

# PGDCR: Post Graduate Diploma In Clinical Research Course Syllabus

Online/Offline

## 1 Fundamentals of Clinical Research

- Introduction to Clinical Research
- History & evolution of Clinical Research
- Drug development process and preclinical studies
- Phases of clinical trials and BA/BE studies
- Stakeholders in clinical research and their roles (Sponsor, Investigator, CRO, Ethics committees, etc.)
- Types of clinical trials and basic trial designs
- Regulatory framework and clinical trial registries
- Ethics in clinical research and informed consent
- Essential documents (Protocol, ICF, CRF, IB, etc.)
- ICH GCP E6 R3
- Good Documentation Practices and ALCOA
- Basics of safety reporting
- Terminologies related to Clinical Research

## 2 Clinical Research Operations

- Site selection & feasibility
- Initiation and ethics approvals
- Subject recruitment and clinical trial conduct
- Monitoring activities and source data verification

- Types of monitoring
- Investigational product management and accountability
- Protocol deviations and safety reporting
- Quality management, audits, and inspections
- Trial close-out, documentation, and archiving

## 3

## Clinical Data Management

- Introduction to Clinical Data Management and its role in clinical trials
- Clinical data management process flow and data lifecycle
- Data collection methods and instruments
- Data management team roles and responsibilities
- Data Management Plan (DMP)
- CRF/eCRF design principles and CDASH standards
- Edit check specifications and validation rules
- EDC systems, database build, and User Acceptance Testing (UAT)
- Data entry, validation, and query management
- Medical coding and safety data reconciliation
- Computer System Validation (CSV) and 21 CFR Part 11
- Database lock, data transfer, and study close-out activities
- CDM quality management, documentation, and compliance

## 4 Pharmacovigilance

- Introduction to Pharmacovigilance
- Adverse events, special situations, and case validity
- Causality & seriousness assessment
- Individual Case Safety Reports (ICSRs)
- Case Processing and Coding
- Safety Reporting & Timelines
- Signal Detection and Risk Management
- Pharmacovigilance Systems and Quality Management
- Pharmacovigilance regulations in India and the global context
- Pharmacovigilance Databases and Tools
- Common terminologies related to pharmacovigilance

## 5 Regulatory Affairs

- Introduction to Pharmacovigilance
- Adverse events, special situations, and case validity
- Causality & seriousness assessment
- Individual Case Safety Reports (ICSRs)
- Case Processing and Coding
- Safety Reporting & Timelines
- Signal Detection and Risk Management
- Pharmacovigilance Systems and Quality Management
- Pharmacovigilance regulations in India and the global context
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