Curio Training & Research Institute (CTRI) & CliMed Research Solutions

Presents

"How to Become a Clinical Research Investigator"

Professional Certificate Training Course for Medical & Dental Students/Professionals

Six-Month Executive Diploma in Clinical Research & Project Management

Gateway to enter the Medical and Pharmaceutical Research & Regulatory Industry

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About the Curio

Curio Training and Research Institute (CTRI) is a constituent unit of CliMed Research Solutions India, dedicated to transforming the healthcare (Medical & Pharmaceutical) industries through specialized training and research initiatives. Our mission is to nurture talent, foster innovation, and drive excellence in these critical sectors.

CTRI offers a diverse range of courses tailored to meet the evolving needs of professionals in the pharmaceutical and healthcare fields. Currently, we provide the following programs:

- **Medical Writing Diploma**
- **Clinical Research Diploma**
- **Pharmacovigilance Training Including Diploma (6 Courses)**
- **Artificial Intelligence and Machine Learning (AI ML) Diploma**
- **Regulatory Affairs Diploma**
- **Industrial Internships**
- **Research Paper Writing Training**
- **ICH GCP E6 (R3) Training**
- **Clinical Data Management (CDM)**
- **Medical Coding Courses**
- **SAS Programming Hands-on Training**
- **Clinical Research Associate (CRA) Training and many more**

About the Course

The Executive Diploma in Clinical Research & Project Management is a comprehensive guide for MBBS, BDS, and other healthcare students aiming to excel as Clinical Research Investigators. It covers every facet of clinical research, from foundational principles to advanced practical skills. Through a blend of theoretical knowledge and hands-on experience, students will learn to design, execute, and manage clinical trials ethically and efficiently. The course emphasizes patient safety, regulatory compliance, and quality assurance, ensuring participants are well-equipped to handle real-world challenges. With expert-led sessions and practical workshops, this program prepares students for a promising career in the dynamic field of clinical research.

Who can enroll:

- *MBBD/BDS/BAMS/BHMS/PharmD Students, Nursing and Physician's assistants*
- *Doctors, Researchers, Academicians & Early-career Working Professionals*
- *Other Healthcare science & Public health Students*
- *Medical & Clinical Research Assistants, Associates*
- *Anyone who wants to learn*

For further eligibility inquiries, contact +91 9380436185

Objectives of the Course:

- **Understand Clinical Research Fundamentals:** Equip medical students with foundational knowledge of clinical research, including its phases, ethical considerations, and regulatory frameworks.
- **Develop Practical Skills:** Provide hands-on experience in drafting protocols and consent forms, managing clinical trials, and performing key responsibilities of a Clinical Research Investigator.
- **Foster Ethical Competence:** Emphasize the importance of ethical practices, informed consent, and patient welfare in clinical trials.
- **Navigate Regulatory Landscapes:** Familiarize students with global and local regulations, including Good Clinical Practice (GCP) guidelines.
- **Enhance Career Readiness:** Prepare students for diverse career opportunities in clinical research through practical training, professional development, and networking opportunities.
- **Master Quality and Safety Standards:** Ensure students understand the importance of quality assurance, adverse event management, and patient safety.

Key Takeaways

- Diploma Certificate
- Additional ICH GCP Guidelines Training with Certificate
- 100% Placement Assistance
- Class Recordings for 12-months

Course Trainers/Instructors

This course is fully designed and will be taken by the mentors working in renowned clinical research industries like GSK, Novartis, Kinapse, IQVIA etc.

Course Curriculum:

Module 1: Introduction to Clinical Research

- *Overview of clinical research*
- *Phases of Clinical Trials*
- *Roles of a Clinical Research Investigator (CRI)*
- *Ethical considerations in clinical research*

Module 2: Regulatory Landscape in Clinical Research

- *Overview of global regulatory bodies: FDA, EMA, ICM*
- *Indian regulatory framework for clinical trials*

Module 3: Study Protocols and Design

- *Components of a clinical trial protocol*
- *Different types of study designs: observational, interventional, RCTs*
- *Inclusion and exclusion criteria*

Module 4: Informed Consent Process

- *Importance of informed consent*
- *Drafting an informed consent form*
- *Conducting the informed consent process ethically*

Module 5: Good Clinical Practice (GCP)

- *Principles of GCP*
- *Investigator responsibilities under GCP*
- *Stakeholders' responsibilities*
- *New GCP updates (GCP E6 R3)*

Module 6: Site Setup and Feasibility Assessment

- *Selecting and setting up a clinical trial site*
- *Conducting site feasibility assessments*
- *Managing site infrastructure and resources*

Module 7: Patient Recruitment and Retention

- *Strategies for patient recruitment*
- *Addressing recruitment challenges*
- *Retention strategies and patient follow-up*

Module 8: Clinical Trial Operations

- *Study initiation and execution*
- *Managing trial documentation*
- *Coordination with sponsors, CROs, and site staff*

Module 9: Adverse Event Reporting and Management

- *Identifying adverse events (AEs) and serious adverse events (SAEs)*
- *Reporting timelines and procedures*
- *Managing patient safety during trials*

Module 10: Data Management and Documentation

- *Importance of accurate data collection*
- *Electronic Data Capture (EDC) systems*
- *Documentation standards and source data verification*

Module 11: Monitoring, Auditing & Inspections in Clinical Research

- *Role of monitors and auditors*
- *Preparing for site monitoring visits*
- *Audits & Inspections*

Module 12: Budgeting and Financial Management

- *Understanding clinical trial budgets*
- *Financial agreements with sponsors and CROs*
- *Managing site expenses and investigator payments*

Module 13: Quality Assurance in Clinical Trials

- *Importance of quality assurance (QA)*
- *QA tools and techniques*
- *Ensuring protocol adherence and compliance*

Module 14: Clinical Research Ethics

- *Role of Institutional Review Boards (IRBs) / Ethics Committees (ECs)*
- *Balancing scientific objectives with patient welfare*

Module 15: Career Pathways and Opportunities

- *Career options in clinical research*
- *Transitioning from investigator to other roles*
- *Networking and professional development*

Module 16: Final Assessment and Certification

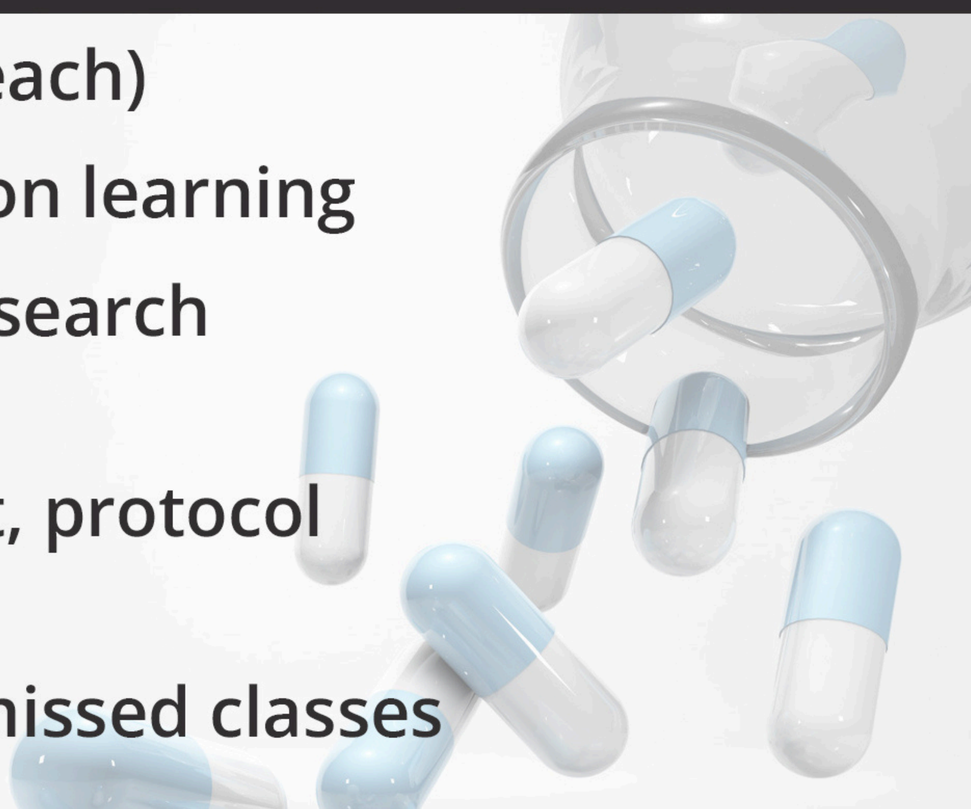
- *Comprehensive exam covering all modules*
- *Practical evaluation through mock clinical scenarios*
- *Certificate of Completion for participants*

Special Module: Scientific Writing & Publication

- *How to write a manuscript*
- *How to select the appropriate journal for publication*

Teaching Methodology:

- Weekly live interactive lectures (2 hours each)
- Assignments and case studies for hands-on learning
- Guest lectures by experienced Clinical Research Investigators
- Practical workshops on informed consent, protocol drafting, and data management
- Recordings will be shared in case of live missed classes



Certification:

- *The Diploma certificate will be given after completing assignments and the final exam at the end of the course.*

Date of Commencement:
March 30, 2025

Limited Seats
50 Only

Last Date of Registration:
March 16, 2025

Mode
Online on Zoom Meetings

Classes:
Every Sunday (11.00AM – 1.00PM)

Course Fees:
4999/- INR *(After 50% Discount on 9999/- INR)*

Registration Link
https://rzp.io/rzp/htbinm

Course Convener

Dr. Ajit Singh

CEO and Founder, CliMed Research Solutions & Curio
Research Scientist for ICMR, Department of Medicine,
Kasturba Medical College & Hospital, MAHE

Dr. Ajit Singh, Founder, and Chief Executive Officer at CliMed Research Solutions & Curio - India, a young entrepreneur & scientist, has completed his Ph.D. in Cardiology from the eminent Manipal Academy of Higher Education (MAHE), a leading organization in research and education in India. Recently, he was appointed as Research Scientist & RAIII for ICMR'' at the Department of Medicine, Kasturba Medical College, Manipal. He also serves as 'National Director for Research' at 'World Youth Heart Federation' (WYHF-India) & 'Principal Investigator for 'Manipal Heart Failure Registry (MHFR).' In July 2021, he was appointed as Vice president of the Medical Artificial Intelligence Wing at Idika AI, Mumbai.

He has published more than 40 papers in different streams of medicine, including Cardiology, Cardio-oncology, and Infectious Diseases. He is the investigator and site coordinator for many international clinical trials. Dr. Singh is an honorary reviewer in many reputed journals, including Oxford Group, BMJ Group, and Spriner Group of Journals. Dr. Singh has been appointed as Editor-in-chief for the Journal of Basic and Clinical Cardiovascular Research and an editorial board member for several medical journals. He has received several international research and travel grants from esteemed organizations, including the European Society of Cardiology, the Indian Council for Medical Research, DST-SERB, and the American College of Cardiology. He received the 'Young Achievers Award 2019' and 'Yung Scientist Award 2020' in Cardiology Research from reputed international organizations. Dr. Singh has traveled to more than ten countries regarding his research presentations and invited lectures.