

Clinical Research Advance module

Duration: 90 Days

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

Clinical Trial Design:

- Confounding
- Trial Objectives
- Data & Endpoints
- Fundamental Trial Designs

- Parallel Group Trial
- Cross Over Trial
- Non-Comparative Trial
- Randomization
 - Stratification
 - Minimization
- Blinding & Masking
 - Open-Label Trial
 - Single Blind
 - Double Blind
 - Double Dummy
 - Triple Blind
- Comparator
- Type of Comparison
 - Difference Comparison
 - Non-Inferiority
 - Equivalence
- How Many Subjects?
- Additional Design Considerations
- Phases of Trials
 - Before The Trial 1 - Protocol And Approvals
 - Before the Trial 2 - Subject Documents
 - Before the Trial 3 - IMP Documents
 - Before the Trial 4 - Administration
 - During the Trial