Master's Degree in Molecular Biology of Cancer
Course Syllabus – Clinical Trials and Translational Research in Oncology

Basic Course Information

Course:	Clinical Trials and Translational Research in Oncology			
Type (Comp/Elec):	Compulsory			
Credits ECTS:	6			
Semester:	1º			
Responsible Departament:	Biochemistry and Molecular Biology			
Course Coordinator: (Name, Dept., e-mail, phone)	Dra. Beatriz González Gálvez	Dept. Biochemistry and Molecular Biology, F. of Pharmacy, UCM	bggalvez@ucm.es	913941857
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Specific Course Information

Descriptor:	This course addresses the most relevant aspects of clinical and translational research in oncology. Specifically, it will cover: • Ethical and legal requirements in clinical research. • Scientific documentation required across the different phases of clinical research, including the preparation of informed consent forms and the specific documentation needed for the submission of clinical trials. • Statistical analysis in preclinical and clinical studies. • Management of patient-derived samples within the context of clinical trials. • Regulations governing the patent system, including examples of their application in the field of oncology and the requirements for preparing a patent application. • Division and organization of tasks in clinical research within the public sector, the pharmaceutical industry, and Contract Research Organizations (CROs). • Main strategies for scientific communication and dissemination in oncology.
Requirements:	None
Recommendations:	None

Learning Outcomes

Knowledge and subject matter	• To understand the fundamental molecular and cellular mechanisms whose deregulation leads to cancer development, with particular emphasis on oncogenic processes and tumor-suppressor pathways. • To understand the molecular and cellular mechanisms involved in the reciprocal interactions between the tumor and its microenvironment, and how these interactions influence tumor progression. • To understand the major genetic and environmental risk factors that predispose individuals to cancer, as well as the principal molecular mechanisms underlying the effects of these factors. • To understand the molecular similarities and differences among the main types of solid and hematological tumors, and their implications for disease progression, diagnosis, and treatment.

	• To understand the principal types of antitumor therapies, with special attention to advanced radiotherapy techniques, cell-based therapies, immunotherapy, nano-encapsulation strategies, and targeted therapies. • To understand the main diagnostic methods used in oncology, both general and tumor-specific, with particular emphasis on molecular diagnostic approaches that enable the identification of specific genetic alterations, as well as early-detection techniques such as liquid biopsy. • To understand the foundations of clinical trial design in oncology, including statistical analysis, the different trial phases, and the main administrative procedures required for their submission, approval, and monitoring. • To understand the key stages involved in the process that enables, from basic research and preclinical models, the intellectual protection, validation, and, where appropriate, the application and commercialization of new biomarkers for cancer diagnosis or prognosis, new chemical, biological, or physical agents, or new pharmaceutical formulations with antitumor activity or capable of alleviating symptoms in oncology patients.
Skills and abilities	• Ability to understand and apply concepts, tools, and methodologies in oncological research, enabling the development of an integrated perspective on scientific advances in this field. • Ability to analyze and comprehend a scientific study from its initial hypothesis and objectives through the preliminary approach and up to the final conclusions. • Ability to present, in a scientific report or manuscript written in English, clear and unambiguous results derived from research in the field of cancer molecular biology. • Ability to communicate scientific findings to both specialized and non-specialized audiences in a clear and unambiguous manner; to engage with, understand, and convey scientific knowledge, research results, and strategies in English. • Ability to develop, based on the knowledge acquired, principles that support the selection or design of appropriate antitumor therapies tailored to each cancer type and stage, in a personalized manner for each patient. • Ability to understand, and when necessary, address the legislative, social, healthcare, and ethical implications of basic, translational, and clinical research in oncology. • Ability to learn autonomously and to conduct critical analyses that support self-directed professional development. • Ability to manage some of the main databases related to molecular oncology, as well as to perform specific analyses using these data and to interpret the results obtained.
Competencies	• To understand the molecular, cellular, and pathophysiological foundations of cancer, enabling continued study in the field of cancer molecular biology in an autonomous or self-directed manner. • To design experimental approaches that allow the analysis of the molecular, cellular, or pathophysiological mechanisms involved in cancer development and progression, as well as the evaluation of the effectiveness of new diagnostic methods or therapeutic strategies. • To interpret results derived from the application of diagnostic methods or from reports generated by oncology professionals for the diagnosis and classification of cancer. • To evaluate the social and ethical responsibilities, as well as the environmental risks, associated with professional practice. • To prepare basic documents, in the appropriate format, that serve as the foundation for patent submissions and for clinical trial proposals in the field of oncology. • To apply the principles of the scientific method, understanding its value and limitations, and incorporating the ethical principles that govern professional practice. • To develop effective communication and dissemination skills related to professional activity, both among specialists and to the broader, non-specialized public. • To be able, based on the knowledge acquired in the field of cancer molecular biology, to evaluate and select appropriate scientific information in order to formulate judgments and interpretations from limited data. • To understand and acknowledge the need for continuous training and study in the field of oncology for effective professional performance. • To develop the ability to work collaboratively in homogeneous or multidisciplinary teams, assuming shared responsibilities.

Objectives

This course aims to introduce the methodology for designing and interpreting the results of clinical trials, as well as the specific features involved in the management and development of clinical trials in oncological diseases.

It focuses on the fundamental role that clinical trials (CTs) play within the field of biomedical research, providing a comprehensive overview of the basic principles of clinical investigation. As a starting point, the course addresses preclinical studies, which constitute the essential foundation for initiating research in human subjects.
Throughout the course, the different types of clinical trials, their specific characteristics, the current regulatory framework, and the role of national and international regulatory bodies responsible for overseeing medicinal products and biological agents will be examined.
The course will explore in depth the process of designing clinical trials, including the key documents that support them: the study protocol, the investigator's brochure, the informed consent form, and the case report form. In addition, the organizational structure of a clinical trial will be analyzed, identifying the main stakeholders—such as sponsors, research centers, specialized organizations, and patients—and their respective roles.
To complement the theoretical content, practical exercises and seminars will be conducted, focusing on the specificities of clinical research across the various therapeutic areas of oncology and the professional profiles associated with this field.

Methodology

Description:

Teaching activities will be carried out through lectures, seminars, tutorials, and the completion of individual or group assignments. The purpose of the lectures is to ensure that students acquire the essential knowledge corresponding to each topic. Student participation will take place through seminars and tutorials, where scientific discussion and critical analysis of selected subjects will be conducted. All materials necessary for understanding and working with the course content (slides, videos, scientific articles, etc.) will be made available to students on the Virtual Campus.

Distribution of teaching activities

	Horas	% presencialidad
Lectures:	30	100
Presentations/seminars:	14	100
Tutorials:	2	100
Assessment:	2	100
In-person work:	48	100
Self-directed work:	102	0
Total:	150	

Assessment

Applicable criteria:

Student assessment will be calculated on the basis of the final examination grade (60%), continuous assessment—including class participation, submission of assignments, and attendance (10%)—and, finally, the submission, presentation, and in-class discussion of final projects (30%).

Students must attend at least 70% of the face-to-face instructional activities. Grades will be based on an absolute scale from 0 to 10 points, in accordance with the system established in Royal Decree 1125/2003.

Semester Organization

The course will be taught during the first semester.

Syllabus

Theoretical program:

1. **Introduction to Clinical Research**

1.1 Clinical research: fundamental concepts and types of studies.
1.2 Phases of clinical research.
1.3 Basic regulations governing clinical trials. Good Clinical Practice (GCP) guidelines.
1.4 Participants in clinical trials. Relationship with the pharmaceutical industry. Key stakeholders and professional roles.
1.5 Transition from laboratory research to the development of a clinical trial.

2. **Methodological Foundations of Clinical Trials**

2.1 The clinical trial: definitions, methodological foundations, and general development of a clinical trial. Definition of objectives, selection of outcome variables, definition of the study population, and sample size calculation.
2.2 Types of study design: parallel, crossover, sequential, therapeutic equivalence. Biases in the conduct of a clinical trial. Randomization and blinding.

	2.3 Analysis and interpretation of clinical trial results. Methods for synthesizing scientific evidence: meta-analysis. 2.4 Pharmacoeconomic analysis in the context of clinical trials. 2.5 Application of methodological principles in the proposal of a clinical investigation and/or clinical trial. **3. Clinical Development: Ethical, Regulatory, and Data Protection** 3.1 Regulation of the clinical development of medicinal products. 3.2 Ethics in clinical research. 3.3 Data protection in clinical research. 3.4 Patents and trademarks. 3.5 Application of regulatory and ethical principles in a clinical trial.
Seminars:	-Workshop: Lectures delivered by experts in clinical trials within the field of oncology. -Preparation of a clinical trial proposal by the students. -Student presentations of their project work.
Bibliography:	- Alejandro R Jadad . Randomised Controlled Trials. A user's guide. 1998. - Gad SC. Clinical Trials Handbook. John Wiley & Sons, 2009. - Chow S-C, Liu J-p. Design and Analysis of Clinical Trials: Concepts and Methologies. John-Wiley &Sons, 1998. - D. L. Demets DL. Statistical issues in interpreting clinical trials. Journal of Internal Medicine 2004; 255: 529–537. - Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010;340:c332. - A J Sutton, S J Duval, R L Tweedie, K R Abrams, D R Jones. Empirical assessment of effect of publication bias on meta-analyses. - Egger M, Smith GD, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. BMJ 1997;315:629-34. - JR Laporte. Principios de Investigación Clínica. - Etminan M and Levine M. Interpreting Meta-Analyses of Pharmacologic Interventions: The Pitfalls and How to Identify Them. Pharmacotherapy 1999;19(6):741-745. - Peter M Rothwell. External validity of randomised controlled trials: "To whom do the results of this trial apply?". Lancet 2005; 365: 82–93. - Montori et al. Validity of composite end points in clinical trials. BMJ 2005;330:594–6. - Lise L Kjaergard, Bodil Als-Nielsen. Association between competing interests and authors' conclusions: epidemiological study of randomised clinical trials published in the BMJ. bmj.com 2002;325:249. - An-Wen Chan, Douglas G Altman. Identifying outcome reporting bias in randomised trials on PubMed: review of publications and survey of authors. BMJ 2005;330;753. -Galende I. Evaluación de Ensayos Clínicos. Fundación Astra-Zeneca. 2006. **RECURSOS WEB DE UTILIDAD** -Real Decreto 1090/2015, de 4 de diciembre, por el que se regulan los ensayos clínicos con medicamentos, los Comités de Ética de la Investigación con medicamentos y el Registro Español de Estudios Clínicos. -Guía de Buena Práctica Clínica de la Conferencia Internacional de Armonización (CPMP/ICH/1995). -Ley 10/2013 de Garantías y Uso Racional Medicamento y Productos Sanitarios. -Orden SCO/256/2007, de 5 de febrero, por la que se establecen los principios y las directrices detalladas de BPC y los requisitos para autorizar la fabricación o importación de medicamentos de investigación de uso humano. -Reglamento UE 536/2014 de 16 abril de 2014, sobre los EC de medicamentos de uso humano.