UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
PHAR-606	Clinical Trials: Issues in Design, Conducts and Evaluation	7.5
Prerequisites	**Department**	**Semester**
None	Life and Health Sciences	2nd
Type of Course	**Field**	**Language of Instruction**
Required	Pharmacy	English
Level of Course	**Lecturer(s)**	**Year of Study**
2nd Cycle	Lefteris Zacharia Marios Adamou Anastasia Sideri	1st
Mode of Delivery	**Work Placement**	**Corequisites**
Distance Learning	NA	NA

Course Objectives:

Clinical trials are an important part of the drug development process where safety and efficacy to humans is tested. They constitute a critical step in the development process that ensures marketing authorization. The purpose of the course is to develop effective regulatory leadership throughout the clinical development and the registration of a new medicine, and provide an understanding of the practical regulatory aspects of global clinical research, in order to offer effective advice on the regulatory issues likely to arise during clinical programs.

Additionally the course aims to:

1. Understand how clinical data are generated

2. Understand how the GCP requirements help ensure the reliability and quality of the data integrity and patient safety

3. Appreciate how clinical trial organization contributes to the efficiency of the clinical development programme

4. Appreciate how exploratory studies differ from confirmatory studies and the different roles of these in supporting an MAA

5. Appreciate how the results of clinical studies may impact labeling claims

6. Understand the regulatory requirements to ensure GCP and smooth conduct of a clinical trial

Learning Outcomes:

After completion of the course students are expected to be able to:

- Illustrate knowledge of the required clinical documentation for a Marketing Authorization
- Appraise, interpret and apply clinical trials legislation and related guidelines (EU Clinical Trial directive) for effective implementation of a clinical trial programme (application) and associated documentation
- Construct, analyze and rank a regulatory strategy plan for the clinical development of a new drug including documentation and risk assessment
- Understand the strategic role of clinical study reports and summaries in obtaining an optimal product label and product information
- Discuss the ethical, legal, scientific and practical aspects which need to be considered in undertaking clinical trials including potential requirements for additional clinical studies.

Course Content:

- The drug development process
    - historical overview, the economic environment, rules and regulations, drug discovery, preclinical testing, clinical development)
- Medicinal product regulations in the 21st century
    - history and background to regulations of medicine, the legal basis of control by regulatory authorities, regulatory aspects of the clinical development programme, marketing applications, the future system of medicinal programme regulation, the regulatory environment in the USA)
- Ethical issues and liability in clinical research
    - declaration of Helsinki, good clinical practice, ethical issues in clinical trial design, European Community good clinical practice guidelines
- Clinical trial design
    - the phases of a clinical development programme, trial design, the elements of trial design, designing a multicentre trial
- Early phase studies, pharmacokinetics and adverse drug reaction
    - Selection of volunteers, design of study, adverse effects, compartmental concept, administration, population pharmacokinetics, early phase drug interactions)
- Phase IV studies
    - constraints, scientific method, regulatory basis of phase IV studies, comparative studies, new indication-dosage-formulation, secondary prevention studies, randomized studies evaluating safety

- The clinical trial protocol
    - definition and purpose of the protocol, writing a protocol, the main decisions to be made, administrative sections, protocol amendments)
- Monitoring
    - Study preparation, study initiation, study conduct and monitoring, study termination
- Drug safety in clinical studies and pharmacovigilance
    - clinical studies, adverse effects, laboratory safety data, presentation of safety data, pharmacovigilance, case control studies, cohort studies, prescription event monitoring
- Outcomes research and health economics
    - outcomes research, efficacy and effectiveness, measuring costs, economic analysis alongside clinical trials, health technology assessment and market access
- Trial master file
    - responsibility for and management of the trial master file, the appearance of the trial master file, essential documents in the trial master file
- Fraud and misconduct in clinical research
- definitions, historical aspects of fraud, the reason for fraud, the detection of fraud, the prosecution of fraud, some recent cases, the sharing of information

Learning Activities and Teaching Methods:

Teaching material including PowerPoint presentations with extended descriptions and explanations, asynchronous video presentations, additional readings (journal articles and e-books), access to additional videos and commercials related to the course, synchronous meetings (WebEx), forums, chats, quizzes, case studies and other formative and summative assessments.

Assessment Methods:

Continuous Assessment (assignments), Final Exam

Required Textbooks / Readings:

Title	Author(s)	Publisher	Year	ISBN
Principles and practice of clinical research.	Gallin, J. and Ognibene, F	Amsterdam: Elsevier/AP.	2012/2017	
Designing Clinical Research.	Hulley, S., Cummings, S., Browner, W., Grady, D. and Newman, T	Philadelphia: Wolters Kluwer/Lippincott Williams & Wilkins	2013	
Drugs.	Ng, R	Hoboken, N.J.: Wiley-Blackwell	2009	