

Clinical Research and Pharmacovigilance

MPL 204T

A Textbook for M. Pharm

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Preface

This book presents the subject Clinical Research and Pharmacovigilance (MPL 204T) in a structured, point-by-point form intended for postgraduate pharmacy students. The subject sits at the meeting point of two disciplines that a modern pharmacist must command: the design and conduct of clinical trials that generate a medicine's evidence, and the science of pharmacovigilance that keeps watch over that medicine for as long as it is used. The material follows the prescribed syllabus unit by unit, and each chapter is written to teach the first-time learner, to serve the reviser, and to prepare the examinee from the same pages.

The treatment is deliberately pointwise. Definitions are stated exactly, classifications are laid out in full, and comparisons are drawn in ruled tables so that the distinctions an examiner tests are visible at a glance. Every chapter opens with its learning outcomes, develops the content through numbered points and figures, and closes with a graded self-assessment of short-answer questions with model answers, long-answer questions with structured guidance, and multiple-choice questions. Original figures, drawn specifically for this book, pair with the prose so that each idea is encountered in words and in a diagram.

Two conventions should be noted. First, drug names are given by their International Nonproprietary Names. Second, where the prescribed syllabus names an instrument whose current form has since moved on, the syllabus framework is taught as the examination spine and the current position is marked as enrichment, so that the reader is both exam-correct and not misinformed. Accuracy has been treated as the first duty of the book throughout.

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Course Objectives

The scope and objectives of this course are:

1. To provide a value addition and current requirement for the students in clinical research and pharmacovigilance.
2. To teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials.
3. To focus on the global scenario of pharmacovigilance and the different methods that can be used to generate safety data.
4. To teach the students in developing drug safety data in the pre-clinical and clinical phases of drug development and in post-market surveillance.

Course Outcomes

Upon completion of the course, the student shall be able to:

1. Explain the regulatory requirements for conducting a clinical trial.
2. Demonstrate the types of clinical trial designs.
3. Explain the responsibilities of key players involved in clinical trials.
4. Execute safety monitoring, reporting and close-out activities.
5. Explain the principles of pharmacovigilance.
6. Detect new adverse drug reactions and their assessment.
7. Perform the adverse drug reaction reporting systems and communication in pharmacovigilance.

Syllabus

Unit	Topics	No. of lectures
I	Regulatory Perspectives of Clinical Trials: Origin and principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines. Ethical Committee: Institutional Review Board, Ethical guidelines for biomedical research and human participant - Schedule Y, ICMR. Informed consent process: Structure and content of an informed consent process, ethical principles governing informed consent process.	12 Hours
II	Clinical Trials: Types and design - experimental study (RCT and non RCT), observational study (cohort, case control, cross sectional). Clinical trial study team, roles and responsibilities of clinical trial personnel: Investigator, study coordinator, sponsor, contract research organization and its management.	12 Hours
III	Clinical Trial Documentation: Guidelines to the preparation of documents, preparation of protocol, investigator brochure, case report forms, clinical study report. Clinical trial monitoring: Safety monitoring in CT. Adverse drug reactions: Definition and types, detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, management of adverse drug reactions: Terminologies of ADR.	12 Hours
IV	Basic Aspects, Terminologies and Establishment of Pharmacovigilance: History and progress of pharmacovigilance, significance of safety monitoring, pharmacovigilance in India and international aspects, WHO international drug monitoring	12 Hours

	programme, WHO and regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centers in hospitals, industry and national programmes related to pharmacovigilance. Roles and responsibilities in pharmacovigilance.	
V	Methods, ADR reporting and tools used in pharmacovigilance: International classification of diseases, international nonproprietary names for drugs, passive and active surveillance, comparative observational studies, targeted clinical investigations and vaccine safety surveillance. Spontaneous reporting system and reporting to regulatory authorities, guidelines for ADRs reporting. Argus, Aris G pharmacovigilance, VigiFlow, statistical methods for evaluating medication safety data.	12 Hours
VI	Pharmacoepidemiology, pharmacoeconomics, safety pharmacology.	12 Hours

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Chapter 1: Regulatory Perspectives of Clinical Trials

Learning Outcomes

After studying this chapter the student will be able to:

- 1. Trace the origin, structure and working process of the International Council for Harmonisation (ICH) and state the purpose of the ICH-GCP (E6) guideline.*
- 2. Enumerate and explain the thirteen principles of ICH Good Clinical Practice and relate them to the essential documents of a trial.*
- 3. Describe the composition, functions, review types and record-keeping of an Ethics Committee / Institutional Review Board.*
- 4. Explain the Indian ethical and legal framework for biomedical research on human participants: Schedule Y, the New Drugs and Clinical Trials Rules 2019, and the ICMR National Ethical Guidelines.*
- 5. Set out the structure, content, documentation and governing ethical principles of the informed consent process, including consent in special populations.*

Introduction

A clinical trial is a systematic study of an investigational product in human participants undertaken to discover or verify its clinical, pharmacological or pharmacodynamic effects, to identify any adverse reaction, or to study its absorption, distribution, metabolism and excretion, with the object of determining safety and efficacy. Because such a study deliberately exposes human beings to an incompletely characterised product, it can be justified only when it is scientifically sound and ethically conducted. The regulatory framework of clinical research exists to guarantee both conditions at once: that the data generated are credible, and that the rights, safety and well-being of participants are protected and prevail over the interests of science and society.

This chapter sets out that framework as it governs a trial conducted in India. It moves from the international standard that harmonises trial conduct worldwide, Good Clinical Practice, through the ethics-review machinery that authorises and oversees each study, to the two Indian instruments that give the framework legal and moral force, and finally to the single