

# Clinical Research Basic module

**Duration: 30days**

## Course Contents

- Background to the Industry
  - The Industry Today
  - New Product Development
  - Patent Protection
  - Product Discovery
- Preclinical Development & Chemistry
- Introduction to Clinical Research
- Stages of Clinical Research
  - Phase I & Early Stage Clinical Research
  - Phase II
  - Phase III
  - Late Phase
  - Phase IIIb
  - Phase IV
  - Post Marketing Surveillance (PMS)
- Overview of Process for a Clinical Trial
  - Protocol
  - Obtain Relevant Approvals
  - Design Case Report Form (CRF)
  - Product Supply
  - Recruit, Manage & Monitor Subjects/Patients
  - Data Management
  - Analyze & Report Data
- Organizations involved in clinical research
- Ethical Guidelines in Clinical Research
- Ethics in Clinical Research
- Regulations in Clinical Research
- Biostatistics in Clinical Research
- Specialist Clinical Trials and Clinical Trial Designs
- Clinical Trial Documentation
- Quality in Clinical Trials
- Soft Skills for a Clinical Research Professional