



Clinical Data Management

Call Us Today!

Testimonial

"Coming from a small town in Andhra Pradesh, I had very little exposure to data science. This course helped me learn Python, machine learning, and real-time projects. Now I'm working as a Data Analyst in Hyderabad. It's a great platform for Telugu students like me."

— Rajesh K., Nellore

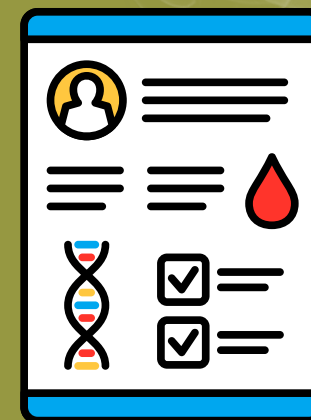
"I was working as a support engineer and wanted to switch to data science. With the help of this course, I gained hands-on experience in Python, ML, and data visualization. I've completed my capstone project and even uploaded it to GitHub!"

— Swetha Rani, Warangal



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ABOUT US

We believe every learner has the potential to shine in the IT industry. Our mission is to guide you step by step — from your first line of code to your first job offer. With caring mentors, real-time projects, and industry-relevant skills, we turn your dreams into a career you can be proud of.



REASONS WHY YOU SHOULD CHOOSE OUR SERVICES

Our advantages are:

Learn from expert mentors, get one-on-one guidance, and master the latest technologies through hands-on projects and internships.

Build real-world applications, prepare for interviews, and gain practical skills employers value.

Benefit from strong placement support and a proven record of student success in top IT companies.

COMPANY VISION AND MISSION

Our Vision

To become a trusted technology partner that helps companies innovate and grow in the digital world.

Our Mission

- Providing relevant and effective technology solutions.
- Providing services with the best quality and competitive prices.







Clinical Data Management (CDM) Course Structure


 **Duration: 3 to 6 months**


- Life science graduates (BPharm, MPharm, BSc, MSc, MBBS, etc.)
- Clinical research professionals
- Data professionals entering healthcare/life sciences


 **Module 1: Introduction to Clinical Research and CDM**

 Overview of clinical research phases (I–IV)


 Role of Clinical Data Management in drug development


 Regulatory bodies (FDA, EMA, DCGI, etc.)


 Stakeholders in clinical trials (sponsors, CROs, sites)

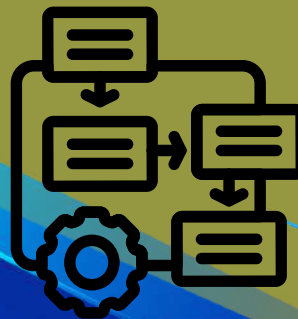
 **Module 2: Good Clinical Practice (GCP) and Regulatory Guidelines**

 ICH-GCP and CDM

 21 CFR Part 11 compliance





 CDISC standards: CDASH, SDTM, ADaM

 Data privacy and security (HIPAA, GDPR)







Clinical Data Management (CDM) Course Structure

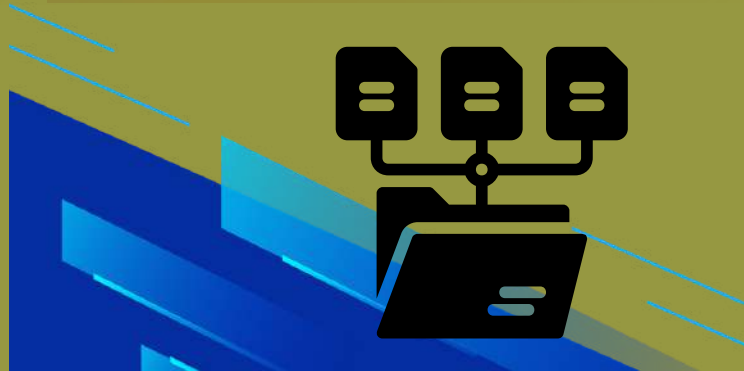
Module 3: Clinical Trial Protocol and Case Report Forms (CRFs)

-  Understanding study protocol
-  CRF design and data points
-  Electronic CRFs (eCRFs) vs. Paper CRFs
-  Source data and source documentation







Module 4: Clinical Data Management Process

-  Data flow in clinical trials
-  Data management plan (DMP)
-  Data entry and validation
-  Data queries and resolutions



Module 5: Electronic Data Capture (EDC) Systems

-  Overview of EDC systems (Medidata Rave, Oracle InForm, etc.)
-  User roles and access controls
-  eSource and remote data entry
-  Hands-on with dummy EDC system (if available)





Clinical Data Management (CDM) Course Structure

✓ Module 6: Data Validation and Query Management

✚ Edit checks and validation rules

- ⚠ Discrepancy management
- 🔄 Query generation and closure
- 📄 Audit trails

📄 Module 7: Coding and Medical Dictionaries

AB CD Introduction to medical coding in CDM

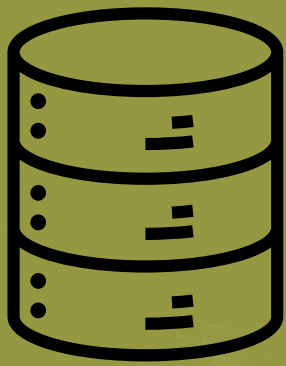
- 📖 MedDRA (Medical Dictionary for Regulatory Activities)
- 💊 WHO Drug Dictionary
- 📌 Coding adverse events and concomitant medications

🚨 Module 8: SAE and Safety Data Management

📄 Serious Adverse Events (SAE) processing





- 🔄 SAE reconciliation between safety and clinical databases
- 🛡 Role of pharmacovigilance









Clinical Data Management (CDM) Course Structure




Module 9: Database Lock and Study Close-Out

-  Data cleaning and final review
-  Interim and final data transfers
-  Database freeze vs. lock
-  Archiving and audit readiness

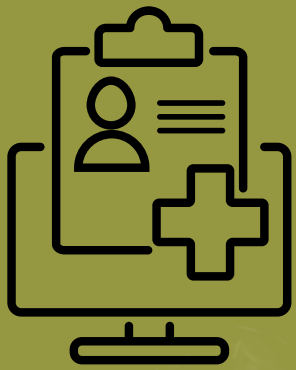
Module 10: Quality Assurance and Compliance

-  Internal and external audits
-  Standard Operating Procedures (SOPs)
-  Metrics and KPIs in CDM
-  Continuous improvement and CAPA

Module 11: Tools & Software Training (Optional/Hands-On)


-  EDC tools: Medidata Rave, Oracle InForm, OpenClinica
-  Data visualization/reporting: SAS basics, Excel
-  CTMS and CDMS integration








Clinical Data Management (CDM) Course Structure

Module 12: Career Guidance and Certification Preparation

 Resume preparation for CDM roles

 Interview preparation and mock interviews

 Overview of certifications (e.g., CCDM® by SCDM)

 Project or internship (if offered)

“Clean data. Clear impact.”



“Power your career with every data point.”

