COURSE NAME:	Clinical Trial & Data Management
TOTAL DURATION:	45 Hrs
MODE OF DELIVERY	PHYSICAL CLASSROOM TRAINING AT RESPECTIVE COLLEGES
TRAINER TO STUDENT RATIO:	1:50
TOTAL MARKS:	75

Table 1	
OVERALL COURSE OBJECTIVE:	1. Evaluate the principles of clinical trials and data management to validate their role in ensuring compliance with global regulatory standards and patient safety. 2. Critique ethical guidelines and Good Clinical Practice (GCP) standards in clinical research, defending their importance in maintaining integrity and reliability in studies. 3. Design comprehensive study protocols, including documentation and reporting frameworks, to address the regulatory and ethical requirements of clinical trials. 4. Develop scalable and efficient data management systems to ensure data integrity, safety reporting, and adherence to industry standards in clinical research. 5. Construct innovative trial methodologies and testing strategies to enhance the efficacy of drug development and medical device evaluations.

LEARNING OUTCOME:	1. Analyze the principles and regulatory requirements for clinical trials and data management, ensuring compliance with industry standards. 2. Evaluate the drug development process and the role of pharmacology in clinical studies for patient safety and efficacy. 3. Create comprehensive study protocols and documentation, incorporating Good Clinical Practice (GCP) and ethical guidelines. 4. Critique the phases of clinical trials and their methodologies, focusing on medical devices and pharmaceuticals. 5. Design efficient data management systems to ensure data integrity, safety reporting, and

	pharmacovigilance.

TABLE 2: MODULE WISE COURSE CONTENT AND OUTCOME				
SL. NO	**MODULE NAME**	**MODULE CONTENT**	**MODULE LEARNING OUTCOME**	**DURATION (HRS)**
1	Introduction to Clinical Research	- Basics of clinical trials and regulatory requirements - Overview of data management in clinical studies	Understand the fundamentals of clinical trials and data management.	9
2	Pharmacology and Drug Development	- Importance of pharmacology in clinical studies - Drug development process and delivery systems	Evaluate the role of pharmacology in drug development and its impact on clinical trial efficacy.	9
3	Ethics and Regulatory Guidelines	- Good Clinical Practices (GCP) - Ethical guidelines for human and animal trials - National and international regulatory frameworks	Analyze and apply ethical guidelines and regulatory requirements for clinical trials.	9
4	Clinical Trial Phases and Design	- Phases of clinical trials - Trial methodologies and protocols - Integration of medical devices in trials	Critique the methodologies and trial designs across all phases of clinical studies.	9
5	Data Management and Safety Reporting	- Documentation and data integrity - Safety reporting and pharmacovigilance - Importance of Quality Control (QC) and Trial Master File (TMF)	Design efficient systems for data management and safety reporting while ensuring quality and regulatory compliance.	9

TABLE 3: OVERALL COURSE LEARNING OUTCOME ASSESSMENT CRITERIA AND USE CASES			
LEARNING OUTCOME	**ASSESSMENT CRITERIA**	**Performance Criteria**	**USE CASES**
Analyze principles and regulatory requirements.	Evaluate clinical trial rules and regulations.	Demonstrates comprehensive understanding of compliance and industry standards.	Optimize a multinational corporation's compliance with regulatory frameworks in clinical research.
Evaluate the role of pharmacology in clinical studies.	Assess the application of pharmacological principles in trials.	Provides detailed evaluations linking pharmacology to trial efficacy and patient safety.	Develop a drug delivery strategy considering pharmacological impacts and trial results.
Create study protocols incorporating GCP and ethics.	Develop protocols for clinical studies following ethical guidelines.	Prepares accurate and compliant study protocols with thorough ethical considerations.	Design a study protocol for testing a new medical device under ethical and GCP standards.
Critique clinical trial phases and methodologies.	Analyze the methodologies of trial designs and phases.	Offers in-depth critiques of methodologies, highlighting strengths, limitations, and innovations.	Propose trial designs for a medical device, addressing phase-specific challenges and methodologies.
Design data management systems for integrity and safety.	Create efficient documentation systems ensuring data integrity and compliance with safety reporting norms.	Produces robust, scalable data management systems aligned with regulatory requirements and safety standards.	Implement a data integrity system for pharmacovigilance in clinical trials involving high-risk pharmaceutical drugs.

TABLE 4: LIST OF FINAL PROJECTS (PROJECTS THAT COMPREHENSIVELY COVER ALL THE LEARNING OUTCOME)	
SL.NO	**FINAL PROJECT**
1	Standard operating procedure for clinical studies
2	Prepare Validation protocol and report for QC instrumentation
3	Preparation of Method of analysis for drug testing
4	Preparation of calibration procedure and report
5	Preparation of Study test protocol

TABLE 5: COURSE ASSESSMENT RUBRICS (TOTAL MARKS: 75)					
ASSESSMENT CRITERIA	**Learning Outcome**	**Fair (1–5)**	**Good (6–10)**	**Excellent (11–15)**	**TOTAL MARKS**
Regulatory Compliance and Principles Analysis	Analyze principles and regulatory requirements.	Limited understanding of regulatory principles; minimal compliance application.	Demonstrates understanding of compliance and applies principles effectively in basic scenarios.	Provides comprehensive analysis and applies principles innovatively to meet complex compliance challenges.	15
Pharmacology and Drug Development Evaluation	Evaluate the role of pharmacology in clinical studies.	Basic evaluation of pharmacology's impact on trials; lacks detailed analysis.	Provides moderate analysis of pharmacology ’s role in trial efficacy and patient safety.	Offers in-depth evaluations linking pharmacology to patient outcomes and trial success.	15
Ethical	Create study	Develops basic	Prepares	Designs	15

Guidelines and Protocol Design	protocols incorporating GCP and ethics.	protocols with limited ethical considerations; lacks adherence to standards.	moderately detailed and compliant protocols, incorporating GCP and ethical standards.	comprehensive and fully compliant protocols, integrating ethical guidelines effectively.	
Trial Phases and Methodologies Critique	Critique clinical trial phases and methodologies.	Provides general critiques of methodologies with limited depth.	Delivers detailed critiques of methodologies, addressing strengths and weaknesses.	Offers exceptional critiques with innovative suggestions for methodology improvements across trial phases.	15
Data Management and Safety Reporting Design	Design data management systems for integrity and safety.	Limited system designs with insufficient attention to data integrity and safety reporting norms.	Creates functional systems for data integrity and safety reporting with moderate compliance standards.	Develops highly efficient and scalable systems ensuring complete compliance and high-quality safety reporting.	15