UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
PHAR-608	Preclinical & Clinical Development and Documentation	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 Yiannis Sarigiannis Eleftheria Galatou	1st
Mode of Delivery	**Work Placement**	**Co-requisites**
Distance Learning	NA	NA

Course Objectives:

Navigating the drug development process from early discovery to Phase I clinical trials can be complex and costly. Success requires a well-organized preclinical development plan. While preclinical research answers basic questions about a drug's safety, it is not a substitute for studies of ways the drug will interact with the human body. "Clinical research" refers to studies, or trials, that are done in humans. As the developers design the clinical study, they will consider what they want to accomplish for each of the different Clinical Research Phases and begin the Investigational New Drug Process (IND), a process they must go through before clinical research begins.

The aim of the course is to cover the application of clinical and preclinical research principles. Moreover, to provide a thorough review of the requirements and critical elements related to the preclinical and clinical examinations, including the design of a technical document ("common technical document") for the preclinical part of the registration file and the necessary clinical documentation in the process of drug registration.

By the end of this course, students will be able to make plans and take decisions for preclinical and clinical development and documentation.

Learning Outcomes:

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

1. Knowledge
2. Analyze the required clinical documentation for a Marketing Authorisation including Good Clinical Practice (GLP) compliance and risk assessment
3. Explain and identify the principles of clinical development from phase I to IV
4. Skills
5. Create, analyse and evaluate a regulatory strategy plan for the clinical development of a new drug
6. Organize & discuss a scientific problem in the form of a written project report
7. Inspect and evaluate the documentation needed to fulfil the non-clinical part of a registration dossier
8. Competencies
9. Discuss and critique non-clinical requirement for specific types of medicines
10. Design preclinical dossier examinations in accordance with the regulatory requirements including good laboratory practices (GLP)

Course Content:

- Overview of pharmacology, pharmacokinetic and toxicology
- Timing of non-clinical studies
- Good Laboratory Practice for preclinical studies
- Interaction with quality
- Interaction with clinical studies
- Predictive value of non-clinical animal studies
- First in Man: pharmacology and kinetics
- First in Man: single dose, repeat dose
- First in Man: genotoxicity, local tolerance and other studies
- Application for first in Man
- Risk assessment
- Global development plan
- General considerations for clinical trials
- Good Clinical Practice – Clinical Trial Operations
- Global Regulatory requirements, FDA/EU legislation
- Ethical Approach in Clinical Studies
- Clinical Protocol
- Clinical study and site management
- Exploratory clinical development
- Statistics and clinical trials
- Interaction with health authorities
- Documentation in relation to the type of application
- Audit and Inspection

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
Fundamentals of Clinical Research Bridging Medicine, Statistics and Operations.	Bacchieri, A. and Della Cioppa, G.	Milano: Springer – Verlag, Milan.	2007	
Principles and Practice of Clinical Trials Medicine.	Chin, R. and Lee, B.	London: Academic	2008	
Principle and Practice of Clinical Research.	Galin, J. and Ognibene, F.	Amsterdam: Elsevier/AP	2012	