

New CRC Syllabus

Module 1: Introduction to Clinical Research

- **Introduction & History of Clinical Research**
- **Key Stakeholders in Clinical Research**
- **Clinical Trial Phases (Preclinical to Phase IV)**
- **Clinical Trial Designs**
- **Role and responsibilities of CRC**

Module 2: Regulatory Framework

- **ICH-GCP Guidelines**
- **Overview of Regulatory Authorities: (FDA, EMA, PMDA, CDSCO etc.)**
- **Ethics Committee**
- **Key Regulations: 21 CFR Parts 11, 50, 54, 56**
- **Informed Consent Process (ICP)**

Module 3: Clinical Trial Process & Documentation

- **Site selection and feasibility**
- **Essential documents in clinical trials (Protocol, ICD, CRF, IB, etc.)**
- **Screening and recruitment of subjects**
- **Managing patient visits and follow-ups**
- **Investigator Site File Maintenance**
- **Source documents**
- **Archival of documents and reporting study results**

Module 4: Communication and Coordination

- **Interaction with stakeholders**
- **Handling monitoring visits**
- **Patient interaction and retention**

Module 5: Data Management and Safety Reporting

- **Basics of clinical data management,**
- **Data Query resolution processes**
- **AE/SAE**

Module 6: Audits and Inspections

- **Preparing for Site Audits**
- **Common findings in Audits & Inspection**
- **Regulatory Inspection Readiness**

Module 7: Practical Insights & Terminology

- **Case Studies**
- **Terminologies**