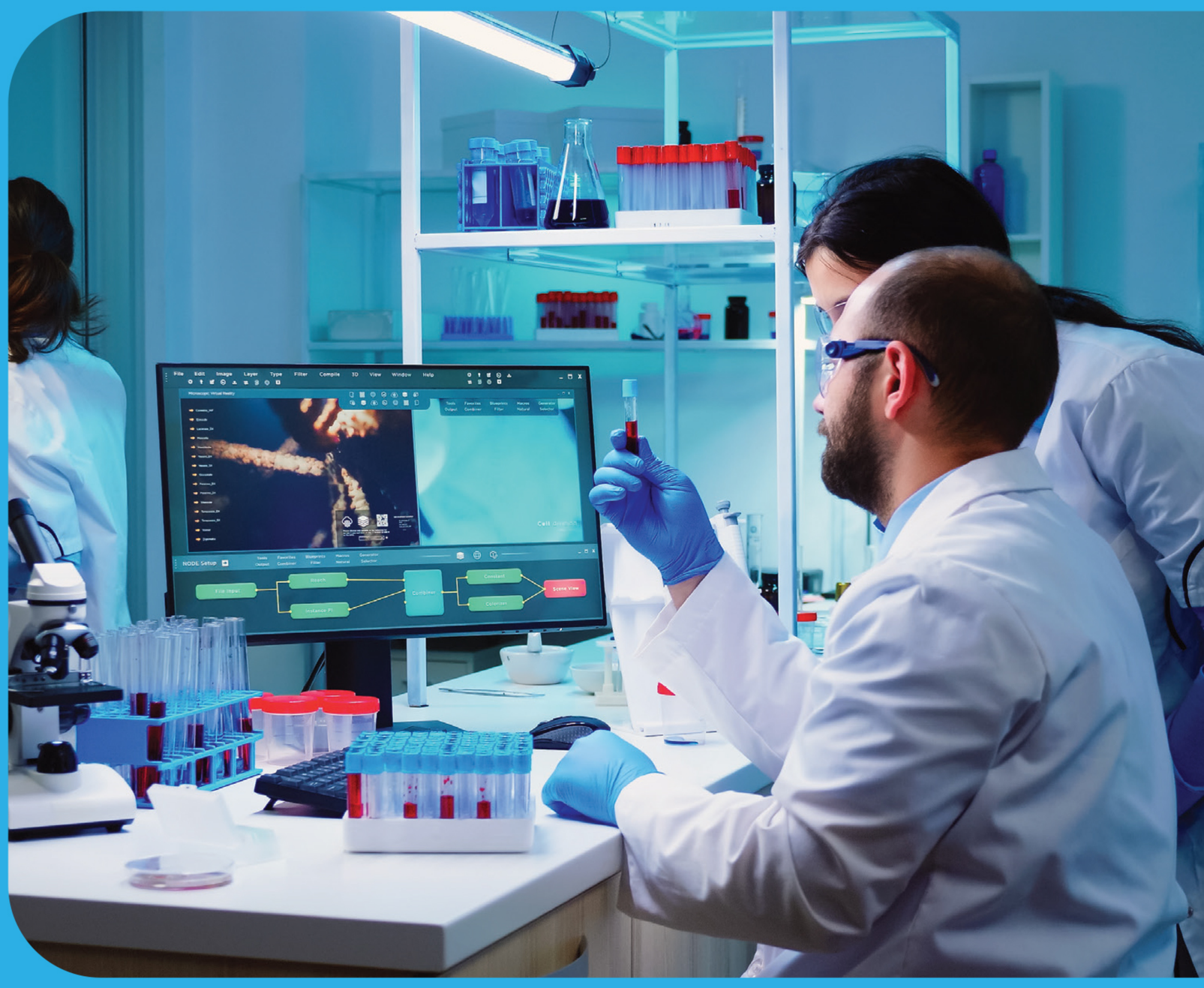
POST GRADUATE
CERTIFICATE COURSE IN

CLINICAL RESEARCH & PROJECT MANAGEMENT



CURIO

CliMed
Research Solutions

Azadi Ka Amrit Mahotsav

SKILL DEVELOPEMENT
PROGRAM

ABOUT THE CURIO

Curio Training and Research Institute (CTRI) is the Constituent Unit of CliMed Research Solutions India, dedicated to providing Pharma and Healthcare Industry Training. Curio is established to transform the pharma and healthcare landscape by nurturing talent, fostering innovation, and driving excellence in these critical sectors.

Curio commits to producing professionals well-versed in theory and equipped with practical skills to lead, innovate, and create positive change. Curio provides industry -oriented value-added, skill development courses, corporate training, and career consultation to individuals and institutions/universities.

MUST READ BEFORE YOU GO TO THE COURSE DETAILS

What is a Clinical Trial?

A clinical trial (also clinical research) is a research study in human volunteers to answer specific health questions. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people and ways to improve health. Interventional trials determine whether experimental treatments or new ways of using known therapies are safe and effective under controlled environments."

Why training is essential?

Every human being has a natural instinct and desire to explore the world around him/ her. That is how the child starts his journey in life. We have the gift of observation and analysis. We need to sharpen these faculties so that our observation and analysis is useful not only for ourselves but also for others. We observe through our own senses and analyze through our understanding. There is a natural bias of our previous learning. To make our observations free from this bias we need to do controlled study and document our findings for acceptance by others. That is why we need some training in research methodology.

How is this course different from other courses in clinical research?

Most courses are lecture oriented only and mostly from one or two routine faculty. Each of our instructors is industry expert and holding more than 10 years of experience in their domain. Also, each instructor is available for consultation and will answer questions from students.

MUST READ BEFORE YOU GO TO THE COURSE DETAILS

If I were already in the industry would this course be worth taking?

Yes, if you want a well-rounded program that provides you with the drug development process from A to Z and a comprehensive understanding of Good Clinical Practices and the International Conference of Harmonization guidelines.

What is the typical background of the students that enrol in this program?

Many of our students are Healthcare professionals (MBBS, BHMS, BAMS, PharmD or Medical Technologist). We also have a large number of students with a college degree (Bachelors, Masters or a PhD) in a social or life science, or Allied Health Field.

What is a typical Entry level position for freshers, and what are the prospects

Clinical Research Coordinator (CRC) and Clinical Trial Assistant (CTA) are typical entry level positions in a CROs or Pharmaceuticals/Biotech/Device companies. Equipped with the foundation given by this course, an individual can start at this level and grow in these allied health fields to become a Clinical Research Associates, Sr. Clinical Research Associates, Research Investigator, Data Analyst, Project Manager etc.

COURSE INFO

CLASS TIMINGS

Weekend (Friday/Saturday or Sunday)

CERTIFICATION

Students must attend 80% classes for being eligible to get certificate.

COURSE FEES

INR 3499/-

~~INR 9999/-~~ 65% INSTITUTION INTRODUCTORY DISCOUNT

*For institution and group registrations, contact +91 9620523426

DURATION OF THE COURSE

The course is of 6 months duration and there is no exemption of subjects for candidates from various academic backgrounds.

LAST DATE TO REGISTER

JANUARY 10, 2024

COURSE COMMENCEMENT

JANUARY 14, 2024

COURSE DETAILS

The present course is a primer for general understanding of clinical trial process and start as CTA, CRC or Data Entry Associate. On job learning would be facilitated by this course. Further courses would be useful to gain in-depth knowledge in the field of interest such as Medical Writing, Pharmacovigilance, Data management, SAS Programming, for further growth and deeper understanding of the respective domain.

REGISTER TODAY!

https://rzp.io/l/CPGCRPM

COURSE HIGHLIGHTS

01 Exclusive Course Design including all domains of Clinical Research

02 Expert resource persons from top-notch companies

03 Extensive coverage on Pharmacovigilance, Regulatory Affairs, Medical Writing, Clinical Data Management & Project Management etc.

04 30-day Industrial Clinical Research Training (Virtual) with Personalized Assignments and Industrial Projects

05 Leadership Dialogues (Live virtual interaction with A-level corporates and academicians)

06 Affordable price with numerous discount facilities

07 Separate Certificates for Course Completion & Industrial Training

08 100% Live classes with real-time query resolution & end-to-end engagement

KEY TAKEAWAYS

- **Course Completion Certificate**
- **Additional Industrial Training Certificate**
- **Brushed-up skills**
- **Recorded Video Sessions**

COURSE SYLLABUS

Clinical Research

- An Overview of Clinical Research and Scope
- Drug Development Process
- Animal studies in drug development, ADME, Pharmacodynamics & Pharmacokinetics
- Protocol contents and Types of Clinical Study Design
- History and Origin of Ethical Principles in Clinical Research
- ICH: history, purpose, principles, guidelines
- Good Clinical Practice (GCP)-ICH E6: Responsibilities of Sponsors, Investigators, Monitor
- Ethics committees: Roles & responsibility of IEC and IRB
- Informed consent form and consenting process

Regulatory Affairs

- International Scenario of Regulatory Aspects: FDA, EMEA, TGA, MHLW-Japan,
- Drug Regulatory Affairs-India (DCGI & CDSCO):
- New Drug Rules 2019
- IND and NDA process

Clinical Monitoring, Audits and Inspections

- Source documents and Trial Master File
- Monitoring process in clinical trials including report
- Different monitoring visits: SIV, Routine and Close out
- Audits/ Inspections: Definition, Types & procedure

Pharmacovigilance & Clinical Safety

- Pharmacovigilance: International procedures/methodologies
- Definitions of AE, ADR, SAE, UADR
- GVP guidelines
- Introduction to PV database and An Overview of Case Processing

Clinical Data Management (CDM)

- CRF designing and data retrieval from CRF
- Database designing and software for clinical data management
- Query raising and query resolution, Database update, data safety and database locking
- Clinical Data Interchange Standards Consortium (CDISC) and 21 CFR Part 11 compliance

Medical Writing

- Medical writing in clinical research and its importance
- Principles of good medical writing
- ICH E3 Structure & Content of Clinical Study Reports;
- Format of Paper for publication (IMRAD structure)

Biostatistics and Data Analysis

- Role of Biostatistics in clinical trial
- Statistical tests of significance and their uses

Project Management

- Principles & Tools of Project Management

Job Readiness support

- How to prepare resume and get ready for an interview
- Opportunity for mock interview

COURSE CONVENER

Dr. Ajit Singh

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

Dr. Ajit Singh, Co-founder & Chief Executive Officer at CliMed Research Solutions – 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 is also serving as 'National Director for Research' at 'World Youth Heart Federation' (WYHF-India) and '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 Springer 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 travelled to more than ten countries regarding his research presentations and invited lectures.