ADVANCED CERTIFICATION IN CLINICAL RESEARCH, AI & DATA SKILLS

Program Duration: 3 Months (12 Weeks)

Mode of Delivery: Live Online Sessions with Practical Assignments

Eligibility: Life Sciences Graduates & Working Professionals

Course Fee: ₹65,000

Commencement Date: Confirm with Counsellor

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1. Program Description

The Advanced Certification in Clinical Research, AI & Data Skills is a comprehensive professional training program designed to equip learners with foundational knowledge, practical skills, and career readiness required for roles in Clinical Research and allied domains.

The program integrates Clinical Research principles, regulatory compliance, clinical operations, data handling, Excel, AI applications, and structured career alignment to ensure industry relevance and employability.

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2. Program Objectives

Upon successful completion of the program, learners will be able to:

- Understand the end-to-end clinical trial lifecycle
- Demonstrate knowledge of global regulatory requirements (ICH-GCP, FDA, EMA)
- Apply clinical operations concepts in real-world scenarios
- Handle clinical data using Excel and industry-standard practices
- Use AI tools ethically to enhance productivity and documentation
- Align their professional profile to specific clinical research career paths
- Prepare for technical and scenario-based interviews

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3. Eligibility Criteria

Eligible Candidates

- Graduates and postgraduates in Life Sciences, Pharmacy, Biotechnology, Nursing, or Allied Health Sciences

- Working professionals in Clinical Research, Healthcare, or related industries

- Candidates seeking transition into Clinical Research, Pharmacovigilance, Medical Writing, or Data-related roles

Not Recommended For

- Candidates seeking only certification without career intent

- Individuals unwilling to participate in practical learning and assessments

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4. Teaching Methodology

- Live instructor-led sessions

- Case-based learning and industry examples

- Practical assignments and simulations

- Interactive discussions and Q&A

- Mock interviews and career guidance sessions

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5. Customised Career Roadmap

During the first month, each learner undergoes a structured career assessment. Based on this assessment, a customised career roadmap is created considering the learner's background, skill gaps, career goals, and constraints.
This roadmap guides learning focus and career preparation throughout the program.

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6. Detailed Curriculum (Module-wise)

Module 1: Clinical Research Fundamentals & Career Orientation

Duration: Weeks 1–2

- Introduction to Drug Development
- Phases of Clinical Trials
- Clinical Trial Lifecycle
- Roles and Responsibilities of Sponsor, CRO, Site, and Ethics Committee
- Overview of Career Paths in Clinical Research
- Introduction to Global Regulatory Framework

Learning Outcome:
Learners gain foundational understanding and clarity on potential career roles.

Module 2: Regulatory Affairs, ICH-GCP & Documentation

Duration: Weeks 3–4

- Principles of ICH-GCP
- Essential Documents and Trial Master File (TMF)
- Protocol, Investigator's Brochure, Informed Consent Form
- Deviations, CAPA, and Inspection Readiness
- Introduction to Audit Processes

Learning Outcome:
Learners understand compliance requirements and documentation standards.

Module 3: Clinical Operations & Monitoring

Duration: Weeks 5–6

- Site Selection and Site Initiation
- Monitoring Activities (On-site and Remote)

- CRA Roles and Responsibilities

- Monitoring Visit Reports

- Risk-Based Monitoring (RBM) Overview

Learning Outcome:
Learners acquire operational knowledge applicable to clinical trial execution.

Module 4: Clinical Data Management & Excel Applications

Duration: Weeks 7–8

- Clinical Data Flow and EDC Overview

- Source Data Verification (SDV)

- Query Management

- Excel for Clinical Research:

  o VLOOKUP / XLOOKUP

  o Pivot Tables

  o Data Tracking Dashboards

Learning Outcome:
Learners develop confidence in data handling and reporting.

Module 5: Artificial Intelligence in Clinical Research

Duration: Week 9

- Introduction to AI in Healthcare and Clinical Research

- AI for documentation & study understanding
- Prompt Engineering
- Data summarization & productivity tools
- Ethical & compliant AI usage

Learning Outcome:
Learners gain exposure to responsible AI usage in regulated environments.

Module 6: Career Expansion Modules

Duration: Week 10

- Pharmacovigilance: Case Processing and Safety Reporting Overview

- Medical Writing: Protocols, CSRs, and Narratives

- Medical Coding: Fundamentals and Industry Relevance

- Introduction to Clinical Data Analysis

Learning Outcome:
Learners understand multiple career pathways within the life sciences domain.

Module 7: Career Alignment & Interview Preparation

Duration: Weeks 11–12

- Role-specific CV Development

- LinkedIn Profile Optimisation

- Technical Interview Preparation

- Scenario-based Interview Questions

- Mock Interviews with Feedback

Learning Outcome:
Learners become interview-ready with aligned professional profiles.

Module 8: Capstone Project

Duration: Week 12

- Documentation and Data-based Assignments

- Quizzes & Assessments

- Presentations

- Final Career Execution Plan

Learning Outcome:

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7. Assessment & Evaluation

- Participation in live sessions

- Practical assignments and case studies

- Capstone project evaluation

- Mock interview performance

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8. Certification

Participants who successfully complete the program requirements will be awarded.

"Certificate of Completion – Advanced Certification in Clinical Research, AI & Data Skills."

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9. Disclaimer

Completion of the program enhances employability and preparedness for industry roles. Placement assistance or job guarantees are not implied.