Clinical Research (Theory) :

- Introduction to Clinical Research
- INDA, NDA, ANDA applications
- Types, Designs and Phases of Clinical Trials
- ICH GCP guidelines (ICH E6)
- Roles and Responsibilities of Investigator and CRA
- Roles and Responsibilities of Sponsor and CRC
- Contract Research Organizations-CRO
- Case Report Form and its Contents with live example
- Contents of protocol
- Explanation of Research protocol with live example
- Informed Consent Form
- Institutional Review boards(IRB)/IEC
- Participant safety and Adverse events reporting
- Safety definitions and reporting requirements
- Monitoring of Study at participating sites
- Source Data Verification
- Investigator's Brochure (IB)
- Standard operating procedures
- Essential documents
- Data Coding using MedDRA and WHODD
- CRF Design Guidelines
- SAE/AE Reconciliation

Clinical Data Management (Theory) :

- Introduction to Clinical Data Management
- Clinical Data Management Process and Life cycle
- Explanation of Study Start Up / Set up
- Explanation of Study Conduct
- Explanation of Study Close out
- Clinical Data Management Plan with Example
- Case Report Forms, Types of CRFs
- Designing of CRFs
- CRF completion Guidelines(CCGs) with Example
- CRF Annotation
- Data Capture Methods and EDC
- Data Entry – First pass and Second Pass Entry
- Edit Check Specifications
- Data Validation Procedures
- Discrepancy Types (Univariate, Multivariate, Manual and Indicator)
- Discrepancy Management
- Query Resolution
- Data Clarification Forms (DCFs)
- Database Locking and Freezing
- Pre closure Checks
- Data Coding and Medical Dictionaries
- SAE Reconciliation
- 21 CFR Guidelines

Practical Hands training on Oracle Clinical Database/RDC :

- Introduction to OC window

- Subsystems in OC
- Defining Programs and Projects
- Defining Organization Units
- Defining Regions
- Defining Planned Studies
- Easy Study Design
- Creating Intervals
- Creating Events
- Creating Investigator, Site Records and Assignments
- Creating Patient Positions and Assignments
- CRF Design
- Creating Questions
- Creating Question Groups
- Creating and Maintaining DVG's
- Creating DCM's, DCI's & DCI Books
- UAT(User Acceptance Testing)
- Test a Study
- Test Data Entry
- Initial Login
- Key Changes
- First Pass Entry
- Second Pass Entry
- Comparison Reconciliation
- Update
- Browse
- Patient Enrollment
- Data Validation(Batch validation)
- Discrepancy Management
- Data Clarification Forms (DCFs)
- Audit Trail
- Locking and Freezing

RDC (Remote Data Capture):

- Data entry in RDC
- Discrepancy Management in RDC
- CRFs in RDC

Pharmacovigilance/ Drug Safety (Theory):

- History and overview of Pharmacovigilance
- Regulatory Authorities country wise
- Pharmacovigilance in India
- Spontaneous reporting
- Active pharmacovigilance
- Cohort Event Monitoring
- Adverse Events and its types
- Drug Safety in clinical trials and post marketed drugs
- Different sources of Adverse Events reporting
- Different types of AE Reporting Forms
- Expedited reporting and its timelines
- Aggregate reporting
- Different departments working on Pharmacovigilance
- Business workflow of Pharmacovigilance
- Minimum criteria for the case
- Causality assessment of the adverse event
- Expectedness assessment of the adverse event
- Seriousness assessment of the adverse event
- MedDRA and WHODD coding
- SAE narrative writing and Templates
- PBRER/PSUR and its submission timelines
- E2A-E2F Guidelines
- PADAR
- Explanation of Safety Signals, Signal Detection at UMC
- Signal publication and communicating signal
- Risk management

Practical Hands-on Training on Oracle Argus Safety Database :

Argus Console

- PV Business process
- Introduction to Oracle Argus Safety Database
- Family, Product and License creation
- Clinical Study configuration
- Access management : Sites, users and Groups creation
- Workflow Configuration
- Case priority Configuration
- Case Numbering
- LAM case Numbering
- Field Validation
- Code list Configuration
- Field label Configuration
- Auto narrative Configuration

Argus Safety Module

- Different icons used during the case processing and their purpose.
- Different tabs used in case processing
- Case Bookin and Data entry
- Case Processing of ICSR
- Case Triage
- Performing Validation
- Case Routing Based on workflow
- Case Quality check, Medical review
- Duplicate case check or verification
- Report Generation for Regulatory Submission
- Expedited Reports and Aggregate Reports
- Creating PSURs, CTPRs, NDA and IND reports
- Creating Case data analysis reports

- Unblinding the clinical trial cases
- Locking and unloking Case
- Follow Up for Case
- Query generation : Action Items
- Resolving queries using contact Logs
- Case Bookin in LAM and Routing to Central Safety database
- MedDRA coding and WHO DD coding
- Narrative Writing

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