Clinical Research and Clinical Data Management:-

Clinical Research-Topics:

- Introduction and Importance of Clinical research
- Basic structure and elements Clinical Research
- Ethics and Regulations in Clinical Research
- Clinical Research contribution to Medical Knowledge
- Evolution of Clinical Research
- Clinical Trial design
- Methodology and management of Clinical research
- Roles and Responsibilities of people involved in Clinical trials
- Phases in Clinical trial activity
- Outcomes of clinical Trials

Clinical Data Management Topics:

- Overview & role of CDM in projects
- Query management
- Validation
- Reconciliation
- Software--Manual
- Inform
- RDC
- Oracle Clinical
- Additional
- Brief overview on Medical coding

SAS Base & Advanced Course:-

- Getting Started with SAS
- Working with SAS syntax
- Getting Familiar with SAS dataset
- Reading SAS datasets
- Reading SAS datasets
- Reading Excel worksheets
- Reading Delimited Raw data files
- Validating and cleaning data
- Manipulating data
- Combining SAS Datasets

- Enhancing Report (ODS systems)
- Summary Reports
- Controlling Input and Output
- Summarizing Data
- Reading Raw Data Files
- Data Transformations
- Processing Data iteratively
- Restructuring a Data set
- TRANSPOSE Procedure

SQL Procedure:

- Introduction to SQL procedure
- Basic Queries
- Displaying Query Results
- Sub queries
- SQL Joins
- Set Operators
- Creating Tables and views
- Interfacing SQL with Macro Language
- Managing Tables
- Use of SQL in Clinical Trials

Macro language (SAS Macro)

- Macro Variables
- Macro definitions
- Data Step and SQL Procedure
- Macro Programs
- Use of Macro language in Clinical Research

Free Sessions :

1. **Excell**
2. **SQL**

Pharmacovigilance Course:-

Module I Pharmacovigilance

- Introduction
- Historical Overview
- Basic principles of Pharmacovigilance in Clinical Trials
- Methodologies for Pharmacovigilance

Module II Regulations in Pharmacovigilance in Clinical Research

- FDA and EU perspectives
- Drug Regulatory Activities MedDRA
- Regulatory Aspects in Pharmacovigilance
- EudraVigilance
- Regulations in Pharmacovigilance in Clinical Research

Module III Adverse Drug Reactions and Safety Reports

- ADR Reporting
- Causality Assessment of Suspected Adverse Drugs Reactions
- Periodic Safety Update Reports (PSURs) For Marketed Drugs (ICH E2C)
- Expedited Reporting Requirements
- Individual case safety reports
- Periodic safety update reports
- Electronic safety reporting
- WHO & safety monitoring

Module IV Signal Analysis

- Definition of signal and type of signal
- Conducting signal detection in clinical and post marketing surveillance
- Defining signal in relation to risk/benefit
- Signal generation to decision making
- Signal Detection Tools
- Understanding signals & benefit risk determinations

Module V Compliance to Clinical Safety and Pharmacovigilance Regulations

- Review of benefit-risk assessments and management
- Scope of Pharmacovigilance inspection and conduct of inspection
- Internal audit of pharmacovigilance activities of a company
- Pharmacovigilance inspection reports
- Pharmacovigilance compliance and inspection
- Quality System in Pharmacovigilance : Good Practices, SOPs, Preparation for Audits & Inspections
- Scope of Pharmacovigilance inspection and conduct of inspection
- Internal audit of pharmacovigilance activities of a company
- Key Functionalities of the Adverse Event Systems
- Quality System in Pharmacovigilance : Good Practices, SOPs, Preparation for Audits & Inspections

Module VI Pharmacovigilance Management and Importance

- Pharmacovigilance Database
- Setting up a Pharmacovigilance Centre in Industry
- Management of Pharmacovigilance Data

- Risk Management in Pharmacovigilance
- Data management & software solutions
- Effective communication in pharmacovigilance
- Pharmacovigilance in special situations
- Pharmacovigilance capacity building

HR-Interview Etiquettes:-

- Communication Skill
- Office etiquettes
- E-mail etiquettes
- Presentation skills and Public speaking
- Interview preparation
- CV preparation
- Mock interviews
- Assessments

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