

II. Clinical Data Management Theory – 15 Hours

- 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