GUJARAT TECHNOLOGICAL UNIVERSITY
Integrated Master of Science (Biotechnology)
Semester: 7
Subject Name: Clinical Research and Regulatory Affairs
Subject Code: 1370409

Prerequisite: Students should have a fundamental understanding of biomedical sciences, drug development, clinical trial design, and regulatory frameworks. Basic knowledge of good clinical practices (GCP), ethics in research, and pharmacovigilance is beneficial.

Rationale: This course provides a comprehensive understanding of clinical research methodologies, drug development, regulatory guidelines, and ethical considerations. It covers clinical trial design, biostatistics, pharmacovigilance, and regulatory frameworks such as FDA, EMA, ICMR, and CDSCO. The course equips students with essential skills for careers in clinical research organizations (CROs), pharmaceutical industries, and regulatory bodies.

Course Scheme:

Teaching Scheme			Total Credits	Assessment Pattern and Marks				Total Marks
				Theory		Practical		
L	T	PR	C	ESE (E)	PA(M)	ESE (V)	PA (I)	
4	0	0	4	70	30	0	0	100

Course Content:

Sr. No.	Course Content	No. of Hours	% of Weightage

1	**Unit 1: Introduction to Clinical Research and Drug Development**
	• **Overview of Clinical Research**
	  ○ Definition, Scope, and Importance
	  ○ Phases of Drug Development (Preclinical to Post-Marketing)
	• **Fundamentals of Clinical Trials**
	  ○ Phase I-IV Trials, Observational and Interventional Studies
	  ○ Study Design (Randomized Control Trials, Cohort Studies, Case-Control Studies)
	• Role of Institutional Review Boards (IRB) and Ethics Committees
	• Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) Guidelines
		12	**20**

	• Recent Advancements: AI in Clinical Research, Virtual Clinical Trials		

2	**Unit 2: Clinical Trial Management and Biostatistics**
	• Clinical Trial Protocol Design and Implementation
	  ○ Essential Documents: Case Report Forms (CRF), Investigator's Brochure (IB)
	• Patient Recruitment, Retention, and Informed Consent Process
	• Data Collection, Monitoring, and Risk Management in Clinical Trials
	• Biostatistics in Clinical Research
	  ○ Descriptive and Inferential Statistics
	  ○ Kaplan-Meier Survival Analysis, Hazard Ratios, P-Values
	• Data Management and Clinical Data Interchange Standards (CDISC, SDTM, ADaM)
		12	**30**

3	**Unit 3: Regulatory Frameworks and Global Guidelines**
	• International Regulatory Agencies and Guidelines
	  ○ USFDA (United States Food and Drug Administration)
	  ○ EMA (European Medicines Agency)
	  ○ CDSCO (Central Drugs Standard Control Organization – India)
	  ○ ICH-GCP (International Council for Harmonisation – Good Clinical Practice)
	• Regulatory Approval Process for New Drugs and Medical Devices
	• Generic Drug Approval (ANDA) and Biosimilar Regulations
	• Ethical Issues and Regulatory Requirements in Gene Therapy and Stem Cell Research
	• Compliance and Quality Assurance in Clinical Research
		12	**20**

4	**Unit 4: Pharmacovigilance and Safety Reporting** • Principles of Pharmacovigilance and Drug Safety Monitoring • Adverse Drug Reactions (ADR) and Signal Detection	**12**	**20**

	• Periodic Safety Update Reports (PSUR) and Risk Management Plans (RMP) • Vaccine Safety Surveillance and Post-Marketing Surveillance (PMS) • Role of AI and Big Data in Pharmacovigilance		
5	**Unit 5: Future Trends in Clinical Research and Regulatory Affairs** • Personalized Medicine and Companion Diagnostics in Clinical Trials • Regulatory Challenges in Cell and Gene Therapy (CAR-T, CRISPR-Based Trials) • Medical Device Regulations and Clinical Evaluations • AI and Blockchain in Clinical Trial Data Management • Global Health Policies and Future Directions in Drug Development	**12**	**20**

Reference Books:

1. Principles and Practice of Clinical Research – John I. Gallin, Frederick P. Ognibene
2. Clinical Trials: A Practical Approach – Stuart J. Pocock
3. Fundamentals of Clinical Trials – Lawrence M. Friedman
4. Pharmacovigilance: Principles and Practice – Ronald D. Mann, Elizabeth B. Andrews
5. Regulatory Affairs in the Pharmaceutical Industry – Javed Ali, Sanjula Baboota

Course Outcome:

After Completion of the Course, Student will able to:

Sr. No	Course Outcomes	RBT Level
1	Explain the fundamentals of clinical research and drug development.	UN, RM, AP
2	Design and analyze clinical trial protocols with biostatistical applications.	UN, RM, AP
3	Interpret global regulatory frameworks and compliance for drug approvals.	AP, AN, CR
4	Evaluate pharmacovigilance principles and safety reporting mechanisms.	AN, EL, CR
5	Integrate AI, blockchain, and digital health tools into clinical research.	AP, CR

*RM: Remember, UN: Understand, AP: Apply, AN: Analyze, EL: Evaluate, CR: Create

List of Experiments:

1. Clinical Trial Design and Development of Study Protocols
2. Informed Consent Process and Ethics Committee Documentation
3. Data Collection and Analysis in a Simulated Clinical Study
4. Adverse Event (AE) Reporting and Pharmacovigilance Case Studies
5. Statistical Analysis of Clinical Trial Data Using SPSS/R
6. Drug Approval Process Simulation (ANDA vs. New Drug Application)
7. AI-Based Drug Safety Monitoring and Signal Detection
8. Real-World Evidence (RWE) and Big Data in Clinical Research

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