Clinical Drug Development

Module Information

2022.01, Approved

Summary Information

Module Code	6004PHASCI
Formal Module Title	Clinical Drug Development
Owning School	Pharmacy & Biomolecular Sciences
Career	Undergraduate
Credits	20
Academic level	FHEQ Level 6
Grading Schema	40

Teaching Responsibility

LJMU Schools involved in Delivery
Pharmacy & Biomolecular Sciences

Learning Methods

Learning Method Type	Hours
Lecture	28
Seminar	6
Workshop	24

Module Offering(s)

Display Name	Location	Start Month	Duration Number Duration Unit
JAN-CTY	CTY	January	12 Weeks

Aims and Outcomes

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.

After completing the module the student should be able to:

Learning Outcomes

Code	Number	Description
MLO1	1	Describe the key processes involved in preclinical and clinical testing during drug development in accordance with GCP-ICH guidelines.
MLO2	2	Discuss the importance of preclinical and computational toxicity in drug development.
MLO3	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.
MLO4	4	Apply and interpret essential statistical requirements when documenting and reporting clinical trials.

Module Content

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
Module Overview	The aim of this module is to gain an awareness and understanding of preclinical testing and management and regulation of clinical trials in the process of drug development.
Additional Information	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

Assessments

Assignment Category	Assessment Name	Weight	Exam/Test Length (hours)	Module Learning Outcome Mapping
Essay	Essay	40	0	MLO1, MLO3
Centralised Exam	Final Exam	60	2	MLO1, MLO2, MLO3, MLO4

Module Contacts

Module Leader

Contact Name	Applies to all offerings	Offerings
Vicki Anderson	Yes	N/A

Partner Module Team

Contact Name	Applies to all offerings	Offerings