Liverpool John Moores University

Title:	CLINICAL DRUG DEVELOPMENT
Status:	Definitive
Code:	**6004PHASCI** (122604)
Version Start Date:	01-08-2020
Owning School/Faculty:	Pharmacy & Biomolecular Sciences
Teaching School/Faculty:	Pharmacy & Biomolecular Sciences

Team	Leader
Vicki Anderson	Y
Kenneth Ritchie	
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Andrew Evans	
Mark Cronin	

Academic Level:	FHEQ6	**Credit Value:**	20	**Total Delivered Hours:**	60
Total Learning Hours:	200	**Private Study:**	140		

Delivery Options
Course typically offered: Semester 2

Component	Contact Hours
Lecture	28
Seminar	6
Workshop	24

Grading Basis: 40 %

Assessment Details

Category	Short Description	Description	Weighting (%)	Exam Duration
Exam	Exam	Written examination	60	2
Essay	CW	Essay	40	

Aims

Upon completion of this module, students should be able to demonstrate an awareness and understanding of preclinical testing and management and regulation

of clinical trials in the process of drug development. In addition, students should be able to discuss the challenges and ethical issues in patient recruitment and retention and the importance of publication of clinical trial data.

Learning Outcomes

After completing the module the student should be able to:

1	Describe the key processes involved in preclinical and clinical testing during drug development in accordance with GCP-ICH guidelines.
2	Discuss the importance of preclinical and computational toxicity in drug development.
3	Identify the challenges with respect to patient recruitment and retention in the different phases of Clinical Trials and the ethical issues of outsourcing of clinical trials.
4	Apply and interpret essential statistical requirements when documenting and reporting clinical trials.

Learning Outcomes of Assessments

The assessment item list is assessed via the learning outcomes listed:

Final Exam	2	3	1	4
Essay	3	1		

Outline Syllabus

Preclinical toxicity testing
Computational toxicity
Adverse Drug Reactions
Clinical trial documentation TMF, CRF, IB
Clinical Trial design
Patient recruitment and retention
Outsourcing of clinical trials
Ethics and Law
GCP-ICH
Standard Operating Procedures
Statistics for Clinical Trials
Trial Closedown and Clinical Trial Data Dissemination

Learning Activities

Workshops apply knowledge and demonstrate understanding of lecture material and further reading;
Formative feedback will be given within the sessions.
Examples can include:
• Case record form Design

• Protocol development
• SOPs - students to design an SOP
• Clinical trial documentation - Documenting and Reporting Clinical Trials – discussion of the essential statistical requirements when documenting and reporting clinical trials.
• Clinical Trial Analysis and Reporting. Statistics - Estimation and Confidence Intervals – measuring the magnitude of a treatment effect and the concept of confidence interval calculation
• The Challenges in Patient recruitment and retention
• The Ethical issues in outsourcing to LEDs (lower economically developed countries).
• Essay writing skills - in preparation for the coursework.

An Essay on Ethical implications of Outsourcing (Summative)
End of module examination (Summative) (50% MCQ and 3 SAQ)
Online MCQ quizzes (formative)

Notes

Emanuel EJ, Grady C, Crouch RA, Lie R, Miller F, Wendler D (Eds.): The Oxford Textbook of Clinical Research Ethics. Oxford University Press 2008.
Fisher J: Medical Research For Hire: The Political Economy of Pharmaceutical Trials. Rutgers University Press 2008.
Klitzman RL: The Ethics Police? The Struggle to Make Human Research Safe. Oxford University Press 2015.
Hawkins JS, Emanuel EJ (Eds.): Exploitation and Developing Countries: The Ethics of Clinical Research. Princeton University Press 2008.
International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) – Website
An Introduction to Randomized Controlled Clinical Trials. JNS Matthews. London: Arnold, 2000
Principles of Biochemical Toxicology, Fourth Edition. John A . Timbrell. CRC Press 2008