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