School of Pharmaceutical Sciences & Technology

Curriculum for
Fellowship Program in

Clinical Research

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Course Title: Clinical Research

Course Type: FELLOWSHIP
Duration: 360 Hours (can be structured as 24 Credits)
Mode: Lectures, Practical's /Hands-on, Project

Overview

The Fellowship in Clinical Research is an intensive, competency-focused postgraduate professional program designed to develop skilled clinical research professionals capable of planning, conducting, monitoring, and managing clinical trials in compliance with international regulatory standards. This fellowship addresses the critical demand for trained personnel in the rapidly expanding clinical research sector in India and globally, preparing fellows for roles in pharmaceutical companies, contract research organizations (CROs), academic research institutions, regulatory agencies, and site management organizations. The program integrates theoretical knowledge of Good Clinical Practice (GCP), regulatory requirements, biostatistics, protocol development, and data management with hands-on training in trial conduct, patient recruitment, informed consent processes, source document verification, safety reporting, and quality assurance. Fellows gain practical experience aligned with ICH-GCP guidelines, USFDA/EMA regulations, CDSCO requirements, and ethical standards outlined in the Declaration of Helsinki. This fellowship bridges the gap between academic understanding and industry requirements, ensuring graduates are immediately employable and capable of contributing to ethical, scientifically rigorous clinical research..

Objectives:

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

- To provide in-depth knowledge of clinical research processes and clinical trial phases.
- To train participants in ethical principles and Good Clinical Practice (GCP) guidelines.
- To develop practical skills in clinical trial documentation, monitoring, and coordination.
- To ensure understanding of regulatory requirements and compliance in clinical research.
- To build competency in data management, safety reporting, and quality assurance.
- To prepare candidates for industry-ready roles in clinical research and clinical trials management.

Course Outcome:

CO No.	Course Outcome
CO1	Understand the fundamentals of clinical research, clinical trial phases, and study designs.
CO2	Apply Good Clinical Practice (GCP) principles and ethical guidelines in clinical trials.
CO3	Prepare, review, and manage essential clinical trial documents in compliance with regulations.
CO4	Demonstrate skills in clinical trial coordination, monitoring, data handling, and safety reporting.

Teaching & Learning Methods:

- Classroom lectures to explain core concepts of clinical research and regulations.
- Practical demonstrations and hands-on sessions on clinical trial documentation.
- Case studies and real-world examples of clinical trials.
- Interactive discussions on ethical issues, regulatory challenges, and compliance.
- Industry exposure through mock trials, audits, and project works.

Syllabus

Theory - 10 Credits (150 Lecture Hours)

Module I-Fundamentals of Clinical Research (35 Lecture Hours)

- Introduction to clinical research
- History and evolution of clinical trials
- Types of clinical research: interventional and observational studies
- Phases of clinical trials (Phase I–IV)
- Roles and responsibilities of clinical research professionals
- Clinical trial stakeholders: Sponsor, Investigator, CRO, EC/IRB
- Overview of drug development process
- Basics of protocol development

Module 2: Ethics & Good Clinical Practice (GCP) (40 Lecture Hours)

- Ethical principles in clinical research (Belmont Report)
- Informed consent process and documentation
- Declaration of Helsinki and ICMR ethical guidelines
- Good Clinical Practice (ICH-GCP E6)
- Roles and functioning of Ethics Committees (EC/IRB)
- Subject safety, rights, and confidentiality
- Vulnerable populations in clinical research
- Audits and inspections related to ethics and GCP

Module 3: Clinical Trial Operations & Regulatory Aspects (40 Lecture Hours)

- Clinical trial protocol and amendments
- Investigator Site File (ISF) and Trial Master File (TMF)
- Regulatory submissions and approvals
- Regulatory authorities: CDSCO, DCGI, USFDA, EMA (overview)
- Clinical Trial Agreements and contracts
- Monitoring of clinical trials (on-site, remote, centralized)
- Quality assurance and quality control in clinical research
- Handling deviations, violations, and CAPA

Module IV: Data Management, Safety & Emerging Trends (35 Lecture Hours)

- Basics of clinical data management
- Case Report Forms (CRFs) and Electronic Data Capture (EDC)
- Source data verification (SDV)
- Pharmacovigilance and adverse event reporting
- Serious Adverse Events (SAE) and SUSARs
- Clinical trial audits and inspections
- Risk-based monitoring
- Emerging trends and career opportunities in clinical research

Practical/Hands-on Component: 8 Credits (120 Lab Hours)

1. **Clinical Research Documentation & GCP Practices (30 hours):**
   - Preparation of informed consent documents
   - Review of clinical trial protocols
   - Essential documents as per ICH-GCP
   - Investigator Site File (ISF) maintenance
   - Mock Ethics Committee submissions
   - GCP compliance exercises

2. **Clinical Trial Operations & Monitoring (30 hours):**
   - Site initiation, monitoring, and close-out activities
   - Monitoring visit reports (MVRs)
   - Source data verification exercises
   - Protocol deviation handling
   - Communication with investigators and sites
   - Mock monitoring visits

3. **Clinical Data Management & Safety Reporting (30 hours):**
   - Design and review of CRFs
   - Data entry and query management
   - Adverse event documentation
   - SAE reporting timelines and procedures
   - Safety narrative preparation
   - Case studies on pharmacovigilance

4. Quality, Compliance & Industry Exposure (30 hours):

- Clinical trial audits and inspections (mock)
- CAPA preparation
- Regulatory inspection readiness
- Case studies based on real clinical trials
- Industry interaction / hospital exposure
- On-the-job training / mini project

Project: 6 Credits (90 Self Study/Research Hours)

The project for the Fellowship in Clinical Research involves planning and execution of a simulated or real clinical study. Fellows work on protocol review, informed consent development, documentation, monitoring, and data handling. Emphasis is placed on ethical compliance, GCP adherence, and regulatory requirements. The project enhances analytical, documentation, and professional skills required for clinical research careers.

References:

Textbooks & Handbooks

1. Principles and Practice of Clinical Research – John I. Gallin & Frederick P. Ognibene (Academic Press)
2. Fundamentals of Clinical Trials – Lawrence M. Friedman, Curt D. Furberg & David L. DeMets
3. Designing Clinical Research – Stephen B. Hulley, Steven R. Cummings & Warren S. Browner
4. Clinical Research Handbook: Guidelines for Good Clinical Practice – World Health Organization
5. Good Clinical Practice: A Question & Answer Reference Guide – Regulatory Affairs Professionals Society (RAPS)
6. Textbook of Clinical Trials – David Machin, Simon Day & Sylvan Green
7. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance – John Sharp (includes packaging and labeling controls).
8. Quality Rules in Packaging (Revised American Edition) – John Sharp (focus on drug packaging GMP).
9. Good Manufacturing Practices for Pharmaceuticals – Graham P. Bunn (GMP foundation including packaging).
10. Principles of Clinical Data Management – Susanne Prokscha
11. Clinical Data Management – Richard K. Rondel, Sheila A. Varley & Colin F. Bagley
12. Statistical Methods for Rates & Proportions – J. L. Fleiss, B. Levin & M. C. Paik
13. Practical Statistics for Medical Research – Douglas G. Altman
14. Textbook of Pharmacovigilance – EudraVigilance / Uppsala Monitoring Centre concepts
15. Pharmacovigilance: Principles & Practice – S. S. K. Malik & A. A. Khan
16. Edwards' Safety Assessment – Stephen E. Evans & K. Bjorn

Regulations, Guidelines & Ethical Standards

International Guidelines

- ICH E6(R3) Good Clinical Practice (Updated version) – International Council for Harmonisation
- Declaration of Helsinki – World Medical Association
- CIOMS Ethical Guidelines – Council for International Organizations of Medical Sciences
- WHO Operational Guidelines for Ethics Committees

India-Specific Regulations

- ICMR National Ethical Guidelines for Biomedical & Health Research involving Human Participants (latest edition)
- CDSCO New Drugs & Clinical Trial Rules (NDCTR) 2019
- Schedule Y of the Drugs & Cosmetics Rules (as applicable)
- Indian GCP Guidelines

US & EU Regulatory References

- US FDA 21 CFR (Parts 50, 54, 56, 312, 314)
- EMA Clinical Trial Regulation (EU CTR) 536/2014
- FDA Guidance Documents on E6 GCP, Safety Reporting, Electronic Records
- ICH Guidelines E2A–E2F (Safety Reporting)

Journals & Periodicals

Clinical Research & Trials

- *Contemporary Clinical Trials* – Elsevier
- *Journal of Clinical Trials* – Hindawi
- *Trials* (BioMed Central)
- *International Journal of Clinical Trials*

Research Ethics & GCP

- *Journal of Medical Ethics*
- *Accountability in Research*
- *IRB: Ethics & Human Research*

Pharmacovigilance & Safety

- *Drug Safety* – Springer
- *Pharmacoepidemiology & Drug Safety* – Wiley
- *Journal of Pharmacovigilance*

Data & Biostatistics

- *Statistics in Medicine* – Wiley
- *Journal of Biopharmaceutical Statistics*

Regulatory Science

- *Regulatory Rapporteur* (RAPS)
- *Therapeutic Innovation & Regulatory Science*