

**POST-GRADUATE DIPLOMA IN**  
**“CLINICAL RESEARCH AND REGULATORY AFFAIRS”**  
**ORGANISED BY**  
**BIOEQUIVALENCE STUDY CENTRE**  
**(ISO 9001 2008 CERTIFIED)**  
**JADAVPUR UNIVERSITY**

***Background of proposed course:***

India is becoming a hub for Clinical research. The demand for professionals in this field is growing rapidly. Clinical research business in India will be worth \$1.5 billion by 2011. Thus, there will soon be a massive demand for clinical research professionals, making it an interesting career option with massive growth potential.

Clinical research is all set to become the next big education in India. A large population with a substantial workforce and cost benefits influence in the future and it also states that more than 50,000 professionals will be required to meet the demands of the industry in India alone. This means Pharmacy Graduates can look forward to exciting and rewarding career in this thrust area. Trained Clinical Research professionals will also be in demand in abroad. Hence this centre would impart the basic training required for the candidates interested to pursue career in this area.

The Bioequivalence Study centre had been carrying out Bioequivalence study, clinical trial for a large number of pharma industries in India and abroad since last 6 years. The infrastructural and instrumental facilities are quite satisfactory to train the candidates in the field of clinical research with a special emphasis on pharmacokinetics. Moreover, the toxicity study on animals is another encouraging field developed by the centre. A brochure is enclosed herewith for further details.

**Course Objective**

To provide participants with a broad understanding of the basic principles employed within Clinical Research and regulatory affairs both domestically and internationally.

**Duration of course:** 6 months + 3 months (which includes project work ) which is divided into 2 semesters

**Course fee:** Rs. 75,000/- which is payable in two installments and includes all examination fees.

DD SHOULD BE DRAWN IN FAVOUR OF “REGISTRAR, JADAVPUR UNIVERSITY” and SEND TO THE COURSE DIRECTOR’S ADDRESS

**No. of seats :** 20 per batch

**Course Timings:** 4 hours per week preferably on Saturdays

**Course Content:** Delivered through fourteen focused modules spanning over nine months.

- **Module I** – Fundamentals of Clinical Operations
- **Module II** – Regulatory Affairs I
- **Module III** - Basic Pharmacology and Pharmacy in Clinical Research
- **Module IV** - Ethical Guidelines in Clinical Research
- **Module V** - Biostatistics in Clinical Research
- **Module VI** - Clinical Data Management I
- **Module VII** - Regulatory Affairs II
- **Module VIII** – Preclinical Studies: Safety & Efficacy
- **Module IX** - Clinical Data Management II
- **Module X** – Regulations in Clinical Research
- **Module XI** - Clinical Trial Documentation
- **Module XII** – Bioavailability / Bioequivalence
- **Module XIII** – Toxicity Study / Pharmacokinetics
- **Module XIV** – Project work

**Classroom teaching** by eminent faculty involving Lectures and Power Point Presentations.

**Assignments** would be given to students, which include preparation of CRF's (Case Record Forms), IC (Informed Consent Forms), PIs (Patient Information Sheets), Protocol Designing, PMS (Post Marketing Surveillance Studies) plan designing.

**Exercises** would be given to students wherein data on Toxicology, Bioavailability, Bio-equivalence would be made available to the students and inferences, graphs and calculations are drawn from the same. Exercises are also in the form of MCQs (Multiple choice questions), Q&A (questions and answers) and Report writing.

**Workshops** would be conducted for students emphasizing on problem-solving through interaction and exchange of information. Students have access to Institute's **Computer and Internet Facilities** enabling them in Data Searches and Computer aided decision-making. Students have access to the **Well-equipped library** on Clinical Research with latest books, periodicals, newspapers, Journals, prints and records are available for reading & reference.

### **Eligibility for this course:**

B.Sc./M.Sc. (All streams of Life Science)

B.E/B.Tech. (Chemical/Biotech/Computer Science)

MCA, B.Pharma, M.BB.S./M.D/B.D.S/M.D.S./Nursing/BHMS/BVSc/BPT

### **Course Director**

**Prof. (Dr.) T.K. Pal, Director, B.E. Centre, JU**

### **Course –Coordinators**

**Dr. Sangita Agarwal**

**Mrs. Debotri Ghosh Sarkar**

**Mrs. Bhaswati Gupta**

### **LIST OF DISTINGUISHED FACULTIES**

## **IN HOUSE FACULTIES:**

- **Dr. T.K Chattaraj, M.B.B.S.,M.D., Ex-Assistant Professor, N.R.S. Medical College & Hospital, Clinical Pharmacology**
- **Dr.Balaram Ghosh, M.B.B.S.,M.D., Lecturer, Bankura Medical College & Hospital, Bankura, WB**
- **Dr. Arunabha Biswas, M.D., National Medical College & Hospital, Kolkata**
- **Dr. T.Sen, Reader in Pharmacology, Dept. of Pharm.Tech. Jadavpur University, Kolkata**
- **Dr. S. Karmakar, Lecturer in Pharmacology, Dept. of Pharm.Tech. Jadavpur University, Kolkata**
- **Mr. Sankar Gupta, Ex Dy Drugs Controller, CDSCO, Kolkata**
- **Dr. Animesh Ghosh, M.Pharm., B.E.Study Centre, JU, Kolkata**
- **Dr. Anirbandeep Bose, M.Pharm., B.E.Study Centre, JU, Kolkata**
- **Dr. Sangita Agarwal, M.Sc., B.E.Study Centre, JU, Kolkata**

- **Mrs. Hira Chowdhury, M.Pharm., B.E.Study Centre, JU, Kolkata**
- **Mr. Amlan Kanti Sarkar, M.Sc., B.E.Study Centre, JU, Kolkata**
- **Mr. Ayan Das, M.Sc., B.E.Study Centre, JU, Kolkata**

## **LOCAL GUEST FACULTIES**

- **Prof. S.P.Mondal, M.D., Clinical Pharmacologist, Head, R.G.Kar College & Hospital Kolkata.**
- **Dr. Avijit Hazra, MBBS, M.D., Associate Professor, Dept. of Pharmacology, IPGMER, & SSKM Hospital, Kolkata.**
- **Dr. K.Ray, MD, Director, School of Tropical Medicines, Kolkata**
- **Dr. Suparna Chatterjee, Dept. of Pharmacology, IPGMER, Kolkata**
- **Dr. D.Deb, M.S (Surgeon) AMRI Hospital, Kolkata**

## **NATIONAL GUEST FACULTIES**

- **Dr. Gautam Palit, MBBS, MD, DyDirector, CDRI, Lucknow**
- **Dr. Mita Nandy, M.D., VP Medical Services & Clinical Research, LG Life Sciences, Haryana**
- **DR. N.R.Biswas, MD, Prof. of Pharmacology, AIMS, New Delhi**
- **Dr. Subhadeep Sinha, M.D. Vice President, Vimta Lab, Hyderabad**