biotecnika
Your Bio Resource

CLINICAL RESEARCH TRAINING PROGRAM WITH

APPLIED ONLINE PROJECT WORK

STARTING 7TH FEBRUARY 2025

"Don't miss this exclusive opportunity to take the first step toward a rewarding career in clinical research!

Course Details

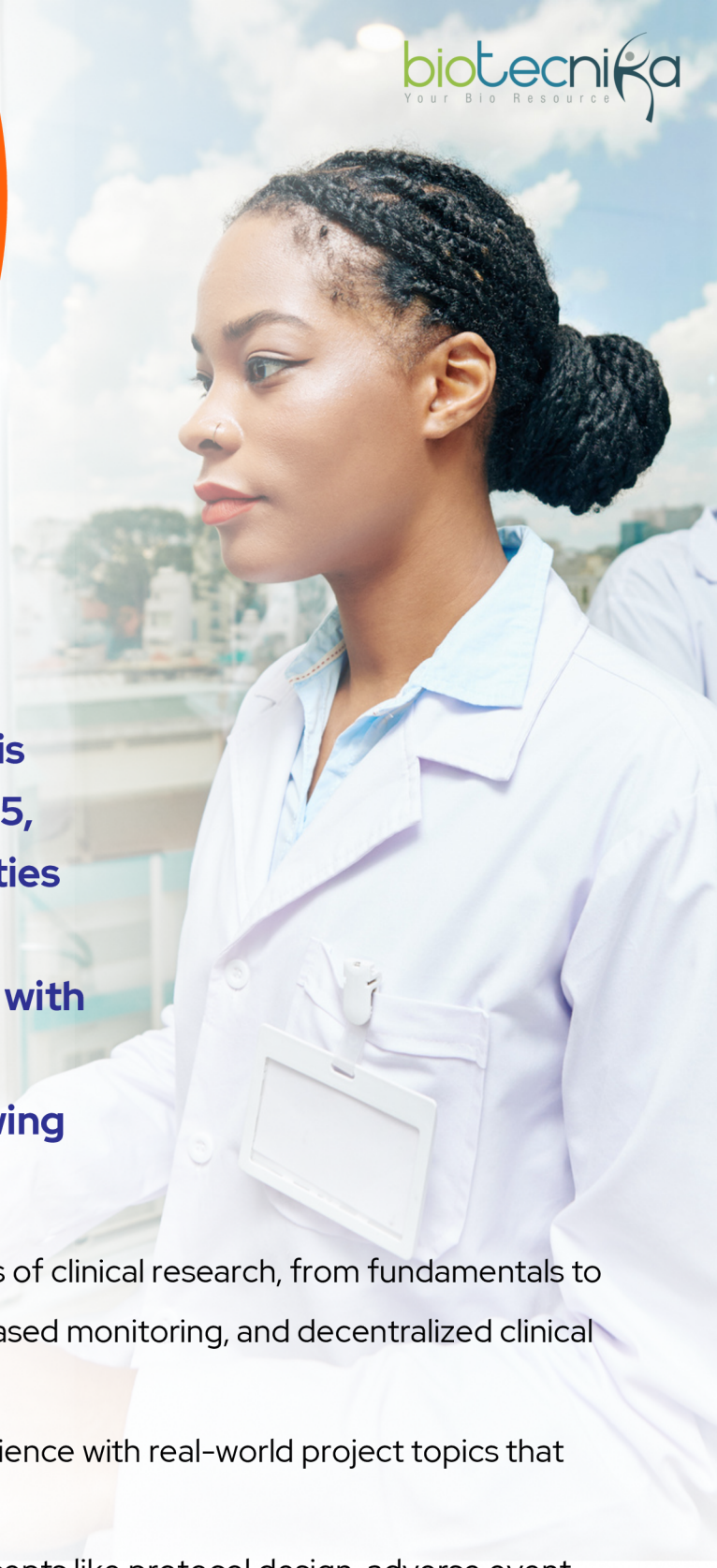
- *Start Date: 7th February 2025*
- *Time: 7:30 - 8:30 PM IST (Monday to Friday)*
- *Duration: 30,60 & (90 Days + Project Work)*

Mail: info@biotecnika.org

stores.biotecnika.org

Master the essentials of clinical research with our 90-day Clinical Research Training & Project Work Program. Designed for aspiring professionals, this comprehensive course offers in-depth knowledge of clinical trials, regulatory frameworks, and the latest industry advancements, along with hands-on project work to prepare you for real-world challenges in the clinical research field.

Why Enroll in the Clinical Research Training Program?



The global clinical research industry is expected to reach $63 billion by 2025, offering countless career opportunities for skilled professionals. This comprehensive program equips you with the knowledge, skills, and practical experience to excel in the ever-growing clinical research field

1. Comprehensive Curriculum: Covers all facets of clinical research, from fundamentals to advanced topics like AI in clinical trials, risk-based monitoring, and decentralized clinical trials.
2. Hands-on Project Work: Gain practical experience with real-world project topics that prepare you for industry challenges.
3. Industry-Relevant Skills: Learn essential concepts like protocol design, adverse event reporting, regulatory environment analysis, and much more.
4. Expert-Led Training: Delivered by seasoned industry professionals with years of clinical research expertise.

Career Guidance: Includes career counseling, resume-building sessions, and open discussions to help you land your dream job in clinical research.

Toll Free - 1800-1200-1818

www.Biotecnika.org

About the Instructor

Ms Ankita M

Clinical Research Professional
Clinical Research Trainer, Biotecnika

With over 5 years of expertise in clinical research and monitoring, Ankita brings a wealth of knowledge and practical experience to the table. Holding a Master's in Microbiology and advanced certifications in Clinical Research and Management, Ankita is a dedicated professional specializing in regulatory compliance, project management, and data analysis for oncology and non-oncology studies.

Her skill set includes proficiency in industry-standard tools such as CTMS, PDMS, and EDC, with demonstrated expertise in KRI assessments, SAE reporting, and comprehensive clinical documentation. Ankita's accolades include the prestigious Star Performer Award at IQVIA, underscoring her commitment to excellence in clinical research.

Passionate about training and mentoring, Ankita aims to bridge the gap between theoretical knowledge and real-world application, empowering students to excel in the dynamic field of clinical research

Course Curriculum

Session no	Unit No. and Topic

UNIT-1: Introduction to Clinical Research

1. Fundamentals of Clinical Research
2. History of Clinical Research
3. Basic terminologies associated with clinical research
4. Basics on clinical trial
5. Unit review and Q&A

UNIT-2: Clinical Trial Phases

6. Introduction to clinical trial phases
7. Classification of clinical trial phases

8 Life cycle of a clinical trial

9 Unit review and Q&A

UNIT-3: Pharmacokinetics and Pharmacodynamics

10 Basic terminologies associated with clinical research

11 Basics on clinical trial

12 Unit review and Q&A

UNIT-4: Preclinical Studies and Drug Manufacture

13 Definitions

14 Preclinical Trials (Lab test and Animal test)

15 New Chemical Entity (NCE) development and Chemistry Manufacture & Control (CMC)

UNIT-4: Drug Discovery and Therapeutic Areas

16 Drug Discovery

17 Drug Therapeutic Area and Mechanism of Action

18 Unit review and Q&A

UNIT-5: ICH GCP

19 Evolution and history of ICH

20 Goals and Process of ICH

21 ICH standards and Bodies associated with ICH

22 13 principles of ICH GCP

23 ICH GCP Requirement

24 IRB and IEC

25 Declaration of Helsinki and it's Principles

26 Unit review and Q&A

UNIT-6: Roles and Responsibilities

27 Responsibilities of Sponsors and CRO (Contract Research Organization)

28 Responsibilities of Investigators, site staff and IRB/IEC

29 Responsibilities of Clinical Research Associate (CRA) and Monitors

30 Remote Monitoring (A new emerging concept)

31 Unit review and Q&A

UNIT-7: Risk based Monitoring

UNIT-8: Blinding and Randomization & Protocol Understanding

38 Blinding and it's Type

39 Randomization and it's type

40 Eligibility Criteria & Schedule of Activities

41 Documents and stakeholders supporting RBM and RBQM

42 Other contents of protocol

UNIT-9: Informed Consent

43 Definition and Guidelines

44 Exceptional Scenarios

45 Unit review and Q&A

UNIT-10: Documentation

46 Essential Documents

47 TMP and SMA

48 Investigator's Brochure, Feasibility Lab and Pharmacy Manuals

49 Case Report Forms (CRF) & eCRF, Interactive Web Response Systems and Case Study Report

50 PROs, ePROs, eDairies etc

51 Identification of Protocol Deviation/Violation

52 Unit review and Q&A

UNIT-11: Adverse and Serious Adverse Events

53 Definitions

54 Reporting Timelines

55 Permitted and Prohibited Therapy

56 Concomitant Medications

57 Unit review and Q&A

UNIT-12: Audit and Inspection & Data Entry of Clinical trial

58 Definition and Differences

59 Important Terminologies

60 Data Entry Process

61 Data Entry Facilities

62 Life Cycle of a Data

63 21 CFR

64 Unit review and Q&A

UNIT-13: Virtually driven Clinical trial

65 eCRF (Electronic Case Report Form) and it's entry process

66 Remote Data Capture

67 Source Documents and it's review and verification (SDR and SDV)

UNIT-14: Site Visits and Types

68 Site Initiation Visits

69 Site Monitoring Visits and Responsibilities

70 Site Closeout visits

71 Unit review and Q&A

UNIT-14: Regulatory Authorities and common Abbreviations

72 Worldwide Regulatory Authorities

73 Regulatory Environment in India (CDSCO ICMR and others)

74 Functions of Regulatory Authorities

75 Detailed knowledge on FDA and EMA

76 Regulatory Submission and Approval Process in India and worldwide

77 Challenges during Regulatory Approvals

78 Unit review and Q&A

UNIT-15: Latest Advancement in Clinical Trial

79 Involvement of AI in subject Recruitment

80 Protocol Designing and Data Analysis

81 Key Risk Indicators and Quality Tolerance Limit

82 Risk Assessment, Centralized Monitoring and Decentralized Clinical Trials

83 Unit review and Q&A

84 Career Counselling

85 Resume building

86 Final Doubt Clearing and Open Discussion

CLINICAL RESEARCH ONLINE PROJECT TOPICS

1. Clinical Trial Design and Protocol Presentation

Objective

Duration: 4–6 weeks

Students will understand the requirement of designing a protocol, including objectives, phases, eligibility criteria, randomization, blinding, schedule of activities, and other protocol content.

Key Deliverables : Complete trial protocol document and a presentation explaining their design.

2.Adverse Event Reporting and Analysis

Objective

Duration: 3–4 weeks

Analyze mock case scenarios to identify adverse events (AEs) and serious adverse events (SAEs). Prepare regulatory-compliant AE reports with appropriate timelines.

Key Deliverables : AE and SAE report submissions, including analysis of concomitant medications and therapy impacts.

3. Risk-Based Monitoring (RBM) Project

Objective

Duration: 4 weeks

Develop a risk-based monitoring plan for a mock clinical trial. Identify key risk indicators (KRIs), quality tolerance limits (QTLs), and monitoring strategies and also work on route cause analysis and mitigation plan

Key Deliverables : Comprehensive RBM/RBQM plan and risk assessment report.

4.Data Analysis and AI Application in Clinical Trials

Duration: 6 weeks

Objective

Use the provided datasets to analyze clinical trial data using basic statistical tools. Demonstrate how data analysis can optimize trial outcomes.

Key Deliverables : Data analysis report, including visualizations and statistical insights.

5. Preclinical to Clinical Transition Project

Objective

Duration: 4 weeks

Identification of preclinical data from mock abstracts/publications and posters and providing the model used, cell line. CMC etc.

Key Deliverables : Transition roadmap and presentation.

6.Regulatory Environment Analysis

Duration: 3 weeks

Objective

Compare regulatory environments in India, the US, and Europe. Highlight similarities, differences, and challenges in gaining approval for clinical trials

Key Deliverables : Comparative regulatory analysis document

7. Real-Time Problem Solving in Clinical Trials

Objective

Duration: 3 weeks

Work on case studies involving protocol deviations/violations, patient recruitment challenges, or quality management issues. Provide solutions based on ICH GCP principles.

Key Deliverables : Detailed case analysis and recommended solutions.

Suggested Timeline for Projects

Short projects (3–4 weeks) can be assigned as individual modules.

Longer projects (4–6 weeks) can be capstone projects or combined into a comprehensive 3-month project with overlapping elements.

By focusing on these projects, students can still gain robust, practical experience in clinical research without relying on virtual simulations.

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Career Opportunities Post-Training

- Clinical Research Associate (CRA)
- Clinical Data Manager
- Regulatory Affairs Specialist
- Medical Writer
- Pharmacovigilance Specialist
- Quality Control/Quality Assurance Officer
- Site Monitoring Officer
- Clinical Project Manager

DID YOU KNOW?

The clinical research industry is booming, with job demand expected to grow by over **13% by 2028, especially for roles like CRAs and Clinical Project Managers.**

Key Learning Outcomes

By the end of this training program, you will:

- Master clinical trial processes from Phase I to Phase IV.
- Understand regulatory guidelines such as ICH-GCP, FDA, EMA, and CDSCO.
- Learn pharmacovigilance concepts, including AE and SAE reporting.
- Gain hands-on experience through applied project work.
- Develop practical skills in risk-based monitoring and decentralized trials

Who Should you Enroll?

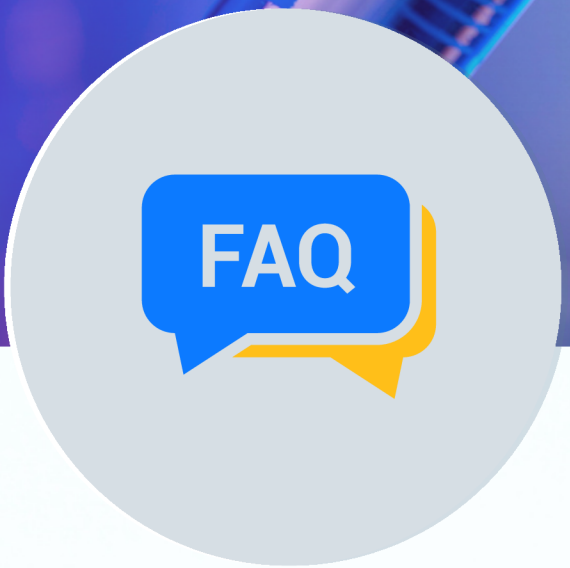
This course is ideal for

- **Life Science/Pharmacy/Medical Graduates**
- **Working Professionals Looking to Transition into Clinical Research**
- **Students Seeking Hands-On Industry Exposure**
- **Individuals Interested in a Career in CROs, Pharmaceuticals, or Biotech Companies**

Tools& Software You'll Learn:

- CTMS (Clinical Trial Management Systems)
- EDC (Electronic Data Capture)
- eCRF (Electronic Case Report Forms)
- AI Tools for Clinical Research

FAQs (Frequently Asked Questions)



Q1: Is this course suitable for beginners?
A: Yes! This program is designed to start from the basics and gradually cover advanced concepts.

Q2: Will I get a certificate after completing the course?
A: Yes, participants will receive a course & Project work completion certificate.

Q3: What kind of project work will be provided?
A: You'll work on real-world clinical trial scenarios like protocol design, risk-based monitoring, and adverse event reporting to gain hands-on experience.

Q4: Can I get job placement assistance after completing the program?
A: Yes, we provide career counseling, resume-building sessions, and access to Biotecnika's job portal to help you land a job in the clinical research industry.

Why Clinical Research is a Lucrative Career Choice?

- **High Demand:** Clinical research professionals are in high demand worldwide.
- **Attractive Salary**: Entry-level roles offer salaries starting from ₹4-6 LPA, with rapid growth potential.
- **Global Opportunities:** Work with pharma giants, CROs, and regulatory agencies worldwide.
- **Impactful Work:** Contribute to life-saving drug discoveries and help improve global healthcare.

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About Biotecnika

Biotecnika is a leading name in life sciences education, providing industry-relevant training programs for students and professionals. With 18+ years of experience in the biotech education space, **we've trained 10,000+ professionals till date in various BIO-IT & allied courses** who are now working in top pharma and CRO companies worldwide.

Join our mission to bridge the gap between academia and industry and prepare yourself for a bright future in clinical research!

Join us today