University of Nicosia, Cyprus

Course Code	**Course Title**	**ECTS**
BIOL-473	Special Topics IV: Clinical Research	4
Department	**Semester**	**Prerequisites**
Life and Health Sciences	Spring/Fall	BIOL-371 Drug Action and Toxicology
Type of Course	**Field**	**Language of Instruction**
Elective	Biology, Medicine	English
Level of Course	**Year of Study**	**Lecturer**
1st Cycle	4th	Dr. Theodoros Kyprianou
Mode of Delivery	**Work Placement**	**Co-requisites**
Face-to-face	N/A	None

Objectives of the Course:

The course aims to provide an introduction to the processes for drug approval through clinical research. The main objectives of the course are to:

- Make students aware of the clinical research process and research terminology used.
- Discuss the basic study designs in health and biomedical setting.
- Review the four phases of interventional trials and the requirements for drug approval.
- Make students aware of regulations, responsibilities and ethical issues related to clinical trials.

Learning Outcomes:

After completion of the course students are expected to:

1. Explain the steps required for a new drug to be approved for human use.
2. Identify the four major clinical phases in the drug development process and explain the rational for each.
3. Describe the basic concepts of clinical pharmacology requirements in drug testing.
4. Name the sources for finding the rules and regulations for new drug development.
5. Describe the roles of various research and regulatory organizations involved in the clinical research process and the approval of new drugs.
6. Discuss the real and perceived conflicts and ethical issues in drug testing.

Course Contents:

1. Drug development introduction.
2. Pre-Clinical drug development.
3. Principles of Clinical Pharmacology
4. Clinical trial designs; advantages and disadvantages

5. Clinical phases
6. Drug safety and monitoring Boards
7. Clinical trials reporting; meta analyses studies
8. Dangers of Biomedical research
9. Biotechnology in Drug Development.
10. Clinical Research ethics

Learning Activities and Teaching Methods:

Lectures, Case studies discussions, Literature reviews.

Assessment Methods:

Individual assignments, Cooperative presentations; Final Exam

Required Textbooks/Reading:

Authors	Title	Publisher	Year	ISBN
1. Grahame-Smith, DG.	Clinical Pharmacology and drug therapy.	Oxford textbook	2000	ISBN – 0192616757
2. Adam Cohen and John Posner	A guide to clinical drug research	Kluwer Academic Publishers	1995	ISBN-: 0792361717

Recommended Textbooks/Reading:

Authors	Title	Publisher	Year	ISBN
1. Atkinson AJ Jr et al.	Principles of Clinical Pharmacology	Academic Press	2007 2nd Ed.	ISBN-0123694175
2. Mark A. Rothstein	Pharmacogenomics : social, ethical, and clinical dimensions	Wiley,	2006	ISBN: 0471737798
3. Kenneth P. Minneman, Lynn Wecker , Joseph Larner, Theodrore M. Brody	Brody's human pharmacology : molecular to clinical	Elsvier Mosby	2005, 4th ed.	ISBN: 032303286

http://www.fda.gov/fdac/special/newdrug/ndd_toc.html

http://www.fda.gov/oc/initiatives/criticalpath