Clinical Research

Delivered through twelve focused modules spanning over six months:-

Module I - Introduction to Clinical Research

Introduction to Clinical Research
Terminologies and definition in Clinical Research
Origin and History of Clinical Research
Difference between Clinical Research and Clinical Practice
Types of Clinical Research
Phases of clinical research
Clinical Trials in India –The National Perspective
Post marketing surveillance
Pharmaceutical Industry – Global and Indian Perspective
Clinical Trial market
Career in Clinical Research

Module II - Basic Information about Drugs in Clinical Research

Introduction to Pharmacology
Concept of Essential Drugs
Routes of Drug Administration

Module III - Development of New Drug

Introduction to Drug Discovery and Development
Hurdles in Drug Development
Sources of Drugs
Basics of Drug Discovery & Development
Approaches to Drug Discovery
Evolutionary Classification of the strategies for Drug Discovery
Emerging technologies in Drug Discovery
Preclinical Testing
Investigational New Drug Application
Clinical trials
New Drug Application and Approval
Pharmacokinetics
Pharmacodynamics
Recent advances – Pharmacogenomics and Protein based therapies
Appendix I FDA 1571 Investigational New Drug Application
Appendix II FDA 1572 Statement of Investigator

Module IV – Laws Governing in Clinical Research

Introduction of Clinical Trial Regulation
European Medicine Agency
Food and Drug Administration (US FDA)
Drug and cosmetic act
Schedule Y
ICMR Guideline

Module V - Guidelines Followed in Clinical Research

Nuremberg code
Declaration of Helsinki
Belmont report
Brief history of ICH
Structure of ICH
ICH Harmonization Process
Glossary of GCP
The Principles of ICH GCP

Module VI – Bodies Regulating Clinical Research

Institutional Review Board / Independent Ethics Committee
Investigator
Sponsor

Module VII - Documentation Required during Clinical Trials

Clinical Trial Protocol and Protocol Amendment(S)
Investigator's Brochure
Essential Documents for the conduct of a Clinical Trial

Module VIII - Management of Trial, Responsibilities of Clinical research Professionals

Project Management
Protocol in Clinical Research
Informed Consent
Case Report Form
Investigator's Brochure (IB)
Selection of an Investigator and Site
Clinical Trial Stakeholders
Syllabus for PG Diploma in Clinical Research
Contract Research Organization (CRO)
Site management organizations (SMO)
Ethical and Regulatory Submissions
Recruitment Techniques
Retention of Clinical Trial Subjects
Monitoring Visits
Investigator Meeting

- Documentation in Clinical Trials
- Regulatory Binder
- Record Retention
- Pharmacovigilance
- Training in clinical Research
- Project Auditing

Inspection
Fraud and Misconduct
Roles and Responsibilities of Clinical Research Professionals

Module IX- Pharmacovigilance Industry

Scope, definition and aims of pharmacovigilance
Adverse drug reactions –evaluation, monitoring, prevention and management of ADR
Adverse drug reaction reporting and monitoring
Drug induced diseases

Module X - Clinical Data Management

Introduction to CDM
CRF Design
Clinical Data Entry
Electronic Data Capture
Data Validation
Discrepancy Management
Clinical Data Coding
SAE Reconciliation
Quality Assurance & clinical Data Management
Guideline & Regulation in Clinical trial data

Module XI- Biostatistics in Clinical Research

Introduction
Probability
Regression
Biostatistics
Various statistical methods i.e. null hypothesis,t- Test,Regression analysis,ANOVA,Chi-square etc
Parametric and Non-parametric tests

Module XII - Soft Skills for a Clinical Research Professional