iLearn CRI

CLINICAL RESEARCH INSTITUTE · PUNE

COURSE BROCHURE · 2026 INTAKE

POST GRADUATE DIPLOMA · 6 MONTHS · PGDCDM

PG Diploma in *Clinical Data Management*

Two disciplines, one credential. Three months of clinical research foundation, then three months of clinical data management — eighteen modules that take you from ICH-GCP to database lock.

DURATION	TOTAL PAYABLE	MODULES	YOU SAVE
6 Months	₹76,700	18	₹15,000
3 + 3, in two parts	₹65,000 + 18% GST · EMI available	Clinical research + CDM	vs both certificates separately

Admissions open — apply for the next batch

ilearncri.com · +91 80559 86767

Tathawade, Pune — Wakad · Hinjewadi corridor

Everything you need to *decide*.

This brochure covers why the two-part structure works, the market you are entering, all eighteen modules, the platforms and portfolio you build, both career tracks it opens, and exactly what it costs.

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ABOUT ILEARN CRI

iLearn Clinical Research Institute is a Pune-based institute delivering industry-led, ICH-GCP-aligned training in clinical research, pharmacovigilance, clinical data management, medical coding and regulatory affairs. Part of the **iLearn** education group, we run from a Tathawade campus inside the Hinjewadi–Wakad pharma corridor — walking distance from the CROs our graduates join. Diplomas are awarded by the **Faculty of Clinical Research and Drug Safety, iLearn CRI**.

50+	50+	₹4.2L	10+
ALUMNI ACROSS PHARMA & CRO	HIRING PARTNERS IN PUNE	AVERAGE INDUSTRY STARTING CTC	YEARS AVERAGE FACULTY EXPERIENCE

Data managers who understand the *trial* get promoted first.

You can learn to clean data without knowing why the protocol asked for it. Plenty of people do — and they stay at coordinator level. This diploma front-loads three months of clinical research so that when you reach the CDM modules, every edit check, every query and every reconciliation makes sense in the context of the study it protects.

PART A · MONTHS 1-3
Clinical Research Foundation
MODULES 01-05 · ICH-GCP & REGULATION

PART B · MONTHS 4-6
Clinical Data Management
MODULES 06-17 · EDC, CODING, LOCK, AI

WHAT THE COMBINATION GIVES YOU

- **Context behind the checks.** You will know what a protocol deviation is before you are asked to query one, and why an SAE must reconcile exactly.
- **Two career doors.** Graduates enter either track — site and monitoring roles, or data roles — and can move between them later.
- **A stronger interview.** CDM candidates who can discuss ICH-GCP, informed consent and monitoring are rare, and interviewers notice.
- **One credential, not two.** A single PG Diploma reads better on a resume than two three-month certificates.

THE VALUE CASE

Certificate in Clinical Research	₹40,000
Certificate in CDM	₹40,000
Taken separately	₹80,000
As this PG Diploma	**₹65,000**

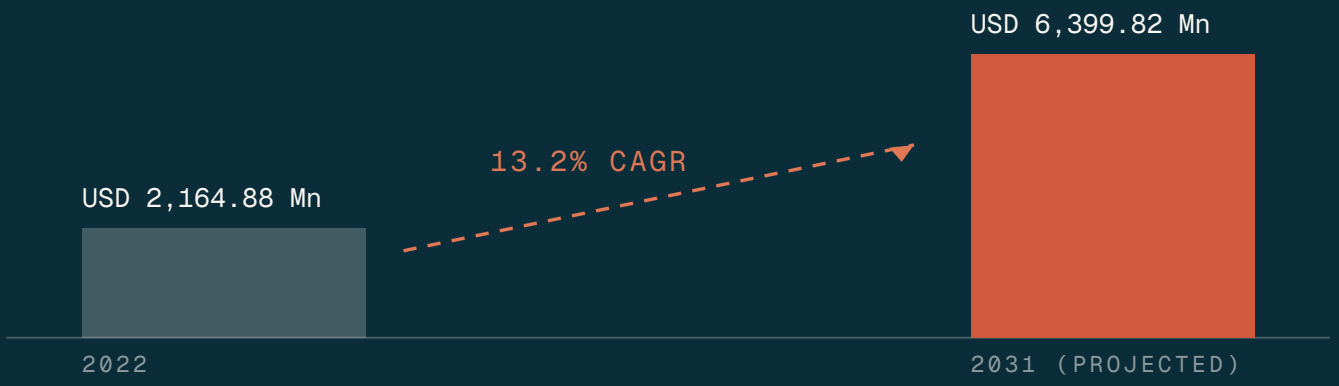
A saving of **₹15,000** before tax — and you receive a Post Graduate Diploma rather than two separate certificates. Fees exclusive of 18% GST.

WHO IT SUITS

- Freshers who want the widest possible entry into the industry
- Graduates undecided between site-based and data-based work
- Anyone who wants a diploma rather than a certificate

A market on track to *triple*.

Rising trial volumes worldwide, an expanding healthcare sector and rapid pharmaceutical advancement are all driving demand for clinical data management systems — and for the trained people who run them.



CLINICAL DATA MANAGEMENT SYSTEMS MARKET · 13.2% CAGR FORECAST 2023-2031 · INDUSTRY PROJECTIONS

/ 01

Cloud is the growth engine

By delivery mode the market splits into licensed enterprise, cloud-based and web-hosted solutions. The cloud segment is the major contributor and its share is rising with virtual trials — better data management, lower risk of data loss and less friction on regulatory compliance.

/ 02

Three buyers, all hiring

By end use, demand comes from contract research organisations, medical device companies and pharma/biotech sponsors — CROs and device makers needing rigorous tracking of clinical data, and sponsors needing stringent process assurance.

/ 03

The platforms to know

The key CDMS players shaping the market are Oracle, IBM, Veeva, Clindex and Ennov — which is why this diploma trains you on Medidata Rave with Oracle Clinical and Veeva Vault at overview level, rather than a teaching tool.

WHERE THE WORK IS

Trustworthy trial data reduces cost, time and risk — so demand is not confined to India. Trained professionals find scope across the **United States, Canada, United Kingdom, Germany, China, Japan, Brazil, Mexico, South Korea** and South-East Asia, in pharmaceutical and biotechnology companies, CROs, medical device firms and academic research groups.

CROs · Pharma sponsors · Biotech · Investigator sites · Medical devices · Academic research · Remote / global delivery

13.2%	≈3×	10+	5
FORECAST CAGR 2023-2031	MARKET GROWTH 2022 TO 2031	COUNTRIES WITH ACTIVE DEMAND	DOMINANT CDMS PLATFORM VENDORS

Six months, *eighteen modules*, two parts.

MONTHS 1-3 · PART A
Clinical research foundation
MODULES 01-05

MONTHS 4-5
CDM operations
MODULES 06-13

MONTH 6
Quality, AI & placement
MODULES 14-18

PROGRAMME FACTS

Programme	PG Diploma in CDM
Code	PGDCDM
Duration	6 months · 18 modules
Structure	Part A: clinical research Part B: data management
Mode	Live online & Pune classroom
Schedule	Weekday evenings & full Saturdays
Fee	₹65,000 + 18% GST = ₹76,700
Language	English

ELIGIBILITY

- **B.Pharm / M.Pharm** graduates
- **B.Sc / M.Sc** in Life Sciences, Biotechnology, Microbiology, Statistics or Chemistry
- **BDS, MBBS, BHMS, BAMS, BPT** and nursing graduates
- **BCA or B.Tech** graduates with a life-sciences interest
- **Working professionals** from pharma or data backgrounds

NO PREREQUISITES

No prior industry exposure, SAS, SQL or EDC experience is assumed. Part A starts from first principles, and Part B builds directly on it.

PROGRAMME DELIVERABLES

- **Comprehensive study material** for all eighteen modules, aligned to current industry expectations
- **Assignments for every module**, marked for continuous evaluation and individual guidance
- **Interactive live sessions** on all key areas, with weekend scheduling for part-time learners
- **Hands-on platform access** — Medidata Rave study build, CDISC reference libraries, SAS practice environment
- **Doubt-clearing session** scheduled before the final examination
- **A dedicated placement module** — resume, portfolio and mock interview rounds

Part A — the *clinical research* foundation.

Months one to three. The industry vocabulary, the ICH-GCP foundation and the regulatory literacy every employer expects on day one — the same curriculum as our Certificate Course in Clinical Research.

01 Foundations of Clinical Research & Drug Development

- The drug development lifecycle, discovery to post-marketing
- Phases of clinical trials (Phase I–IV) and their objectives
- Key stakeholders: sponsors, CROs, sites, investigators, IRB/IEC
- How the Indian and global clinical research industry is structured

02 ICH-GCP & Ethics

- ICH-GCP E6(R3) principles and the core requirements
- The Declaration of Helsinki and ethical foundations
- Informed consent process and documentation
- Roles of sponsor, investigator and monitor

03 Regulatory Framework

- CDSCO and the New Drugs and Clinical Trials Rules 2019 (India)
- USFDA 21 CFR Parts 11, 50, 56 and 312 — overview
- EMA and the EU Clinical Trials Regulation — overview
- Regulatory submissions and approval pathways at a glance

04 Clinical Trial Documents & Data

- Protocol, Investigator's Brochure and the essential document set
- Case Report Forms (CRFs) and source documentation
- Introduction to EDC and the Trial Master File (TMF)
- ALCOA+ data integrity principles

05 Monitoring & Safety Basics

- Types of monitoring visits and the CRA's role
- Source data verification (SDV) fundamentals
- Adverse events, serious adverse events and safety reporting
- Protocol deviations and quality management

WHERE PART A HANDS OVER

By the end of month three you can read a protocol, explain why a document exists and describe how a trial is monitored. Part B then puts you inside the systems that capture and clean the data those documents govern.

Part B — *clinical data management*.

Months four to six. The full CDM curriculum, sequenced from study build through database lock — built around how Pune CROs actually run data operations.

06 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

07 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

08 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

09 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

10 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

11 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

Lock, quality, the tool stack — and *AI*.

The closing stretch covers the high-stakes procedures, the platforms hiring managers test, and two modules on how AI is reshaping trials and data work.

12 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

13 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

14 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

15 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

16 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

17 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

You leave with *work samples*, not just a diploma.

Most training in India is theoretical — you read about edit checks in a slide deck and watch screen recordings of Rave. This curriculum is built on live datasets, real Rave study builds and instructor-led case studies.

HANDS-ON DEPTH

Medidata Rave

The Indian CRO market leader. You build study forms, configure edit checks, run dummy data through workflows and produce reports.

OVERVIEW LEVEL

Oracle Clinical Veeva Vault EDC

Architecture, where each is used and how to map your Rave skills across systems, so a platform mismatch never costs you an interview.

STANDARDS & CODE

CDISC & SAS

CDASH, SDTM domain mapping, ADaM and Define-XML — plus Base SAS and PROC SQL at the data-reviewer level early roles require.

THE THREE ARTEFACTS YOU KEEP

/ ARTEFACT 01

A full Rave study build

Forms, folders, edit checks and reports for a sample protocol, taken through UAT and go-live. Demonstrable proof of platform fluency.

/ ARTEFACT 02

An SDTM mapping exercise

Raw CRF data mapped to SDTM domains with controlled terminology — the clearest signal that you are a clinical data professional rather than a generic analyst.

/ ARTEFACT 03

A query-lifecycle case study

A discrepancy traced end to end: identification, query raise, site communication, resolution and closure, documented as you would for an audit.

18 Career Readiness & Placement Prep

- Clinical research and CDM resume building for freshers
- Mock interviews with practising clinical research professionals
- Industry roles, entry paths and choosing between the two tracks
- Certification pathways and next steps after the diploma

MODULE 18 RUNS ACROSS THE FINAL WEEKS, ALONGSIDE THE CLOSING PART B MODULES

Taught by people who still *do the work*.

Our instructors do not teach from textbooks. They teach from the actual study builds, edit-check failures and lock-day escalations they handled in the last quarter.

CLINICAL RESEARCH

CRA Level III Professional

Monitoring experience across multi-site Indian trials. Teaches Part A — ICH-GCP, regulation, documents and monitoring.

EDC & RECONCILIATION

Senior Clinical Data Manager

Nine years across IQVIA and Syngene. Teaches the EDC modules, discrepancy management and SAE reconciliation.

STANDARDS & CODE

CDISC SME & SAS Programmer

SDTM mappings for 30+ regulatory submissions. Teaches CDASH, SDTM, ADaM, Define-XML, Base SAS and PROC SQL.

HOW YOU ARE ASSESSED

- **Module assignments** across all eighteen modules for continuous evaluation and individual guidance
- **Practical exercises** on Rave, SDTM mapping and query resolution, reviewed by faculty
- **A doubt-clearing session** before the final examination
- **A final online proctored examination** at the end of the programme
- **Participant feedback** collected at the end of every module using structured questionnaires

CLASSROOM CONDUCT

Every student is expected to maintain disciplined conduct through classes, assessments and examinations, and to follow faculty instruction. Acts of indiscipline are recorded in the participant's academic report.

YOUR AWARD

Post Graduate Diploma in Clinical Data Management

Awarded by the Faculty of Clinical Research and Drug Safety, iLearn CRI, on successful completion of all eighteen modules, the assignments and the final proctored examination. Identical for online and classroom batches.

The curriculum is aligned to **ICH-GCP E6(R3)** and to CDISC standards — the global hiring benchmarks. But the diploma is only half of it: the portfolio behind it is what most technical interviews actually examine.

One diploma, *two doors*.

Graduates enter either track. Most choose data roles for the technical ladder and remote flexibility; some prefer site-based work first and move into data management later.

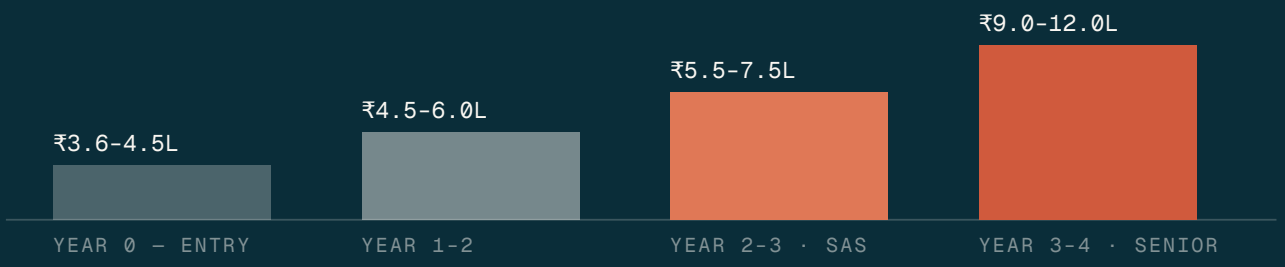
TRACK A · CLINICAL RESEARCH

Clinical Research Coordinator Site-based trial coordination	₹3.0-4.0 LPA
Clinical Trial Assistant Sponsor / CRO administration	₹3.0-4.0 LPA
Trainee / In-House CRA Monitoring and site management	₹3.5-4.5 LPA

TRACK B · CLINICAL DATA MANAGEMENT

Clinical Data Coordinator Data review and query management	₹3.6-4.5 LPA
Clinical Data Associate End-to-end study data handling	₹4.0-5.5 LPA
EDC Study Builder Database build and edit checks	₹4.5-6.0 LPA

WHERE BOTH TRACKS LEAD



/ 01

Resume calibration & portfolio

Your resume is rewritten to surface both the GCP foundation and the EDC, CDISC and SAS work — and the three artefacts become work samples you can put in front of an interviewer.

/ 02

Mock interviews & introductions

Technical, scenario-based and behavioural rounds with data managers from Pune CROs, then direct introductions across our 50+ pharma and CRO partners.

WHERE OUR NETWORK PLACES

Participants and alumni across the iLearn CRI network work with employers including **IQVIA, ICON, Parexel, PPD, Labcorp, Syneos Health, Syngene, Veeda, Lambda Therapeutic Research, AstraZeneca, Novartis, Bayer, Eli Lilly, Cipla, Sun Pharma, Lupin, Glenmark, Emcure, Serum Institute, TCS, Infosys, Accenture, Cognizant, Genpact, Indegene** and The Emmes Company.

Everything *transactional*, in one place.

PROGRAMME FEE

₹76,700

TOTAL PAYABLE

Programme fee	₹65,000
GST @ 18%	₹11,700
Total payable	**₹76,700**

No separate examination, certification or placement charges. EMI and multi-instalment plans available.

WHAT THE FEE COVERS

- Study material for all eighteen modules
- Hands-on Medidata Rave study build access
- CDISC reference materials — CDASH, SDTM, ADaM
- SAS practice environment
- Module 18 placement preparation and mock interviews

HOW TO APPLY

- **1.** Share your details with admissions — there is no application fee
- **2.** Receive the full syllabus, fee plan and batch dates on WhatsApp
- **3.** A short counselling call to confirm eligibility and the right batch
- **4.** Confirm your seat — early applicants get placement priority

Is this the same as taking both certificates?

The curriculum is the same eighteen modules, but you pay ₹65,000 rather than ₹80,000, study them in a deliberate sequence, and receive a Post Graduate Diploma rather than two separate certificates.

Can I join Part B only?

Yes — that is our three-month Certificate in Clinical Data Management. Choose the diploma if you want the clinical research foundation, the diploma credential and the combined fee.

Do I need SAS or EDC experience?

No. Base SAS and PROC SQL are taught from scratch, tailored to clinical data, and no prior EDC exposure is assumed — Part A introduces the concepts before Part B puts you inside the systems.

Is the online batch equivalent to the classroom?

Yes — same curriculum, same faculty, same placement support, with independent remote access to the same platforms, so the portfolio you build is equivalent.

Build a clinical data career in *Pune*.

Batches start regularly with limited seats to protect faculty attention, hands-on platform access and placement quality. Admissions usually reply within an hour on business days.

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