Certification in Clinical Research

Clinical research refers to all research carried out on humans (healthy or patient). It focuses on improving knowledge of diseases, developing diagnostic methods and new treatments or medical devices to ensure better patient care. Clinical trials are regulated by specific regulatory authorities.

This course is designed by industry experts to provide participants with a comprehensive understanding of the principles, processes, and best practices involved in conducting clinical research. Through this training, participants will acquire the skills necessary to navigate the complex landscape of clinical trials, from protocol development to regulatory compliance.

The program has the following tempting features which are definite to benefit one to all participants of the program.

- Comprehensive industrial training and skills
- Exceptional knowledge of the industry by making the trainees familiar and able to understand the principles and concepts
- Practical and professional training about the industry regulations and work processes
- Good hold on the framework of the industry leading to availability of best employment options
- To master basics concepts on how to communicate written and oral scientific results

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Module 1

- Introduction to Clinical Research
  - Definitions and significance of Clinical Research
  - Functions of Clinical Trials
  - Drug Development Process
  - Clinical Trial Design and Phases

Module 2

- Applicable Regulations and Law in Clinical Research
  - Historic Perspective and Evolution
  - ICH GCP Guidelines
  - GDP Guidelines
  - NDCT Rule 2019

Module 3

- Essential Documents
  - Investigator's Brochure development, usage and importance
  - Protocol development and review
  - Inform consent process and documentation
  - Protection of human subjects, Vulnerable population and special consideration
  - Case Report Forms (designing and use)

Module 4

- Regulatory Compliance and Ethics
  - Institutional Review Board (IRB) and Ethics Committee
  - Regulatory Submission and Approvals

Module 5

- Site selection and management
  - Site Identification and Qualification
  - Site Initiation Visits (SIV) and Site Activation
  - Site Training, Monitoring, and Close-Out Visits

Module 6

- Site activities and handling
  - Participant recruitment and retention
  - IMP/Drug inventory management
  - Bio-Analytical Overview Training

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Module 7

- Data Collection and Management
  - Data Collection, Entry, and Validation
  - Overview of software system in use for clinical database and record keeping
  - Source Data Verification (SDV) and Data Quality Assurance
  - Statistical Analysis Plans (SAPs) and fundamentals of Data Interpretation

Module 8

- Clinical Trial Monitoring and Quality Assurance
  - Monitoring Plan Development and Execution
  - Protocol compliance and deviation
  - Risk-Based Monitoring (RBM) and Centralized Monitoring
  - Audits, Inspections, and Corrective Action Plans

Module 9

- Pharmacovigilance and safety reporting
  - Adverse Event Reporting and Safety Monitoring
  - Serious Adverse Event (SAE) Handling and Reporting
  - Introduction to PVPI
  - Introduction to E2A and E2F

Module 10

- Study Close-out and Reporting
  - Study Close-out procedure and documentation
  - Final Study Report Preparation
  - Dissemination of Results and Publication Ethics

Eligibility: BTech/Bsc in Biotechnology/ Microbiology/ Botany/ Zoology/ B.Pharm/M Pharm/MSc / MBBS/ BDS/ BHS/ BUMS/ BAMS/ Graduation in Life science disciplines are eligible for the program.

Mode: Online and/or Offline Sessions

Duration: 6 months (Freshers/Students) and 3 months (Working Professionals)

Examination & Certificate: Online MCQ Exam/Dissertation, Certification Accredited by Arise Foundation

Complementary courses:

1. Microsoft Excel (Required skills for the course)
2. Preparation of CV and interview guidance