits taught by teacher	Office and hour of attention
GOMEZ ARBONES, XAVIER	xga@medicina.udl.cat	2,4	
SANCHEZ DE LA TORRE, MANUEL	sanchezdelatorre@cmb.udl.cat	,4	
SCHOENENBERGER ARNAIZ, JUAN ANTONIO	shoenenberger@mex.udl.cat	1	
ZAPATA ROJAS, AMALIA	amalia.zapata@infermeria.udl.cat	,1	

Subject's extra information

Guest lecturers: Susana Peñuelas , Laura Rumi, Maria Ruiz, Montse Solanillas, Francesc Verges and Amalia Zapata.

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

Students must 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".

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

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Competences

Specific skills:

Be able to design, monitor and evaluate protocols for clinical trials.
Other specific skills:
Understand the fundamental principles of bioethics and clinical research
Kown the main legislation on human research, especially related to clinical trials
Be able to design, execute and analyse research studies and protocols (especially clinical trials).
Qualification for the evaluation of clinical trials.
Be prepared to do monitoring and coordination of clinical trials.
In short, be able to propose, design, analyze, monitor and evaluate clinical research studies.

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.
CEIC. .
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 the researcher II
Clinical trials and research projects. Perspective of industry
Product management research in the context of clinical trials (1h class). Monitoring research (1h class)
Assays based on records.
Evaluation proojects I
Evaluation projects II
Biobank (storage and custody of samples) (1h class). Informed consent (1h class)
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 CEIC
Visit a biobank
Participation in research projects
Tutoring by teachers
Oral presentations

Development plan

Dateilebn cronogram in the catalan guide

Evaluation

The evaluations is based on:

Continuous assessment of attendance and class participation (lectures, seminars and group work).
Practical work and resolution of activities.
Exam (of all learning activities).

The first day we will deal about the conditions of the student evaluation.

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