iLearn Clinical Research Institute

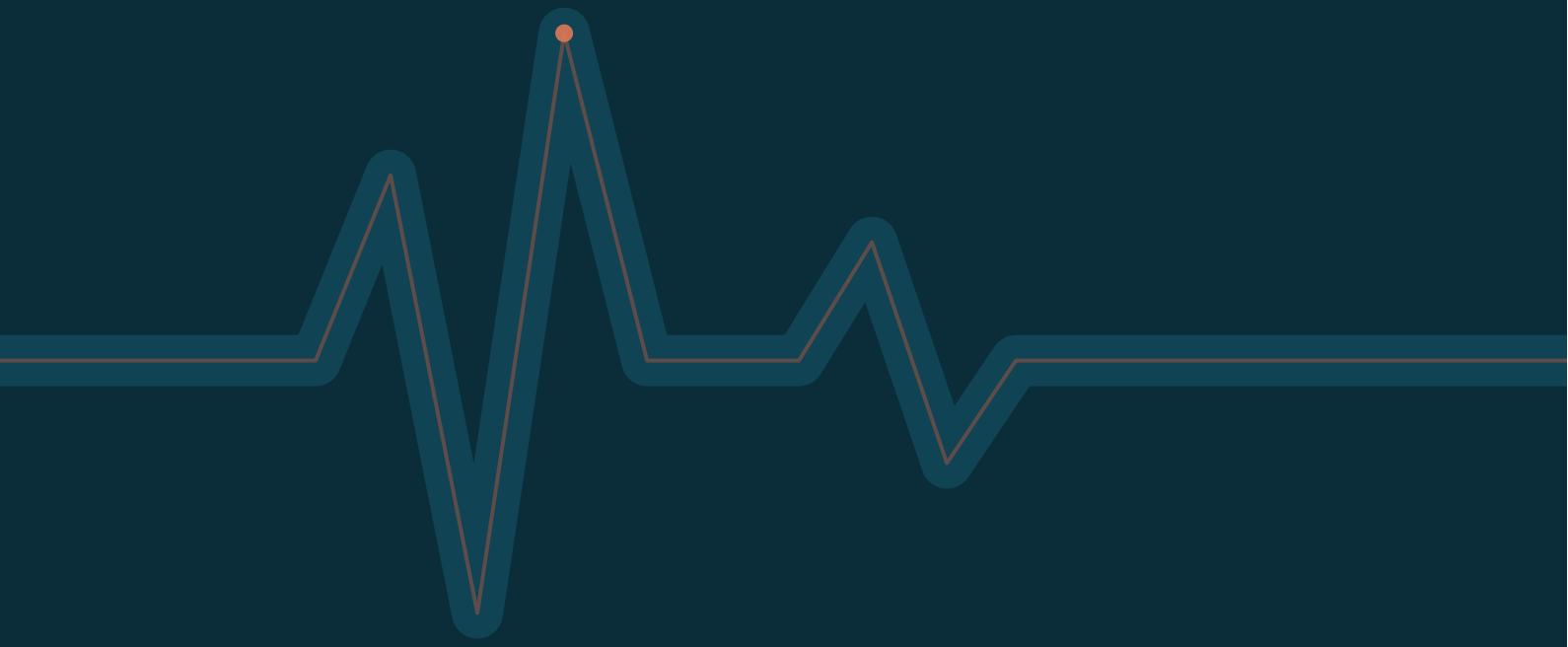
PUNE, INDIA

ADMISSIONS OPEN · NEW BATCH EVERY MONTH

CERTIFICATE PROGRAMME · 2026 INTAKE

Certificate Program in Clinical Research

A three-month, ICH-GCP E6(R3) aligned foundation — 21 modules, industry faculty, and a capstone project that ends in a job-ready portfolio.



DURATION

3 Months

21 modules · weekday evening & weekend batches

MODE

Offline / Online

Tathawade campus, Pune · live instructor-led online

PROGRAMME FEE

₹47,200

₹40,000 + 18% GST · EMI available · no hidden charges

CAMPUS

iLearn Clinical Research Institute
Office No. 331, Metro Life Bizzbay, Tathawade,
Pune, Maharashtra 411033, India

ADMISSIONS

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01 — PROGRAMME OVERVIEW

A fast, structured entry into the clinical research industry.

The Certificate Program in Clinical Research is built for graduates who want to enter the industry quickly — without committing to a year-long programme before they know their specialisation.

In three months you build the industry vocabulary, the **ICH-GCP foundation**, and the regulatory literacy every clinical research employer expects on day one. The curriculum is deliberately broad: rather than pushing you into one narrow role, it maps the whole landscape — pharmacovigilance, clinical data management, trial monitoring, medical writing and regulatory affairs — so you choose your path with real understanding rather than guesswork.

Faculty are practising professionals — CRAs, drug safety scientists and data managers — not full-time academics. The programme closes with **Placement Mastery, industry case studies and a capstone project**.

PROGRAMME AT A GLANCE	
DURATION	3 months · 21 modules
MODE	Classroom (Pune) & live online
SCHEDULE	Weekday evenings & full Saturdays
LANGUAGE	English
INTAKE	Monthly · limited seats per batch
AWARD	Certificate in Clinical Research, iLearn CRI
FEE	₹40,000 + 18% GST = ₹47,200 · EMI available

ELIGIBILITY

Who can apply

- B.Pharm / M.Pharm graduates
- B.Sc / M.Sc in Life Sciences, Biotechnology, Microbiology, Chemistry
- BDS, MBBS, BHMS, BAMS, BPT graduates
- Nursing graduates (B.Sc Nursing, GNM) entering clinical research
- Working professionals from adjacent fields seeking a recognised credential

OUTCOMES

What you walk away with

- Working command of ICH-GCP E6(R2)/E6(R3) and trial ethics
- Regulatory literacy across CDSCO, NDCT Rules 2019, USFDA, EMA, MHRA, TGA
- Hands-on familiarity with protocols, ICDs, CRFs, TMF and CSR documents
- Practical grounding in pharmacovigilance, data management and QA
- An interview-ready résumé, four mock interviews and a capstone project

Why Pune. The Hinjewadi–Wakad–Bhosari corridor houses clinical operations for CROs including Syngene, Veeda, Lambda Therapeutic, IQVIA, ICON and Parexel, alongside sponsors such as Cipla, Sun Pharma, Lupin, Glenmark and Emcure — all hiring entry-level clinical research talent continuously.

02 — CURRICULUM

Twenty-one modules, module by module.

The syllabus is delivered across three months. Each module combines instructor-led sessions with assignments; assessment runs continuously rather than as a single end-of-course exam.

Month 01 — Foundations, Ethics & Regulation

MODULES 01-07

01 Introduction to Clinical Research

- Definition and history — the basics
- Structure of the clinical research industry
- Clinical research vs. clinical trials
- Clinical research terminology
- General medical terminology

02 General Pharmacology & Mechanism of Drug Action

- Basics of pharmacology; branches of pharmacy
- History of pharmacy
- The Indian pharmaceutical industry
- Pharmacodynamics and pharmacokinetics
- Routes of administration and dosage forms

03 Drug Discovery & Drug Development

- History of drug discovery
- The drug discovery process
- Target identification
- Lead identification and lead optimisation
- Discovery genomics; preclinical studies

04 Historical Perspectives of Clinical Research

- Evolution of the ethical & regulatory framework
- Nuremberg Code, 1946
- Declaration of Helsinki
- Thalidomide tragedy; Belmont Report
- Schedule Y, Drugs & Cosmetics Act 1945; history of ICH

05 Ethical Issues & Global Regulations

- ICH guidelines — ICH-GCP E6(R2) and E6(R3)
- ICMR ethical guidelines
- Ethics on the use of placebo in clinical trials
- CDSCO and ICMR, India
- USFDA (USA), EMA (Europe), MHRA (UK), TGA (Australia)

06 Stakeholders & Core Team: Roles and Responsibilities

- Investigator — roles and responsibilities
- Sponsor — roles and responsibilities
- Contract Research Organisation (CRO)
- Ethics committee (IRB / IEC); regulatory agencies
- Clinical Research Coordinator (CRC) and Associate (CRA)

07 Clinical Research Documentation

- Essential documents before, during and after the trial (ICH-GCP)
- Protocol
- Informed consent documents
- Investigator's Brochure; Case Report Form
- Clinical Study Report

· Month 1 assessment

- Module-wise assignments submitted after each module
- Terminology and GCP principles quiz
- Guided reading: ICH-GCP E6(R3) core principles
- Faculty feedback questionnaire at module close

ALIGNMENT

ICH-GCP E6(R3)

The whole syllabus maps to the latest ICH-GCP guideline — the global benchmark CROs and sponsors hire against.

PACE

Seven modules a month

Roughly two modules a week across weekday-evening and full-Saturday sessions, so working professionals can keep their jobs.

EVALUATION

Continuous, not one exam

Assignments after every module, plus a final online examination and capstone viva at programme close.

Month 02 — Methodology, Data, Safety & Quality

MODULES 08-14

08 Research Methodology & Applied Biostatistics

- Defining the research problem
- Sampling design
- Hypothesis testing
- Parametric and non-parametric tests
- Scientific writing

09 Types & Designs Used in Clinical Research

- Diagnostic and treatment trials
- Interventional and observational studies
- Case-control and cohort studies
- Randomised controlled trials
- Quasi-experiments

10 Clinical Trial Data Management

- Introduction to data management
- Electronic data records
- eCRF and Interactive Web Response Systems
- Database locking and unlocking
- Good documentation practices

11 Pharmacovigilance & Safety Monitoring

- Adverse drug reactions
- Serious adverse events (SAE) and reporting timelines
- Pharmacovigilance methods
- Signal detection and data mining
- PvPI; risk management plan

12 Quality Assurance & Quality Control in Clinical Trials

- Introduction to the quality management system
- Quality assurance
- Quality control
- Audits and inspections; types of audits
- General audit observations

13 Pharmacoepidemiology & Pharmacoeconomics

- Pharmacoepidemiology — methods
- Clinical application of pharmacoepidemiology
- Principles of pharmacoeconomic analysis
- Pharmaceutical outcomes evaluations

14 Medical Device Clinical Trials (MDCTs)

- Medical Devices Rules, 2017
- Classification of medical devices
- Materiovigilance
- Phases of medical device clinical trials

· Month 2 assessment

- Study-design classification exercise
- SAE narrative and reporting-timeline drill
- Mock audit observation write-up
- Continuous evaluation assignments per module

TEACHING METHOD

Practitioner-led

Sessions are taught by working CRAs, drug safety scientists and clinical data managers, using live trial scenarios rather than textbook cases.

STUDY MATERIAL

Module-wise, in hard copy

Comprehensive material for every module, aligned to current industry expectations, with self-assessment assignments throughout.

SUPPORT

Doubt-clearing sessions

Dedicated doubt-clearing sessions are scheduled before each assessment, in addition to interactive live classes on all key areas.

Month 03 — Writing, Digital Trials, AI & Placement

MODULES 15-21

15 Medical Writing for Trials & Regulatory Submission

- Case reports and article writing
- Designing a clinical trial protocol
- CRF designing
- Informed consent documents
- Clinical study reports

16 Virtual Clinical Trials (Role of AI and ML)

- e-Consent (audio-visual consent)
- e-Patient Reported Outcomes (e-PRO)
- IWRS; telemedicine
- Patient e-diaries
- Remote patient monitoring

17 Clinical Trials — Latest Updates (2019 to date)

- ICH-GCP E6(R3)
- NDCT Rules 2019 and the 2023 amendment
- ICMR-HMSC
- Recent CDSCO notices
- NABH ethics committee standards

18 AI in Clinical Research

- Introduction to AI; evolution of AI in healthcare
- Machine learning basics; deep learning
- Types of healthcare data, databases and software
- Modern clinical trial design
- Application of AI in clinical research

19 Placement Mastery

- Résumé building for clinical research roles
- Communication skills, aptitude and soft skills
- Corporate etiquette
- Interview preparation
- Four mock interviews with practising professionals

20 Industry-Based Case Studies

- Real trial scenarios drawn from partner CROs and sponsors
- Protocol deviation and CAPA walkthroughs
- Site-level problem solving and escalation
- Group presentation and faculty critique

21 Capstone Project

- End-to-end project applying the full curriculum
- Documentation set: protocol synopsis, ICD, CRF, safety plan
- Mentor-guided review cycles
- Final submission and viva — forms your interview portfolio

· Programme close

- Final online examination
- Capstone evaluation and portfolio review
- Certificate issuance
- Introduction to partner CRO and pharma hiring managers

Modules 19–21 form the placement block. Every participant completes résumé review, four mock interviews with hiring managers from partner CROs, and a capstone project that doubles as an interview portfolio.

CAPSTONE DELIVERABLE

A portfolio, not just a certificate

Participants leave with a documented project — protocol synopsis, informed consent document, CRF and safety plan — that can be walked through in an interview.

03 — HOW THE PROGRAMME RUNS

Delivery, assessment and certification.

Programme deliverables

- Comprehensive study material for all modules, in hard copy, aligned to current industry expectations
- Assignments for every module for continuous evaluation and guidance
- Interactive live sessions on all key areas, with flexibility for working participants
- Online live / part-time classes conducted on weekends, plus a doubt-clearing session before each examination
- Assessment and evaluation across all modules to build job-applicable competency
- Structured faculty feedback collected from participants at the close of every module
- All learning and training delivery conducted in English

Two ways to attend

Live online batch

Fully instructor-led sessions with the same curriculum, faculty and placement support — designed for students across India and working professionals who cannot relocate.

Classroom batch — Pune

In person at the Tathawade campus in the Hinjewadi–Wakad corridor, with face-to-face faculty time and maximum hands-on practice.

Examination & certification

Participants submit completed assessment assignments during the programme — usually after every module — and appear for an online examination at the end. On successful completion, participants are awarded the **Certificate in Clinical Research by iLearn Clinical Research Institute**.

The curriculum is aligned to ICH-GCP E6(R3) and internationally recognised competency frameworks, so it is understood by CROs and pharma sponsors hiring for entry-level roles across Pune's pharma corridor. The certificate also credits directly into the iLearn CRI PG Diploma pathway.

Discipline in classes and examinations

Every participant is expected to observe disciplined behaviour during classes, assessments and examinations, and to follow instructions from the faculty. Any act of indiscipline may result in discredit and will be recorded in the participant's academic report.

Placement assistance & corporate relations

Placement is treated as a deliverable, not an afterthought. The placement cell — staffed by senior HR and talent-acquisition professionals — maintains close links with industry and works continuously to promote participant employability.

- Clinical research résumé review and professional CV writing
- Mock interviews with hiring managers from partner CROs
- Direct introductions to 50+ pharma and CRO hiring partners
- Ongoing corporate networking and industry engagement

50+	₹4.2L	100%	50+
ALUMNI WORKING ACROSS PHARMA & CRO	AVERAGE INDUSTRY STARTING CTC	PLACEMENT ASSISTANCE SUPPORT	PHARMA & CRO HIRING PARTNERS

04 — AFTER THE PROGRAMME

Roles graduates step into.

ROLE	TYPICAL STARTING CTC
Clinical Research Coordinator (CRC)	₹3.0–4.0 LPA
Clinical Trial Assistant (CTA)	₹3.0–4.0 LPA
Trainee CRA / In-house CRA	₹3.5–4.5 LPA
Site Coordinator	₹3.0–4.0 LPA
Drug Safety Associate (entry)	₹3.5–4.5 LPA
Clinical Data Associate (entry)	₹3.5–4.5 LPA

Indicative ranges. Actual offers vary with degree, batch performance and role.

WHERE OUR ALUMNI WORK

CIPLA · SUN PHARMA · LUPIN · SYNGENE · LAMBDA THERAPEUTIC · VEEDA · IQVIA · ICON · PAREXEL · SYNEOS HEALTH · PPD · GLENMARK · EMCURE · SERUM INSTITUTE · RELIANCE LIFE SCIENCES · MYLAN · DR. REDDY'S · DIVI'S LABORATORIES · TORRENT PHARMA · AUROBINDO PHARMA · JUBILANT LIFESCIENCES · NOVARTIS · VENUS REMEDIES · GVK BIOSCIENCES · FISHER CLINICAL SERVICES · SRL DIAGNOSTICS · TCS · COGNIZANT · ACCENTURE

FEES & PAYMENT

PROGRAMME FEE	₹40,000
GST @ 18%	₹7,200
TOTAL PAYABLE	₹47,200
INCLUDES	Study material, ICH-GCP training, assessments, certification and placement preparation
EMI	Available — most participants opt for a multi-instalment plan
HIDDEN CHARGES	None. No separate examination, certification or placement fee

PROGRESSION PATHWAY

Where this certificate leads

- **PG Diploma in Clinical Research** — 6 months, broader coverage with more hands-on work
- **Advance PG Diploma in Clinical Research** — 1 year, with an extended capstone internship
- **Certificate in Pharmacovigilance & Regulatory Affairs** — the most in-demand office-based specialisation
- **Certificate in Clinical Data Management** — the technical, remote-friendly path

ADMISSION PROCESS

01
Enquire
Message admissions on WhatsApp or submit the enquiry form for the full syllabus and current batch dates.

02
Counselling call
A short conversation about your degree, background and career target to confirm the programme fits.

03
Enrol
Submit documents, choose classroom or online batch, and select a full-payment or EMI plan.

04
Begin
Receive study material and batch schedule. Seats per batch are limited to protect faculty attention.

iLearn Clinical Research Institute

PUNE, INDIA

APPLY FOR THE NEXT BATCH

Build a clinical research career in Pune.

Industry-led training, real placements with pharma and CRO partners, and a faculty drawn from active research practice. Batches start every month with limited seats — early applicants get priority for placement preparation and corporate introductions.

TALK TO ADMISSIONS

+91 80559 86767

Call or WhatsApp — usually answered within an hour

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