



Universitat de Lleida

DEGREE CURRICULUM
**CLINICAL TRIALS: DESIGN AND
MANAGEMENT**

Coordination: GOMEZ ARBONES, XAVIER

Academic year 2016-17

Subject's general information

Subject name	CLINICAL TRIALS: DESIGN AND MANAGEMENT			
Code	14702			
Semester	1st Q(SEMESTER) CONTINUED EVALUATION			
Typology	Degree	Course	Typology	Modality
	Master's Degree in Biomedical Research	1	COMMON	Attendance-based
ECTS credits	4			
Groups	1GG			
Theoretical credits	2.4			
Practical credits	1.6			
Coordination	GOMEZ ARBONES, XAVIER			
Department	CIENCIAS MEDIQUES BASIQUES,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			

Teaching staff	E-mail addresses	Credits taught by teacher	Office and hour of attention
GOMEZ ARBONES, XAVIER	xga@medicina.udl.cat	2,6	
SANCHEZ DE LA TORRE, MANUEL	sanchezdelatorre@cmb.udl.cat	,4	
SCHOENENBERGER ARNAIZ, JUAN ANTONIO	shoenenberger@mex.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

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

Know 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 projects 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

Cronogram

0/11/2016. 10-12. Presentation. Introduction to the different types of research projects. Clinical trials.
10/13/2016. 10-12. Introduction to ethical and methodological aspects of clinical trials
18/10/2016. 10-12. EBM and clinical research. Role of research and clinical trials
10/24/2016. 16-18. 1 hour. Regulatory and legal issues in clinical trials. 1 hour. The CEIC.
10/25/2016. 10-12. Clinical trials. Results and significance in decision-making in health.
03/11/2016. 10-12. Clinical trials and research projects. View of the industry
11/08/2016. 10-12. Units and structures supporting research and clinical trials
10/11/2016. 10-12. Methodological and statistical aspects of clinical trials
11/15/2016. 10-12. Project evaluation I
11/22/2016. 10-12. Clinical trials and research projects. Researcher's point of view I
11/29/2016. 16-18. Management of research products under clinical trials (1h class). Monitoring research (1h class)
12/01/2016. 10-12. Assays based on records.
12/13/2016. 10-12. Clinical trials and research projects. Researcher's point of view II
12/15/2016. 10-12. Project evaluation II
12/20/2016. 10-12. Session
01/10/2017. 10-12. Quality assurance
12/01/2017. 10-12. 1 hour. Biobank (storage and custody of samples) 1 h. Informed consent
01/17/2017. 10-12. Session
01/19/2017, 01/24/2017 and 27/01/2017 *

To determine in 2017

2h. Morning. Practice in the Biobank (groups)
2h. Morning. Evaluatins of CEIC projects.
2h. Last Thursday afternoon of each month. CEIC guest assistance (in groups).

* The houes of these sessions are devoted to go to CEIC, evaluate some of the projects and go to the biobank (2017)

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