biotecnika
Your Bio Resource

CLINICAL RESEARCH TRAINING PROGRAM WITH

APPLIED ONLINE PROJECT WORK

100% PLACEMENT ASSISTANCE

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

GET WORK EXPERIENCE LETTER

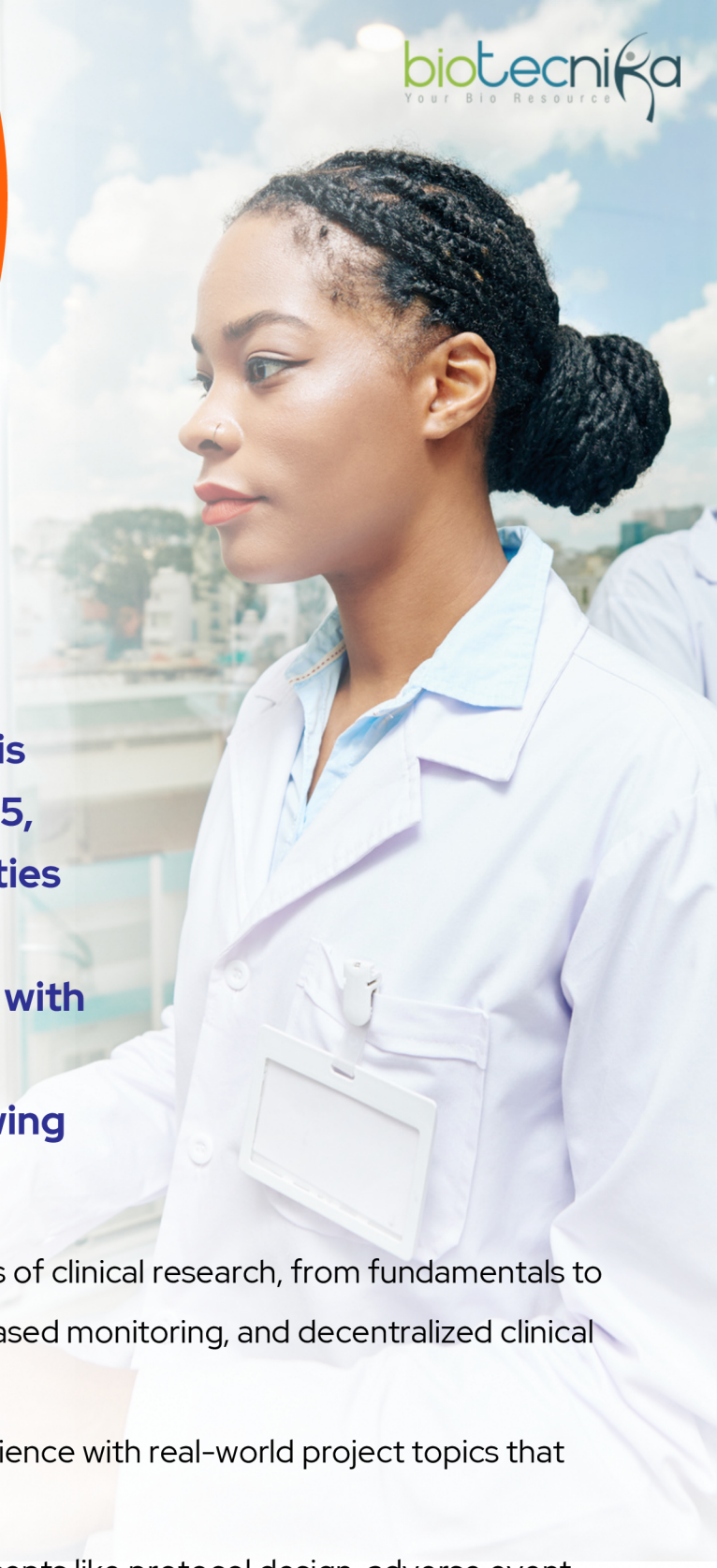
DURATION: 90 DAYS TRAINING + 1,3 & 6 MONTHS PROJECT

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 GEETHANJALI

Clinical Research & PV Trainer at Biotecnika
Expert in Pharmacovigilance, Drug Safety Opera
MedDRA Coding, and Patient Counseling

Ms. K. Geethanjali is an experienced pharmaceutical professional with a strong academic background and hands-on industry exposure in Clinical Research, Pharmacovigilance, and Drug Safety. She holds an M.Pharm in Pharmaceutics from PSG College of Pharmacy, Coimbatore, and has been involved in academic and applied research projects related to drug delivery systems and clinical studies on metabolic disorders, giving her a solid understanding of both preclinical and clinical development processes.

She brings valuable industry experience from her role as a Drug Safety Associate at Bioclinica Ltd., where she worked in regulated clinical environments handling adverse event processing, case evaluation, MedDRA coding, and safety database operations using ARGUS. Her experience as a community pharmacist further strengthened her expertise in prescription review, medication safety, patient counseling, and ethical healthcare practices, all of which are essential to high-quality clinical research conduct.

As a faculty member of Biotecnika's Clinical Research and Pharmacovigilance Training Programs, Ms. Geethanjali guides students through industry-aligned learning and practical exposure, with a strong emphasis on patient safety, data integrity, regulatory compliance, and ethical research practices. Her structured teaching approach and real-world insights help learners develop the confidence and competence required to transition into professional roles within the clinical research, drug safety, and regulatory affairs domains.

About the Instructor

Ms Kavita

Clinical Research Trainer at Biotecnika
Expert in GCP, trial operations, and protocol compliance.

Kavitha is a dedicated Clinical Research Professional with three-plus years of hands-on experience in clinical research and clinical operations. With a strong foundation in Good Clinical Practice (GCP) guidelines and regulatory requirements, Kavitha has supported the planning, coordination, and execution of clinical trials across various phases.

As a Clinical Research Trainer, she is passionate about sharing knowledge and supporting the professional development of research teams. She specializes in creating and delivering training sessions that cover essential clinical research concepts, site operations, protocol compliance, and ethical practices. Her approach is practical, engaging, and focused on building confidence and competence in new professionals entering the clinical research field.
With a keen eye for detail and a commitment to quality and compliance, Kavitha aims to foster a learning environment that supports operational excellence and high standards in clinical trial conduct.

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. Clinical Trial Overview & its Importance
5. Unit review and Q&A

UNIT-2: Clinical Trial Phases

6. Introduction & classification to clinical trial phases
7. ClinicalTrials.gov & WHO ICTRP

8 Life cycle of a clinical trial | Clinical Trial Phases_Case Studies

9 Unit review and Q&A

UNIT-3: Pharmacokinetics and Pharmacodynamics

10 Introduction to PK/PD and basics of pharmacology

11 Introduction to Pharmacovigilance and its role in CR

12 Route of Administration, dosage forms, dose findings

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-5: Drug Discovery and Therapeutic Areas

16 Drug Discovery Overview

17 Drug Therapeutic Area and Mechanism of Action

18 Drug Bank Overview & Other databases (PubChem; ZINC, etc)

UNIT-6: 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-7: 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-8: Risk based Monitoring

UNIT-9: Blinding and Randomization & Protocol Understanding

38 Blinding and it's Type

39 Randomization and it's type

40 Eligibility Criteria & Schedule of Activities

41 Introduction to Protocol Content, Clinical Trial Design & Planning Tools (Open Epi & CONSORT Guidelines)

42 Other contents of protocol

UNIT-10: Informed Consent

43 Definition and Guidelines

44 Exceptional Scenarios

45 Unit review and Q&A

UNIT-11: Documentation

46 Data Management in Clinical research - 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-12: Adverse and Serious Adverse Events

53 Definitions

54 Reporting Timelines

55 Permitted and Prohibited Therapy

56 Adverse events_Case Studies | Concomitant Medications

57 Unit review and Q&A

UNIT-13: Audit and Inspection & Data Entry of Clinical trial

58 Definition and Differences

59 Important Terminologies

60 Data Entry Process & demonstration using tools

61 Data Entry Facilities

62 Life Cycle of a Data

63 21 CFR

64 Unit review and Q&A

UNIT-14: 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-15: 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-16: Regulatory Authorities and common Abbreviations

72 Worldwide Regulatory Authorities & its functions

73 Regulatory Environment in India (CDSCO ICMR and others)

74 Regulatory, Ethics & Reporting Tool (ICMJE/Open Science Framework)

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-17: Latest Advancement in Clinical Trial

79 Involvement of AI in subject Recruitment

80 Protocol Designing and Data Analysis using OHDSI

81 Key Risk Indicators and Quality Tolerance Limit

82 Risk Assessment, Centralized Monitoring and Decentralized Clinical Trials

83 Decentralized Clinical Trials Data Analysis using Phython

84 Role of AI tools in Clinical Research advancement (ChatGPT, Gemini, Co-Pilot)

UNIT-18: Career Roadmap, Doubt clearing and open discussion

85 Career Path: Required Qualifications, skills, certifications, career path (entry-higher level); salary trends, stakeholders

86 Growth Opportunities in Biotech & Pharma in India & Abroad

87 Resume building & networking strategies (Industry associations, LinkedIn, Conferences)

88 Final Doubt Clearing and Open Discussion

CLINICAL RESEARCH ONLINE PROJECT TOPICS

ONE MONTH PROJECT WORK

PROJECT_1. Clinical Trial Design and Protocol Writing

- Objective: Students will design a clinical trial protocol, including objectives, phases, eligibility criteria, randomization, blinding, and other protocol content.
- Duration: One month

Key Deliverables: Complete trial protocol document and a presentation explaining their design (Study design justification eg: RCT, open-label, single arm).

PROJECT_2. Case Report Form (CRF) Design and Data Entry

- Objective: Create a CRF and enter mock clinical trial data into an eCRF system, can also provide a protocol synopsis for the CRF context. Learn how to ensure data accuracy, handle discrepancies, and understand data lifecycle.
- Duration: one month

Key Deliverables: Completed CRF and mock database with entries (Populate the CRF with at least 10–15 fictional patient records).

PROJECT_3. Adverse Event Reporting and Analysis

- Objective: Develop a risk-based monitoring plan for a mock clinical trial. Include key risk indicators (KRIs), quality tolerance limits (QTLs), and monitoring strategies.
- Duration: One month

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

PROJECT_4. Risk-Based Monitoring (RBM) Project

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- Objective: Develop a risk-based monitoring plan for a mock clinical trial. Include key risk indicators (KRIs), quality tolerance limits (QTLs), and monitoring strategies.
- Duration: One month

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

PROJECT_5. Regulatory Submission Process Simulation

- Objective: Create mock regulatory submission documents for a new drug application (NDA) or clinical trial application (CTA) based on ICH GCP guidelines (industry standard protocol template, ICH E6-compliant).
- Duration: One month

Key Deliverables: Regulatory submission dossier, including required documents such as investigator brochures and protocol.

PROJECT_6. Data Analysis and AI Application in Clinical Trials

- Objective: Use the provided datasets to analyze clinical trial data using basic statistical tools. Demonstrate how data analysis can optimize trial outcomes.
- Duration: One month

Key Deliverables: Data analysis report, including visualizations and statistical insights with sample size & statistical planning.

PROJECT_7. Preclinical to Clinical Transition Project

- Objective: Design a roadmap detailing the transition from preclinical studies to clinical trials for a hypothetical drug, covering NCE development, CMC processes, and IND submission requirements.
- Duration: One month

Key Deliverables: Transition roadmap and presentation.

PROJECT_8. Regulatory Environment Analysis

- Objective: Compare regulatory environments in India, the US, and Europe. Highlight similarities, differences, and challenges in gaining approval for clinical trials.
- Duration: One month

Key Deliverables: Comparative regulatory analysis document.

PROJECT_9. Real-Time Problem Solving in Clinical Trials

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

Key Deliverables: Detailed case analysis and recommended solutions.

Extended Projects

3 Months Project Work

Project 1: Design a Full Randomized Controlled Trial (RCT) Protocol

- Goal: Train students to develop a full RCT proposal from scratch.
- Steps:
- Define a clinical question (PICO format)
- Determine study population, intervention, control, outcomes
- Specify sample size and randomization plan
- Ethical considerations and CONSORT checklist
- Tools:
- SPIRIT checklist (protocol writing guide)
- OpenEpi or Epitools for sample size
- CONSORT for reporting quality

Skills learned: Study design, methodology, ethics, trial reporting

Project 2: Ethics in Trials: A Modern Retrospective

- Project: Pick an unethical or controversial trial (Tuskegee, Henrietta Lacks, Pfizer Nigeria) and do:
- Ethics violation breakdown
- What modern GCP principles were missing
- Design a compliant version of that study today

Project 3: Understanding the Impact of Diabetes on Quality of Life

- Objectives:
- 1. To assess the quality of life (QoL) among patients with diabetes.
- 2. To identify the factors that influence QoL in diabetic patients, including physical, emotional, and social aspects.
- 3. To compare the QoL between Type 1 and Type 2 diabetes patients.
- 4. To provide recommendations for improving QoL based on the findings.
-
- Tools and Methods:
- 1. Survey Development:
- - Create a comprehensive questionnaire that includes:
- - Demographic information (age, gender, duration of diabetes, type of diabetes).
- - Standardized QoL assessment tools (e.g., WHOQOL-BREF, Diabetes Quality of Life Measure).
- - Open-ended questions to gather qualitative data on personal experiences.

- 2. Data Collection:
- - Administer surveys online, ensuring confidentiality and ethical considerations.
- - Utilize statistical software (e.g., SPSS, R) for data analysis.
-
- 3. Statistical Analysis:
- - Use descriptive statistics to summarize demographic data.
- - Employ comparative analysis (e.g., t-tests, ANOVA) to evaluate QoL differences between Type 1 and Type 2 diabetes patients.
- - Conduct regression analysis to identify factors influencing QoL.
-
- Expected Results:
- 1. Quality of Life Scores:
- - Present average QoL scores for Type 1 and Type 2 diabetes patients, highlighting significant differences.
-
- 2. Influencing Factors:
- - Identify key factors that significantly affect QoL, such as age, duration of diabetes, comorbidities, and social support.
-
- 3. Qualitative Insights:
- - Summarize themes from open-ended responses, providing a deeper understanding of patients' emotional and social challenges.
-
- 4. Recommendations:
- - Develop actionable recommendations for healthcare providers to enhance patient support and interventions based on the findings.
-
- 5. Presentation:
- - Prepare a comprehensive report and presentation to share findings with stakeholders, including healthcare professionals, patients, and community organizations.

Project 4: Systematic Review on COVID-19 Vaccine Adverse Events

- Objective: To evaluate and categorize reported adverse events associated with COVID-19 vaccines from published literature.
- Duration: 3 months

1. Tasks:

- Frame research question using PICO format
- Conduct literature search (PubMed, Scopus)
- Screen studies, extract data
- Categorize adverse events (mild/moderate/severe)
- Frame research question using PICO format; Conduct literature search (PubMed, Scopus); Screen studies, extract data; Categorize adverse events (mild/moderate/severe)

2. Deliverables:

- PRISMA Flowchart
- Summary tables of adverse events
- Draft manuscript/report of systematic review

Project 5: Virtual Clinical Trial Protocol Design

- Objective: To design a protocol for a virtual clinical trial on a selected therapeutic area (e.g., Type 2 Diabetes).

- Duration: 3 month

- Tasks:

- Define study objectives, endpoints, and population
- Draft inclusion/exclusion criteria
- Plan remote data collection & safety monitoring
- Write protocol with mock consent form

- Deliverables:

- Complete Clinical Trial Protocol (ICH-GCP format)
- Mock informed consent document
- PowerPoint presentation for project defense

Project 6: Online Survey on Clinical Trial Awareness Among Healthcare Students

- Objective: To assess the awareness, perception, and willingness to participate in clinical trials among healthcare students.

- Duration: 3 months

- Tasks:

- Design online survey (Google Forms/SurveyMonkey)
- Distribute to students via social media/email
- Analyze responses (quantitative & qualitative)
- Generate insights on educational gaps

- Deliverables:

- Survey instrument (validated)
- Response analysis (charts and tables)
- Presentation/report of findings with recommendations

Project 7: Critical Appraisal of Published Randomized Controlled Trials (RCTs)

- Objective: To assess the methodological quality of 5 published RCTs using standard tools (e.g., CONSORT, JADAD scale).

- Duration: 3 months

- Tasks:

- Select 5 peer-reviewed RCTs from high-impact journals
- Evaluate design, bias, and reporting quality
- Apply tools like JADAD, Cochrane RoB tool
- Suggest improvements in reporting

- Deliverables:

- Appraisal summary sheet per article
- Comparative table of quality scores
- Report highlighting key findings and gaps
- By focusing on these projects, students can still gain robust, practical experience in clinical research without relying on virtual simulations.

Project 8. Clinical Trial Design and Protocol Writing

- Objective: Students will design a clinical trial protocol, including objectives, phases, eligibility criteria, randomization, blinding, schedule of activities, and other protocol content.
- Duration: Three months
- Key Deliverables: Complete trial protocol document and a presentation explaining their design (Study design justification eg: RCT, open-label, single arm).

Project 9: Data Analysis of Public Clinical Trial Dataset (According to 3 months)

- Objective: To analyze and interpret patient-level data from a publicly available clinical trial (e.g., ClinicalTrials.gov or Project Data Sphere).

- Tasks:

- Select an open-access dataset
- Perform data cleaning and descriptive statistics
- Conduct subgroup and outcome analysis
- Interpret findings and assess clinical relevance

- Deliverables:
-
- Cleaned dataset with analysis summary
- Statistical report (SPSS/R outputs)
- Final interpretation report (PDF)

6 Months Project Work

Project_1. Descriptive Analysis of a Clinical Dataset (Any Disease)

- Goal: Understand and describe patient demographics and outcomes.
- Dataset: Open datasets like MIMIC-IV, ClinicalTrials.gov, or any CSV from Kaggle (https://www.kaggle.com/datasets).
- Tasks:
- Count how many males vs. females
- Average age, most common diagnoses
- Number of patients receiving different treatments
- Tools: Excel, Google Sheets, or Python (Pandas)
- Skills learned: Data loading, filtering, simple plots (bar, pie), summarizing data

Project_2. Tracking Patient Visits Over Time

- Goal: Plot how many patients visited the clinic each month.
- Data: Simple date-wise records of patient check-ins.
- Tasks:
- Convert date to month/year
- Count visits per month
- Line graph or bar chart of visit trends
- Tools: Excel, Google Sheets, or Python (Matplotlib, Seaborn)

Skills learned: Time-based grouping, basic visualization

Project_3. Adverse Event Frequency Count

- Goal: Identify the most common side effects reported in a dataset.
- Data: CSV with patient ID, treatment, and adverse event columns.
- Tasks:
- Count total adverse events
- Group by type of adverse event
- Find the top 5 most frequent
- Tools: Python (Pandas), Excel
- Skills learned: Grouping data, sorting, counting frequencies

Project _4. Treatment Group Comparison

- Goal: Compare average recovery time in two treatment groups.
- Data: Simple dataset with treatment type and recovery days.
- Tasks:
- Group by treatment type
- Calculate average recovery days
- Maybe try a t-test
- Tools: Excel (with Analysis Toolpak), or Python
- Skills learned: Group comparisons, mean, std dev, intro to statistical testing

PROJECT_5. Create a Mini Clinical Trial Report

- Goal: Simulate a trial and summarize the results like a research report.
- Steps:
- Make-up data: 10 patients per group, 2 treatment arms
- Note age, gender, treatment, outcome
- Calculate and report: success rate, average age, dropout count
- Format: Word document or PowerPoint with charts and tables
- Skills learned: Data summarization, basic reporting, presenting findings

Project_6: Data Analysis of Public Clinical Trial Dataset

- Objective: To analyze and interpret patient-level data from a publicly available clinical trial (e.g., ClinicalTrials.gov or Project Data Sphere).

- Tasks:

- Select an open-access dataset
- Perform data cleaning and descriptive statistics
- Conduct subgroup and outcome analysis
- Interpret findings and assess clinical relevance

- Deliverables:

- Cleaned dataset with analysis summary
- Statistical report (SPSS/R outputs)
- Final interpretation report (PDF)

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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?

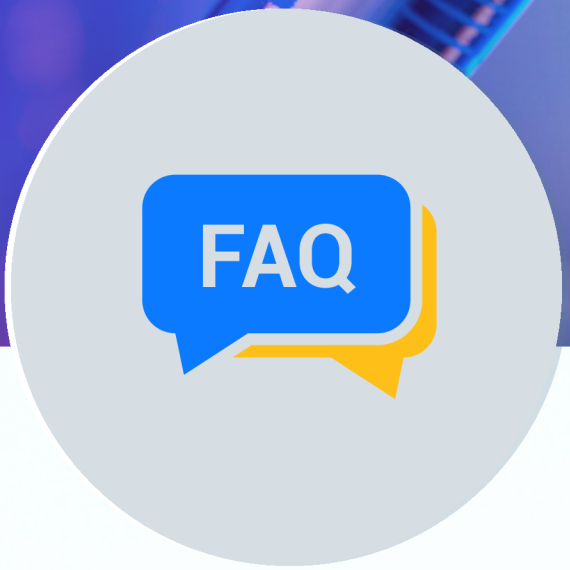
This course is ideal for

- 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 placement assistance from day 1 of your joining the course. Apply for Exclusive Freshers jobs, get trained by our mentors & Placement team. Get Work experience letter with long term project work. For more details contact our team at 1800-1200-1818

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