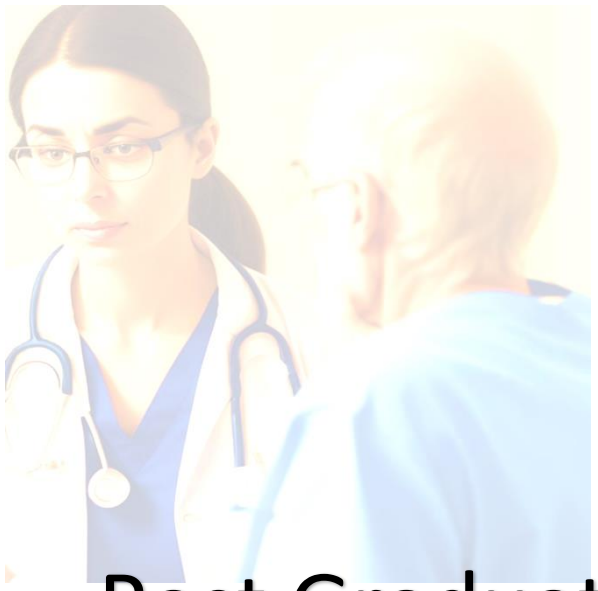

Post Graduate Diploma in

Clinical Research

Organised By

Tuliphall CliniResearch Private Limited (TCR)

in Collaboration with

Kolkata Gynecological Oncology Trials and Translational Research Group (KolGOTrg)

Objectives of the Programme:

- Primarily focuses on the practical aspects of clinical trials and intensive practical training on clinical trials.
- This program is designed for those who wish to have a thorough understanding of clinical trials before entering the field and who have general or specialized experience in clinical trials to experience roles in the design, management, analysis, and expansion of clinical trials.
- This course will enable experienced healthcare professionals to contribute to clinical research delivery and will develop future leaders.
- Clear understanding of the fundamental principles of Clinical Trials (CTs) and its regulatory requirements.
- Course topics are addressed with perspectives from both academic research and the pharmaceutical industry.
- Learning activity contains 1. Lecture sessions, 2. Classroom based activities, 3. Project work, 4. Preparation for assessments along with self-directed learning guided by experienced teachers.

Overview of the Programme

- This course contains 60 credits in 9 months' time.
- This course is Hybrid format and students can choose to attend in person in Kolkata or online.
- Hybrid lectures will be arranged weekly once for 3 hours per session along with 2 hours classroom-based activities.
- This course is designed towards more practical sessions for 3 months (480 hours cover 48 credits) than classroom sessions for 6 months (120 hours covers 12 credits).

Who should attend?

This course is open to clinical research professionals, research managers, statisticians, and other academics with an interest in clinical trials, and anyone who wants to understand the rigorous evaluation of medical interventions.

When course will start?

Course dates: September' 2023, **Only 10 seats are available in each batch.**

Minimum Qualification Required?:

Minimum eligibility criteria for application to the course would be either of the following:

- MBBS, BAMS, BDS, BHMS, Physiotherapy and Occupational Therapy Graduates
- Nurses Graduate, B.Pharm/M.Pharm, BSc/ MSc in Sciences/Life sciences/ Biosciences with any of the following subjects-Chemistry, Botany, Zoology, Biochemistry, Statistics, Microbiology, Genetics and Biotech with min 50% can apply.

Immediate Job Profiles

- Clinical Research Coordinator
- Clinical Research Associate
- Clinical Trial Assistant
- Drug Safety Associate
- Clinical Data Associate / Data Process Associate
- Study Startup Specialist
- Regulatory Affair Executive
- Medical Writer

Duration& Credit

Total duration 9 months for 60 credits (600 hours)
(6 months (12 credits) theory sessions, weekly 5 hours contains 3 hours blended lecture sessions and 2 hours of classroom-based work.
3 months (48 credits) hands-on practical sessions, weekly 40 hours along with project work.
Practical Hands-on experience certificate will be issued after successful completion of 480 hours of practical session.

Potential Employers

Contract Research Organizations, Pharmaceutical Companies, IT Companies, Premier Hospitals

Course Fees

The course fee for 2023 batch of both online and in person is given below:

1. **Anyone interested to attend only one/few modules**– ₹ 10,000 INR each course module (Note: Course completion certificate will only be issued to those complete total 8 modules (contains core subjects and elective subjects)
2. **Anyone wants to pay full cost of the course**–₹ 50,000 INR (if paid one time)
3. **Anyone want to pay fees by installment**–₹ 70,000 INR total breakdown ₹ 20,000 INR in advance and then monthly ₹ 10,000 INR (by 5th day of each month, else ₹ 100 INR will be added daily basis until the date of payment) in 5 installments.
4. **Anyone interested to attend only hands-on practical session minimum for 6months** (will be eligible for Paid Internship) will pay ₹ 10,000 INR monthly (by 5th day of each month, else ₹ 100 INR will be added daily basis until the date of payment).

Course content

The topics to be covered will include:

- Design of RCT: randomization, blinding, trial size
- Ethical conduct: participant consent, data monitoring and when to stop early.
- Good Clinical Practice (GCP) training
- Introduction to statistical methods for design and analysis
- Phases and designs for clinical trials
- Reporting: how to write, and critique, a clinical trial report
- Clinical trials in practice
- Practical experience in development of a clinical trial protocol.

(Participants will work in small groups to develop and present trial protocols.)

Key Teachers Portfolio:

1. **Dr Amlan Kanti Sarkar** (PhD in Pharmacy from Jadavpur University, having 18+ years of Clinical Research Experiences and worked as HOD in Clinical Research and Project Manager in Global Clinical Trials, Managing Director of Tuliphall CliniResearch Pvt. Ltd. and also the active member of Kolkata Gynecological Oncology Trials and Translational Research Group (KolGoTrg), the only GCIG member group from South Asia participating in international academic clinical trials in women's cancer)
2. **Dr Asima Mukhopadhyay, MD, PhD, MRCOG, CCT** (Consultant Gynaecological Oncology and Clinician Scientist, James Cook University Hospital and Northern Cancer Alliance, UK) and Clinical Senior Lecturer, Population Health Sciences Research Institute, Newcastle University, UK. She is an alumni of London School of Hygiene and Tropical Medicine in Clinical Trials, adjunct faculty of Sister Nivedita University Kolkata, and is the director of the Kolkata Gynecological Oncology Trials and Translational Research Group (KolGoTrg)- the only GCIG member group from South Asia participating in international academic clinical trials in women's cancer.
3. **Dr Atanu Bhattacharjee** (Statistician / Epidemiologist)
   Atanu Bhattacharjee is a Statistician of the Leicester Real World Evidence Unit, Diabetes Research Centre, University of Leicester. He completed his PhD in Statistics with Bayesian longitudinal analysis in 2012 at Gauhati University. He worked at Malabar Cancer Centre as Lecturer Biostatistics and Assistant Professor Biostatistics at Centre for Cancer Epidemiology, Tata Memorial Centre, Mumbai. His main research interests are survival, longitudinal data analysis, Bayesian inference, high dimensional data analysis and R package development. (https://www.lrwe.org.uk/our-team-blog/atanu-bhattacharjee)

More information please

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