Course Highlights:

- Optimal duration- 9 months (Including 3 months project works)
- Industry standard curriculum
- Proper training and Evaluation
- Optimal course fee
- Optimal faculty mix from Academia, Industry & Institutions
- ♦ Highest faculty : Student ratio
- ❖ 100% Placement assistance



Career Opportunities

Pharmaceutical Companies, Clinical Research Organizations (CROs),

Business Process Organizations (BPOs) companies, Regulatory Agency i.e. DCGI Office & CDSCO need professionals with good understanding of medical ethics, clinical research, pharmacovigilance practices and patient safety, western regulations and effective communications.



Certificate course in "Pharmacovigilance in Clinical Research" is designed to cover all aspects of clinical trials, Pharmacovigilance and drug safety management.

Placement Assistance

- The Clinical Research Unit of Medica Superspecialty Hospital will also provide vital information/ insights about Pharmaceutical Industry (Clinical Research Industry & Pharmacovigilance industry) function, work culture and job openings.
- CVs of the potential candidates will be forwarded to pharmaceutical companies & Contract Research Organization to facilitate placement of the students.

Complete application along with DD in favour of Registrar, Jadavpur University to be sent at the following address:

Dr. T.K Chatterjee
Director-Clinical Research Centre (CRC)
Jadavpur University, Kolkata-700032
Contact Number: 03324146666 (Ext. 2058/2041)

e-mail: crctkc@gmail.com

Certificate Course: "Pharmacovigilance in Clinical Research"

Eligibility: Students having B.Sc. (All streams of Life Science), B.Pharm, M.Pharm, B.Pharm(Ayur) M.BB.S./M.D/B.D.S/M.D.S. /Nursing/BHMS/BVSc/BPT /Diploma in Paramedical Courses.

Duration : NINE MONTHS- One Semester with 16 weeks per Semester & 50 lectures per Semester and further three months for project work.

Time : Saturday (1.00 pm to 5 pm) : No. of Seats : 25 **Tuition fees :** Rupees sixty thousand (Rs. 60,000/-) only.

Course structure:

(21 CREDITS/700 MARKS)

Theoretical Papers	Subject Code	Contact hours/week	Credits	Marks
Clinical Pharmacology	CER/PVCR/T/111A	3	3	100
Ethics and Guidelines	CER/PVCR /T/112A	3	3	100
Introduction to Clinical Research	CER/PVCR /T/113A	3	3	100
Clinical Trial Management-I	CER/PVCR /T /114A	3	3	100
Clinical Trial Management-II	CER/PVCR /T /115A	3	3	100
Pharmacovigilance	CER/PVCR /T /116A	3	3	100
PROJECT & SEMINAR	CER/PVCR /S /121A	3	3	100

Classifications of Grades

% of Marks Obtained	Performance	Grade	Grade Points
90 and above	Outstanding	S	10
80 to 89	Excellent	A	9
70 to 79	Very Good	В	8
60 to 69	Good	С	7
50 to 59	Fair	D	6
Less than 50	Unsatisfactory / Fail	X	0

FACULTY for the course

Dr Karabee Mukherjee MBBS, MD (PH), CIP

Manager, Clinical Trials & Research Dept. Apollo Gleneagles Hospital, Kolkata

Dr Arindam Kar MD, DNB, FNB, MNAMS, EDICM

HOD-Critical Care Medicine Dy Director-Clinical Research Medica Superspecialty Hospital

Dr Subhrojyoti Bhowmick MBBS,MD (Clinical Pharmacology)

Consultant-Clinical Pharmacology Manager-Clinical Research Medica Superspecialty Hospital

Dr Avijatri Datta, MBBS Senior Registrar-Critical Care Medicine

Manager-Clinical Research Medica Superspecialty Hospital

Prof B. Sa, M.Pharm, PhD

Professor, Ex Head of dept of Pharm Tech Jadavpur University.

Dr Subhadeep Sinha, MD (Visiting Faculty) Head & Associate Vice President-Clinical Development and Medical Affairs Hetero Drugs Limited, VIMTA.

Dr Chirag Trivedi, Ph.D (Visiting Faculty) Associate Director-Project Management and Strategic Initiatives Sanofi Aventis

Ms Suranjana Datta M.Sc (Clinical Research)

Senior Executive, Clinical Research & Quality Assurance, Apollo Gleneagles Hospital, Kolkata

Dr. P.K. Sharma, MD

Associate Vice President (R&D), Emami Ltd. Kolkata

.....several more luminaries in our list.



CLINICAL RESEARCH CENTRE (CRC), Jadavpur University, Kol-32

In Collaboration with



OFFERS

The
CERTIFICATE COURSE:
"PHARMACOVIGILANCE IN CLINICAL RESEARCH"

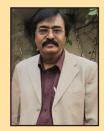
Information Brochure







Message From Dr. T.K. Chatterjee, Director, CRC, JU



It is my immense pleasure to announce that the new laboratory of our Clinical Research Centre (CRC), Jadavpur University is going to start a certificate course in "Pharmacovigilance in Clinical Research" in collaboration with Medica Superspecialty Hospital, Kolkata.

All through the last few years, the Clinical Research has emerged as a vital field in health care system. It is now

certain that the medicinal products must not only be efficacious but also be safe when administered. Therefore, before bringing a medicinal product in market for use, the product has to endure rigorous screening through toxicity, preclinical and different phases of clinical studies and pharmacovigilance. Pharmaceuticals, health and medicinal products, whether it is a small molecule, large molecule or botanical extract, are considered as ever mounting and unsaturated area of health management. In the present state of affairs, the establishment of safety and efficacy of the health products is of the paramount importance. And this requires generation of trained and highly skilled personnel. The Clinical Research is growing at a express pace and India has been recognized as an excellent partner for global Clinical Trials. Consequently, there is a great need for Clinical Research professionals not only in India but also in abroad. I anticipate this certificate course of Clinical Research Centre (CRC), Jadavpur University, is a right course to offer expertise, create manpower for meeting this requirement for the Pharmaceutical Industries. And this will give a new impetus to strengthen the clinical research in India. This type of course is inimitable and first of its kind in Eastern India. The aim and objective of our course is to facilitate both the quality and efficacy of clinical research activities. We will offer comprehensive knowledge of clinical trial services and provide the basis for regulatory approval of new pharmaceuticals and medical devices. The course has plans to explore the unexplored areas, to enable early clinical experience, to evaluate treatment effectiveness in everyday clinical setting and post marketing pharmacovigilance.

Clinical research industry in the last 5 years or so has also become a much sought after career opportunity. A vital part of drug development, clinical trials and their outcome affect all of us whether we are part of the research process or the final consumer of the drugs. However lack of information and a lot of misinformation abounds amongst most people regarding the requirements, challenges, and future prospects in this field. This course on Clinical research will focus on the different areas, which come under the umbrella of clinical research like CRO operations, Clinical trials, medical writing, Data Management, safety reporting and opportunities in each area. The scientific course will elaborate on the requirements, expectations, current trends and future opportunities not only in India but also internationally. Lectures of the course will be delivered by faculty from Academic, Industry and Institutions.

Message From Dr. A. Roy, Chairman & MD, Medica Superspecialty Hospital, Kolkata



Clinical Research is an emerging field in India. Due to certain prized attributes like large and diverse patient pool, comparative cost advantage and changes in regulatory framework has made India one of the choicest destinations for clinical research outsourcing. With Eastern India being an unexplored zone in this field,

the CRC will throw light upon the fact that, there is a huge scope of work in this area. So any clinical research professional should be aware of it and understand the trends and requirements of this field of work.

The industry is growing at an unparalleled rate. In the last 5 years it has achieved a respectable height and has opened up new vistas of employment for a large number of trained professionals. The clinical trials market world- wide is now worth over billions of dollars.

Clinical Research offers good career opportunities for students in the field of pharmacy, life sciences, biotech and medicine. Medica Superspecialty Hospital collaborates with CRC, Jadavpur University to launch a course in Pharmacovigilance in Clinical Research to meet the growing demands for a trained clinical research professional. The course curriculum is set in a manner so as to give both theoretical and practical knowledge to the students along with a soft skills development program.

Medica Superspecialty Hospital is one of the largest Superspecialty hospitals of eastern India, which is committed to bring the best in healthcare. The Hospital aspires to become a Centre of clinical excellence by offering modern, cutting-edge technology and therapeutic options to patients at an affordable rate. In its continuous journey to achieve Clinical Excellence, Medica Superspecialty Hospital has identified Clinical Research as an effective tool. The Hospital is committed to conduct ethical and scientifically sound clinical research. The Hospital has undertaken many initiatives for Clinical research capacity building in Eastern India like conducting Ethics Committee Member workshop and Good Clinical Practice workshops.

The main objective of Clinical Research Centre (CRC) at Jadavpur University is to facilitate the quality and efficiency of clinical research activities in the country.

One such initiative is collaboration with CRC, JU where apart from basic & clinical research activities active academic collaboration is also on the cards. The Hospital will partner with CRC to develop and run a course Pharmacovigilance in Clinical Research with the aim to train develop world-class Clinical Research Professionals from Eastern India.

About Jadavpur University

Jadavpur University is at present an internationally recognised premier university of the country. It is an urban university with a global perspective and is dedicated to creating leaders who will fashion a more humane and just world. Following in the footsteps of its predecessor, the University not only engages itself in teaching and research of international quality, but also provides societal services for the benefit of rural and urban populations. The programmes are directed towards achieving excellence in education and extending the benefits of improved technology to the society as a whole.

The faculty members are encouraged to add value to the courses so that students can secure employment or attempt entrepreneurship. Extension programmes and several other courses provide opportunities for the drop-outs at different levels to continue their education. The objective is that they should be able to earn a living and derive the impersonal pleasure of learning at the same time. The University also contributes in evolving modes of digital distance education as part of the National Mission on Education.

About Medica Superspecialty Hospital

Medica Superspecialty Hospital, a unit of Medica Synergie Pvt. Ltd. and one of the largest integrated healthcare delivery providers in eastern India, brings you the finest ambience and services for inpatient and outpatient treatment.

Medica Superspecialty Hospital is a tertiary care hospital with 500 beds and will provides state-of-the-art facilities in Cardiology and Cardiac



surgery, Neurology and Neurosurgery, Orthopaedics, Joints and Spine treatment, with a large Dialysis facility, advanced Urology services and a host of other support services under the same roof

The Clinical Research unit formed at Medica Superspecialty Hospital is governed by a group of experienced and qualified physicians and healthcare professionals.

Course Objective

Certificate course in "Pharmacovigilance in Clinical Research" is a program of 9 months duration with a primary focus on Clinical research and Pharmacovigilance. The course is designed to prepare aspirants for a career in Pharmacovigilance in clinical research and includes focus on Drug discovery and clinical trial processes, Good Clinical Practices (GCP) guidelines, Drug regulatory affairs, roles and responsibilities of various clinical trial, Pharmacovigilance & soft skills training.

