MEDCLINIGEN

CLINICAL RESEARCH

Professional Syllabus • Advanced Study & Career Preparation

CLINICAL RESEARCH SYLLABUS

10 structured modules covering fundamentals, GCP, trial design, documentation, ethics, regulatory submissions, operations, data & safety, biostatistics, and interview preparation.

Module 1 | Clinical Research Fundamentals

- Introduction to Clinical Research & Clinical Trials
- Drug Discovery & Development
- Preclinical Research & Toxicology
- Clinical Trial Phases — Phase 0, I, II, III & IV
- Types of Clinical Trials
- Experimental & Observational Studies

Module 2 | ICH & Good Clinical Practice

- ICH Guidelines
- ICH Efficacy Guidelines
- ICH-GCP Principles
- Roles & Responsibilities under GCP
- GCP Compliance

Module 3 | Clinical Trial Design

- Randomized Controlled Trials
- Non-Randomized Trials
- Single-Arm Studies
- Cohort Studies
- Case-Control Studies
- Cross-Sectional Studies
- Case Reports & Case Series
- Prospective, Retrospective & Ambispective Studies
- Randomization & Blinding/Masking

Module 4 | Clinical Trial Protocol & Documents

- Clinical Trial Protocol
- Protocol Amendments & Deviations
- Case Report Form (CRF/eCRF)
- Source Documents
- Essential Documents
- Investigator’s Brochure
- Standard Operating Procedures (SOPs)
- Clinical Study Report (CSR)

Module 5 | Ethics & Informed Consent

- Research Ethics
- Nuremberg Code
- Belmont Report
- Declaration of Helsinki
- CIOMS Guidelines
- IRB/IEC
- Informed Consent Process & ICF
- Vulnerable Subjects
- Confidentiality & Participant Rights

Module 6 | Regulatory Submissions

- Investigational New Drug (IND)
- Types of IND
- New Drug Application (NDA)
- Abbreviated New Drug Application (ANDA)
- Generic vs Brand Drugs
- Bioavailability & Bioequivalence
- FDA & Regulatory Requirements

Module 7 | Clinical Trial Operations

- Site Selection & Feasibility
- Investigator Selection & Responsibilities
- Study Coordinator/CRC Responsibilities
- Sponsor & CRO Responsibilities
- Clinical Trial Pharmacist
- Trial Recruitment & Screening
- Participant Retention
- Investigational Product Management
- Clinical Trial Monitoring

Module 8 | Clinical Trial Data & Safety

- Clinical Data Management
- Data Management Plan
- EDC & Database Management
- Data Cleaning & Query Management
- Database Lock
- Adverse Events (AE)
- Serious Adverse Events (SAE)
- Safety Reporting
- Safety Monitoring Plan
- DSMB
- Quality Assurance (QA)
- Quality Control (QC)
- Auditing

Module 9 | Biostatistics & Clinical Trial Analysis

- Role of Biostatistician
- Sample Size & Study Design
- Randomization
- Statistical Analysis Plan (SAP)
- Data Analysis
- Interpretation & Reporting of Results

Module 10 | Clinical Research Interview Preparation

- 100+ Important Clinical Research Interview Questions
- Clinical Trial & GCP Concepts
- Regulatory & Ethics Questions
- Protocol & Documentation Questions
- Safety & Pharmacovigilance Basics
- Practical & Scenario-Based Questions