Post Graduate Diploma in Clinical Research

Syllabus

Session 2021-22

Objectives:

• To understand the key concepts in the responsible conduct of research and be able to conduct research that conforms to the highest standards for the protection of human research subjects.

• Clinical research is a current knowledge-intensive and booming industry. It is one of the industries growing at an astonishing rate and opening up a wide scope of employment opportunities for trained professionals.

The outcome of the course:

1. To make students work in MNC's, pharmaceuticals companies, Clinical Research Associate (CRA), Clinical data management (CDM) Clinical Research Organization (CRO) Clinical Monitor or Trial Monitor, Biostatistician, Drug Safety Associate

2. Start business as a Site Management Organization

SECTION A:

INTRODUCTION TO CLINICAL RESEARCH

A. Phases in Clinical Trials
- PHASE I
- PHASE II
- PHASE III
- PHASE IV

B. Drug Development Process
- Aim of Drug
- Different Phases of Drug
- Pre-Clinical Studies

C. History of Clinical Research
    - Sulphanilamide Disaster
    - Jewish Chronic Disease
    - Thalidomide Disaster
    - Willow brook Study
    - Tuskegee study

D. Good Clinical Practices and of International Conference of Harmonization
    - Principles of GCP
    - ICH, Goal

E. The Principles of International Conference of H Harmonization (Guidelines)
F. ICMR Guidelines

Section B:
Players in Clinical Research

A. Roles & Responsibilities:
    - Investigator
    - Sponsor
    - Ethics Committee
    - Independent Ethics Committee(IEC) or Institutional Review Board(IRB) Contract Research Organization (CRO)
    - Site Management Organization (SMO)
    - Monitor/Clinical Research Associate(CRA)
    - Clinical Research Co-ordinator (CRC)
    - Auditor
    - Data Manager
    - Project Manager
    - Biostatician
    - Regulatory Authority (Drug Contorller General of India,US Federal Drug Administration)

Section C:
DOCUMENTS IN CLINICAL RESEARCH

- Informed Consent Form & Process
- Clinical Trial Protocol: BA/BE Study ,Different Therapeutic area's Protocol will be explained
- Investigator's Brochure
- Source Documents
- Case report form
- List of Essential Documents
- Documents needed before, during & after the study trial
- Distributing, Storing & Inventory of Investigator Drug

Section D:

- Clinical Trial Methods
- Monitoring
- Safety Management,
- Clinical Trial Types, Designs
- Randomized Controlled Trial

Clinical Data Management

- Overview:
- Types of Query and Electronics data entry in different Software's

Pharmacovigilance Overview

- Roles and Responsibilities