All India Institute of Medical Sciences, Nagpur

Department of Pharmacology

Certificate Course in Clinical Research

All India Institute of Medical Sciences, Nagpur

CURRICULUM FOR
CERTIFICATE COURSE IN CLINICAL RESEARCH

1. GOAL

The program aims to provide a robust foundation in clinical research, and encompass the related knowledge, skills, and attitudes which will enable the student to perform various roles in clinical research in the healthcare and pharmaceutical industries. The program is meant for all those keen on being a part of the Clinical Research industry, so all graduates, postgraduates and even working professionals can apply for the program and affirm a strong position in the industry.

The goal of the program is

- To provide comprehensive knowledge and practical skills in clinical research.
- To develop an understanding of Good Clinical Practice (GCP) guidelines and international regulatory requirements.

2. PROGRAM OUTCOMES

On successful completion of the certificate course in clinical research, the student will

- Have a thorough understanding of the clinical research process, from concept development to post-marketing surveillance.
- Be able to conduct, and manage clinical trials in compliance with regulatory standards.
- Be conversant with the functioning of ethics committee
- Understand ethical considerations and patient safety in clinical research.
- Be able to do accurate data entry and interpret clinical data.
- Develop a skill to effectively work with other research team members for effective implementation of trial conduct
- Be conversant with counseling techniques. Communicate effectively and demonstrate caring and respectful behavior when interacting with research participants to protect their rights, safety, and well-being.
- Be prepared for roles such as Clinical Research Coordinator, Regulatory Affairs Associate, Clinical Trial Assistant, Pharmacovigilance associate, etc.

3. ELIGIBILITY CRITERIA

- **Essential qualification:**
- A bachelor's degree in life sciences, pharmacy, medicine, dentistry, nursing, or related fields (MBBS, BAMS, BHMS, BDS, BSc, BSC nursing, BPharm, PharmD).
- Professionals working in healthcare or the pharmaceutical industry seeking to enhance their clinical research skills are also eligible (as per criteria mentioned above). Submission of NOC is mandatory for working professionals.
- **Desirable qualification:**
- Postgraduation in above mentioned streams, PhD (subject related to life sciences)

4. SELECTION OF THE CANDIDATE

- There will be an entrance examination
- 25 marks MCQ test (25 MCQs) based on subject concerned
- No negative marking
- Merit list will be displayed for eligibility

5. DURATION OF THE COURSE

Total duration of training: 12 months

6. COURSE CONTENT

Semester 1: Introduction to Clinical Research (4 months)

- **Module 1: Basics of Clinical Research**
  - Introduction to Clinical Research
  - Phases of Clinical Trials
  - Difference between biomedical research & clinical trials
- **Module 2: General Pharmacology**
  - Basics of Pharmacology
  - Routes of administration
  - Dosage form
  - Pharmacokinetics/Pharmacodynamics
  - Drug therapy for common communicable and non-communicable diseases
- **Module 3: Drug development process**
  - Drug discovery
  - Target identification
  - Lead identification/optimization
  - Preclinical studies

Semester 2: Clinical Trial Management (4 months)

- **Module 4: National and International Regulations Governing Clinical Trials**
  - Evolution of ethical and regulatory framework: Historical perspective
  - ICH-GCP guidelines
  - ICMR ethical guidelines
  - NDCT rules 2019 by CDSCO, India
- **Module 5: Clinical Research Stakeholders: Roles and Responsibilities**
  - Investigator
  - Sponsor
  - Contract Research Organization (CRO)
  - Clinical Research Coordinator (CRC)
  - Clinical Research Associate (CRA)
- **Module 6: Conduct of clinical trials**
  - Types of Clinical Trials
  - Study Design and Protocol Development
  - Randomization and Blinding
  - Ethical Considerations in Clinical Research
  - Informed Consent Process
  - Essential documents in clinical trials

Semester 3: Clinical Trial Data Management (4 months)

- **Module 7: Role of Ethics committee in clinical trial management**
  - Ethical review procedure
  - Risk benefit assessment
  - Assessing vulnerability
  - Handling COI
  - Handling serious adverse events
  - Documentation and maintenance of records
- **Module 8: Handling clinical trial data**
  - Introduction to data management
  - Electronic data records
  - E-CRF & Interactive Web Response System
  - Database locking and unlocking
  - Site Management and Monitoring
  - Reporting Protocol deviations and amendments
  - Documentation and Reporting in Clinical Trials

- Source data and source documents
- Data Analysis Tools and Software
- **Module 9: Pharmacovigilance and Safety Monitoring**
- Data safety monitoring board
- Adverse Drug Reactions and Adverse events
- Periodic safety update reports
- SUSAR & CIOMS
- Serious Adverse Events (SAE)
- SAE Reporting timelines
- Pharmacovigilance methods
- Signal Detection and Data Mining
- Pharmacovigilance program of India (PvPI **)**

7. TEACHING PROGRAMME

Teaching learning methods:

- Didactic lectures/tutorials related to clinical research
- Clinical trial site visit to observe Clinical trial-related activities like data entry in CRF, informed consent process etc, documentation, correspondence with ethics committee,
- Observe ethics committee functioning including conduct of EC meeting, review procedure, documentation, correspondence with various stakeholders etc
- Observe the process of ADR collection and reporting
- Conduct journal club, small group discussions, e-learning, seminar and symposium on topic related to clinical research
- Visit to clinical research organization/clinical trial site/SMO office in Nagpur.
- Attend workshops/guest lectures related to clinical research

8. SCHEDULE OF POSTING

Ethics committee	3 months
Trial site	2 months
ADR monitoring unit	3 months

9. LOGBOOK

- The student will maintain logbook containing details of his training. Students should complete the log book regularly, noting all relevant activities, learnings, and feedback.
- Faculty members and mentors will review the log book periodically and provide necessary feedback.
- This log book will serve as part of the continuous assessment for the course.

10. ASSESSMENT

Type of assessment	**Schedule**	**Examination**	**Marks**	**Pattern and marks distribution**
Formative examination	One month prior to summative/Exit examination	Theory	50Marks	MCQ (20 marks) Short notes: 4 X 5 marks = 20 marks LAQ: 1 X 10 marks = 10 marks
		Practical	50 marks	-3 case scenario based exercises related to clinical research (30 marks) -Viva voce (20 marks)
Summative assessment/Exit examination	At the end of 12 months	Theory	50 Marks	MCQ (20 marks) Short notes: 4 X 5 marks = 20 marks LAQ: 1 X 10 marks = 10 marks
		Practical	50 marks	-3 case scenario based exercises related to clinical research (30 marks) -Viva voce (20 marks)

Eligibility to appear for Summative/Exit examination:

1. Completion of GCP training workshop (Physical/online) is mandatory to become eligible for summative examination
2. Candidate should secure a minimum of 40% marks in Theory and Practical separately in formative assessments
3. Minimum 75 % attendance is mandatory
4. Satisfactory completion of log book

Summative/ Exit Examination

- Minimum 50% marks required in Theory & Practical separately, to be declared successful in Exit examination.
- For candidates, who fail to clear summative examination, repeat Summative Exam will be conducted in 45 days after declaration of result.

11. POTENTIAL PLACEMENT OPPORTUNITIES

Candidates who complete the present certificate course have job opportunities in CRO/ SMO/Pharmaceutical industry/Ethics committee/Pharmacovigilance unit.

12. SUGGESTED BOOKS

- Drug Discovery & Clinical research by SK Gupta and Sushama Srivastava
- Postgraduate Pharmacology by Saugat Sarkar, Vartika Shrivastava, Manjushree Mohanty
- National ethical guidelines for biomedical and health research by ICMR (ICMR 2017, ICMR 2020 guidelines)
- ICH-GCP guidelines
- New drug and clinical trial rules 2019