Clinical Data Management Training Program
Basic to Advanced With Hands-on Experience & Project Work

Course Module

Week 1: Introduction to Clinical Data Management

- Day 1: Overview of Clinical Data Management: Definition, Scope, and Importance
- Day 2: The Clinical Trial Process: Phases and Regulatory Guidelines
- Day 3: Types of Clinical Trials and Stakeholders in CDM
- Day 4: Roles and Responsibilities of a CDM Professional
- Day 5: Introduction to Clinical Data: Types, Sources, and Formats
- Test/Quiz/ Assignment

Week 2: Regulatory Frameworks and Standards

- Day 6: Regulatory Frameworks: ICH GCP, 21 CFR Part 11, GDPR, ISO standards
- Day 7: Career Opportunities in CDM: Roles, Skills, and Pathways
- Day 8: Introduction to CDASH and SDTM Standards
- Day 9: Metadata Management in CDM
- Day 10: Overview of Clinical Data Management Systems (CDMS)
- Test/Quiz/ Assignment

Week 3: Data Integrity and EDC Systems

- Day 11: Introduction to EDC Systems: Features and Benefits
- Day 12: ALCOA+ Framework for Data Integrity, Data Quality Metrics and Their Importance
- Day 13: Validation and Verification in CDM
- Day 14: SAS Programming
- Day 15: SAS Programming & Introduction to SAS Studio
- Test/Quiz/ Assignment

Week 4: Practical Use of EDC Tools

- Day 16: Introduction to REDCap
- Day 17: Introduction to Medidata Rave & Open Clinica
- Day 18: Introduction to Castor
- Day 19: Case Report Forms (CRFs): Design and Customization
- Day 20: Data Entry in Castor
- Test/Quiz/ Assignment

Week 5: Core Data Operations in CDM

- Day 21: Managing Source Data
- Day 22: Query Management in Practice
- Day 23: Lock and Unlock Procedures
- Day 24: Tips for Data Accuracy
- Day 25: Data Cleaning and Validation
- Test/Quiz/ Assignment

Week 6: Safety and Study Setup

- Day 26: SAE Reconciliation and Safety Data Management
- Day 27: Timeline and Deliverable Management
- Day 28: Practical on Castor
- Day 29: Handling Data Discrepancies
- Day 30: Regulatory Updates and Their CDM Impact
- Test/Quiz/ Assignment
- Assessment test (Day 1 - Day 30)

Week 7: Advanced Practical Training

- Day 31: Query Resolution and Reporting with practical
- Day 32: Data Migration Strategies
- Day 33: Working with CROs and Sponsors
- Day 34: Vendor Management
- Day 35: Introduction to Veeva Vault & Configuring a Study in Veeva Vault
- Test/Quiz/ Assignment

Week 8: Hands-on CDM Execution

- Day 36: Practical: CRF Design and Deployment
- Day 37: Practical: Data Entry and Validation
- Day 38: Practical: Query Management
- Day 39: Practical: Reports and Dashboards
- Day 40: Practical: Audit Trails and Compliance
- Test/Quiz/ Assignment

Week 9: Mid-study Adaptation and Innovation

- Day 41: Handling Mid-Study Changes
- Day 42: Emerging Trends: AI, ML, Decentralized Trials
- Day 43: Monitoring in EDC
- Day 44: eConsent for Investigator Role
- Day 45: Types of Recruitment in Clinical Trials
- Test/Quiz/ Assignment

Week 10: Detailed EDC

- Day 46: Navigating Across Studies in EDC
- Day 47: Audit Trails and Reporting
- Day 48: Participant Enrollment, Data Entry, and Responding to Queries
- Day 49: Performing eSignatures in EDC
- Day 50: Practical session on eSignatures in EDC
- Test/Quiz/ Assignment

Week 11: Deep Dive and Professional Integration

- Day 51: Freelancing in CDM
- Day 52: Career Paths: Regulatory Affairs & Pharmacovigilance
- Day 53: Clinical Research Coordinator and CRA Roles
- Day 54: Data Manager Responsibilities
- Day 55: Clinical Operations & Project Coordination
- Test/Quiz/ Assignment

Week 12: EDC System Mastery

- Day 56: Creating Studies in EDC
- Day 57: Monitoring and Audit in EDC
- Day 58: User Role Management
- Day 59: Data Extraction and Study Dashboards
- Day 60: Troubleshooting and Compliance
- Test/Quiz/ Assignment
- Mid-term Assessment (Day 31 - Day 60)

Week 13: Roles and Responsibilities in CDM

- Day 61: Data Manager Role and Responsibilities
- Day 62: Data Monitoring Processes in Clinical Trials
- Day 63: Administrator Role in Clinical Data Management
- Day 64: Clinical Research Associate Role
- Day 65: Career Mapping and Industry Readiness
- Day 66: Investigator Role in EDC
- Day 67: Clinical Research Coordinator Role
- Test/Quiz/ Assignment

Week 14: Practical Implementation and Study Management

- Day 68: Understanding Study Structures in EDC
- Day 69: Creating Studies in EDC
- Day 70: Managing Studies in EDC
- Day 71: Adding Participants in EDC
- Day 71: Monitoring Data in EDC
- Day 72: User Roles and Permission Management in EDC
- Day 73: Dashboard Updates and Study Monitoring in EDC
- Day 74: Filling Study Forms in EDC
- Test/Quiz/ Assignment

Week 15: Advanced CDM Concepts and Digital Transformation

- Day 75: Skills Required for a CDM Professional
- Day 76: eConsent and Its Role in Clinical Trials
- Day 77: Decentralization and Remote Trials
- Day 78: LinkedIn Profile Optimization for CDM Professionals
- Day 79: Types of Documents Produced in Clinical Trials (Part 1)
- Day 80: Types of Documents Produced in Clinical Trials (Part 2)
- Test/Quiz/ Assignment

Week 16: PROJECT – Hands-on experience in building study

- Day 81: Project Discussion
- Day 82: Project topic distribution
- Day 83: Overview of project

Weeks 17–20: Project Work & Mock Interview

- Day 84 onwards: Project work completion by learners and grading by expert
- Mock Interview Sessions for learners

PROJECT TOPICS

Clinical Data Management Project Work

Tool Used: Open Clinica & Castor EDC (All the projects can be executed using Castor EDC & Openclinica, choice will be given to students to select the tool).

- **Open Clinica:** Its a free downloadable version available for researchers. One can download the latest release of OpenClinica Community Edition from the OpenClinica website without any cost.

- **Castor EDC**: Castor EDC is available online. Students can use and submit the project works.

- **SAS**: SAS studio 'SAS on demand for academics' offers a free platform to learn and explore SAS programming. Students can register with their credentials and can use it. It offers a lifetime free access.

1. Basic CRF design and study setup in the EDC tool.

2. Creating a CRF with conditional fields in any EDC tool.

3. Role-based access control and user Management in any EDC tool.

4. Design a Case Report Form for Adverse Events using EDC tool.

5. DBL planning and execution.

6. Data Management Plan using DMP tool.

7. Create a Data Flow diagram of Data flow in the EDC.

8. Create a CRF for Diabetes study in children in the EDC.

9. Create a 50 no's patient list using the Demographics dataset.

10. Draft the importance of data normalization using a dataset and Keys.

11. Create a Study design, CRF form, and a Dataset with at least 10 variables for Adverse Event, Concomitant Medications, and Patient History.

12. Create a CRF using EDC tool for Dental caries in children (50 participants) and related datasets.

13. Draft a Study Design for Oncology study, create CRF, datasets, and reports using Proc Print, Proc Stat, Proc Graph.

14. Draft a simple DMP, create user roles in EDC, datasets, and study design.

15. Draft a complete Study design and select variables for key datasets.

16. Create a CRF form, dataset with at least 10 variables, and relevant patient history details.

17. Draft a complete Study design for Diabetes in young children using real world data.

18. Draft a simple DMP for Phase 1 study, create user roles, datasets, and study design.

19. Draft a complete Study design for PCOS in young children using real world data.

20. Create a CRF form, dataset with at least 10 variables, and relevant patient history details.