

CDM Course Curriculum

· Module1:

Clinical Research and Clinical Data Management

- o Introduction to Clinical Research and Clinical Data Management
- o Different Phases of clinical trials
- o IND, NDA Applications
- o ICH-GCP Guidelines
- o Responsibilities of Clinical Trial Team
- o Protocol and Informed Consent Forms
- o Clinical Data Management Process and Life cycle
- o Data Management Plan
- o Case Report Forms, Types of CRFs
- o Designing of CRFs
- o CRF Annotation
- o Data Capture Methods and EDC
- o Data Entry – First pass and Second Pass Entry
- o Edit Check Specifications
- o Data Validation Procedures
- o Discrepancy Management
- o Data Clarification Forms (DCFs)
- o Database Locking and Freezing
- o Data Coding and Medical Dictionaries
- o SAE Reconciliation

· Module2:

Open Clinica Database

- o Introduction to OC window
- o Subsystems in OC
- o Defining Programs and Projects
- o Defining Organization Units
- o Defining Regions
- o Defining Planned Studies
- o Easy Study Design
- o Creating Intervals
- o Creating Events

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- o Creating Investigator, Site Records and Assignments
- o Creating Patient Positions and Assignments
- o Creating Questions
- o Creating Question Groups
- o Creating and Maintaining DVG's
- o Creating DCM's, DCI's & DCI Books
- o Test a Study
- o Test Data Entry
- o Initial Login
- o Key Changes
- o First Pass Entry
- o Second Pass Entry
- o Comparison Reconciliation
- o Update
- o Browse
- o Patient Enrolment
- o Data Validation(Batch validation)
- o Discrepancy Management
- o Data Clarification Forms (DCFs)
- o Locking and Freezing

· Module3:

REDCap Database

- o Creating Study in REDCap
- o Configuring Study in REDCap
- o Creating Events in REDCap
- o Creating Data Collection Instruments in REDCap
- o Add or Edit Records in REDCap
- o Record Status Dash Board in REDCap
- o Data Entry in REDCap
- o Data Validation in REDCap
- o Status Complete in REDCap
- o Accessing diff apps in REDCap
- o Data Analysis in REDCap
- o Report Generation in REDCap
- o Freeze & Locking in REDCap
- o Conclusion

*** END OF THE DOCUMENT ***

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