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 Enrolment
- 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

Medidata RAVE EDC training:

- Introduction to Rave EDC and Understanding EDC
- Logging into Rave EDC
- Benefits of Rave EDC
- Understanding Menus and Icons in tool
- Selecting Study, Site and subject
- Browsing in the tool
- Accessing CRF pages (form layout)
- Understanding subject home page
- Adding New subject
- Task Summaries
- Assessing form pages with open queries
- Discrepancy Management (Query resolution)
- System Queries and Manual Queries
- Query Writing
- Adding Stick notes and protocol Deviations
- Lab and lab ranges Configuration
- Accessing Audit trail
- Auto-coding and manual coding with MedDRA
- Data entry lock and hard lock
- Data review and verification
- Accessing Folders and forms from Grid view
- Accessing and adding the log forms
- Handling missing data
- Electronic Signatures and batch Signature Functionality
- Exercises on Adding subject, accessing CRFs, identifying Discrepancies, resolving queries, adding additional events and adding log forms