MEDCLINIGEN

CLINICAL DATA MANAGEMENT

Advanced Course Syllabus • Clinical Data • Database • Quality Management

ADVANCED CLINICAL DATA MANAGEMENT SYLLABUS

12 structured modules covering CDM fundamentals, study start-up, data collection, validation, medical coding, database management, closeout, standards, audits, technologies, careers and practical interview preparation.

Module 1 | Introduction to Clinical Data Management

- Introduction to Clinical Research
- Clinical Data Management (CDM)
- Scope, Objectives & Importance of CDM
- Roles & Responsibilities in CDM
- Clinical Data Lifecycle

Module 2 | CDM Study Start-Up

- Study Setup & Start-Up
- CRF Design & Development
- Paper CRF & eCRF
- CRF Completion Guidelines
- CRF Annotation
- Database Design & Development
- Database Testing
- Edit Checks & Validation

Module 3 | Clinical Data Collection & Entry

- Paper Data Capture
- Electronic Data Capture (EDC)
- Remote Data Capture (RDC)
- CRF Tracking
- Data Entry
- External Data
- Data Integration
- Data Transfer

Module 4 | Data Validation & Discrepancy Management

- Data Validation
- Edit Checks
- Manual Data Review
- Data Cleaning
- Discrepancy Identification
- Query Management
- Query Generation & Resolution
- Data Quality Control

Module 5 | Medical Coding & Safety Reconciliation

- Medical Coding
- MedDRA
- WHODrug/WHODDE
- Coding of Adverse Events
- Coding of Medications
- Safety Data Reconciliation
- SAE Reconciliation

Module 6 | Clinical Database Management

- Clinical Database Structure
- Database Management Systems
- Database Design Best Practices
- Database Testing & Validation
- User Acceptance Testing (UAT)
- Database Security & Privacy
- Database Maintenance

Module 7 | Study Closeout

- Data Cleaning & Final Review
- Clean File
- Database Freeze
- Database Lock
- Unlock Scenarios
- Final Data Extraction
- Database Transfer
- Electronic Archival

Module 8 | CDM Regulations, Guidelines & Standards

- ICH-GCP
- 21 CFR Part 11
- SCDM & GCDMP
- CDISC
- CDASH
- SDTM
- ADaM
- Controlled Terminology
- HIPAA
- eCTD

Module 9 | Audits & Quality Management in CDM

- Introduction to CDM Audits
- Internal Audit
- External Audit
- Customer Audit
- System Audit
- Data Audit
- Process Audit
- Quality Audit
- Compliance Audit
- Security Audit
- Risk-Based Audit
- Mock Audit

Module 10 | CDM Tools & Technologies

- Clinical Data Management Systems (CDMS)
- Electronic Data Capture (EDC) Systems
- Clinical Trial Management Systems (CTMS)
- Data Management Systems
- Data Validation & Cleaning Tools
- Data Visualization & Reporting Tools
- Statistical Analysis Tools
- Data Integration Tools
- Risk-Based Quality Management Tools
- Overview of Industry CDM Platforms

Module 11 | Clinical Data Management Team & Career

- Clinical Data Manager
- Database Administrator
- Database Programmer
- Clinical Data Coordinator
- Clinical Data Associate
- Data Entry Roles
- Safety Data Manager
- Dictionary Coder
- CDM–Programming–Biostatistics Interfaces
- Career Opportunities in CDM

Module 12 | Practical & Interview Preparation

- CDM Interview Questions
- Scenario-Based Questions
- CRF & Database-Based Questions
- Data Validation & Query Management Scenarios
- Database Lock Scenarios
- Regulatory & Standards Questions
- Practical CDM Workflow