iLearn CRI
CLINICAL RESEARCH INSTITUTE

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COURSE SYLLABUS & FEES · 2026

Certificate Course in Clinical Data Management (CCCDM) in Pune

iLearn CRI's 3-month Clinical Data Management course in Pune covers EDC platforms (Medidata Rave, Oracle Clinical), CDISC standards, SAS programming, database lock, and Pune CRO placement support.

DURATION	MODE	FEES	EMI
3 months	Live online & classroom (Pune)	₹40,000 + 18% GST	Available

Eligibility

- B.Pharm, M.Pharm graduates
- B.Sc / M.Sc in Life Sciences, Statistics, Computer Science, Bioinformatics
- BDS, BHMS, BAMS graduates seeking analytical pharma careers
- Working professionals from data analytics or pharma backgrounds

Complete syllabus, module by module

01 Introduction to Clinical Data Management

- The Clinical Data Management process and its objectives
- CDM team structure: data manager, coordinator, programmer
- Introduction to CDM tools and software
- Role of CDM within the clinical trial lifecycle
- Indian and global CDM landscape and career pathways

02 Guidelines & Data Standards for CDM

- Documentation scenario for data collection and management
- International studies and data privacy requirements
- Guidance for industry: ISO, ICH, HL7, CDISC and CDASH
- Electronic source data in clinical investigations

03 Study Setup & CRF Design

- Protocol-to-CRF mapping and design principles
- Edit check specification and validation logic
- User acceptance testing (UAT) and go-live procedures
- Annotated CRF (aCRF) and CRF Completion Guidelines
- EDC study build: Medidata Rave hands-on

04 Data Entry & Discrepancy Management

- Data entry workflows in EDC systems
- Manual review vs automated edit check resolution
- Data review metrics and site performance tracking
- Discrepancy identification and the query lifecycle
- Site communication for query resolution

05 Standard Coding & Safety Reporting

- MedDRA coding: hierarchy, conventions and version migration
- CDISC standards: CDASH, SDTM and ADaM overview
- WHO-DD drug coding and dictionary management
- Coding consistency and quality control

06 Data Review & Data Transfer

- External data reconciliation: lab, ECG, IRT, ePRO
- Listings review and data cleaning sign-off
- Data transfer specifications and integration standards
- CDISC Define-XML and Reviewer's Guide preparation

07 SAE Reconciliation

- SAE reporting workflow: site to sponsor to safety database
- Discrepancy identification and resolution between databases
- CDM–safety database reconciliation process
- Regulatory reporting timelines and CDM's role

08 Database Closure & Archiving

- Pre-lock checklist and quality review procedures
- Post-lock unlock procedures and documentation
- Long-term data retention and regulatory requirements
- Database lock protocols and authorisation workflow
- Trial Master File (TMF) archiving requirements

09 Quality Control (QC) & Quality Assurance (QA)

- QC vs QA: definitions and scope in CDM
- Audit trail review and data integrity checks
- Inspection readiness for CDM systems and processes
- Risk-based data monitoring principles
- GCP compliance in data management operations

10 Tools: Medidata Rave, Oracle Clinical, CDISC

- Medidata Rave: study build, forms, edit checks and reporting
- CDISC SDTM mapping exercises
- Veeva Vault EDC overview and industry adoption
- Oracle Clinical / InForm: overview and when it is used
- SAS programming basics for CDM: data steps and PROC SQL

11 AI in Clinical Research

- Introduction to AI, machine learning and deep learning basics
- Modern and adaptive clinical trial design
- Remote patient monitoring and patient e-diaries
- Evolution of AI across healthcare and the drug development lifecycle
- Virtual and decentralised trials: e-consent, ePRO, IWRS, telemedicine

12 AI in Managing Clinical Data

- Types of healthcare data, databases and AI-enabled platforms
- NLP for automated coding and unstructured clinical narratives
- Governance, validation and 21 CFR Part 11 expectations for AI tools
- ML-assisted CRF design and risk-based data review
- Anomaly detection and central statistical monitoring

13 Career Readiness & Placement Prep

- CDM resume building for freshers and career-changers
- Industry roles and entry paths in clinical data management
- Mock interviews with practising clinical data managers
- Certification pathways and next steps after the certificate

Career outcomes

ROLE	AVERAGE CTC
Clinical Data Coordinator	₹ 3.6–4.5 LPA
Clinical Data Associate	₹ 4.0–5.5 LPA
EDC Study Builder	₹ 4.5–6.0 LPA
Data Reviewer	₹ 3.8–5.0 LPA
SAS Programmer (Clinical)	₹ 5.5–7.5 LPA
Senior CDM (after 3-4 years)	₹ 9.0–12.0 LPA

Placement support built in

100% placement assistance for every student: resume calibration, mock interviews with practicing professionals, and direct introductions to 50+ pharma & CRO hiring partners. Average starting CTC across placements: ₹4.2L. Separate live online and classroom batches — same curriculum, same fees, same support.

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