M. Sc. COURSE IN CLINICAL RESEARCH

M.Sc course in Clinical Research is available at Amrita Institute of Medical Sciences & Research Centre at Kochi. It is a specially designed program to provide theoretical and practical training in coordinating clinical trials and clinical research efforts. The two years’ post graduate course will involve lecture components on key aspects on clinical research: namely, ICH/GCP Guidelines, Study design, Pre-clinical drug development strategies and methodologies, legal and regulatory aspects of clinical trials, ethical aspects, Statistical design and analysis, Data management and some exposure to pharmacology, anatomy, pathology, biochemistry, microbiology & physiology and also to personality development, communication skills & business development & management. In addition to the lecture component the unique aspect of this course is direct involvement of the students with the ongoing clinical research programs and an opportunity to manage and coordinate an existing clinical research projects under the direct guidance of the Principal Investigator. Each student will receive one-on-one attention in this practical component of the course. Currently, a number of clinical research projects are underway in the different clinical departments; both government funded research as well as pharmaceutical industry-sponsored clinical trials. All the students will therefore have ample opportunity to be directly trained in conducting and managing trials. Also, the students will get opportunity to work in a Pharma company to enable him/her to get practical training in working in an industry set up. The course also offers practical training in data entry and management and statistical analysis of data using statistical softwares, SAS and SPSS. A student may reach a level of involvement in an existing clinical research whereby they would need to make an Institutional Scientific Review Committee and Institutional Ethical Committee Presentation. They would also need to prepare and present project reports. In short, each student will be immediately ready to be absorbed as a clinical research coordinator / associate / manager at the end this program.

CAREER OPPORTUNITIES

There is a huge demand for qualified and trained Clinical Research Professionals. Clinical Research as well as pharmaceutical industries are rapidly expanding in India, creating exciting opportunities for trained professionals. During the last 5 years it has increased from Rs. 20 crores to more than Rs. 100 crores. It is expected that Clinical Research industry would require more than 50,000 jobs in clinical research with the demand increasing steadily. There is always a shortage of trained manpower in India where there are about 500-1000 investigators; while US has 50,000 investigators (Source, FICCI).

It is projected that India will need at least 10,000 investigators to meet the present requirement. With the implementation of product patent regime from 2005, many international pharmaceutical companies and CROs have set up their R&D base in India leading more number of clinical trials and thereby the job opportunities.

Clinical Research Associates (CRAs) are employed in both the hospital sector and the research industry and can advance to management roles. Clinical teams work in a broad range of research settings, including: Academic health centers, Research organizations, Companies involved in Pharmaceuticals, Biotechnology and Medical device firms.
Successful candidates can look forward to rewarding careers as Clinical Research Associates, Clinical Research Coordinators, Project managers etc. Clinical Research Associates play a very important role in monitoring and overseeing the conduct of the clinical trials in order to meet international / national guidelines as also national regulatory requirements. Clinical Research Associates can progress to become Clinical Research Managers. Their role is usually within the clinical or medical departments of a Company or in a Contract Research Organization.

**COURSE DETAILS**

**Duration of the course:** Two academic years

**BASIC QUALIFICATION TO APPLY FOR THE COURSE:**

MBBS, BDS, BAMS, BHMS, B. Pharm., B.Sc. in Biotechnology / Allied Health Sciences / Life Sciences / Nursing.

The Syllabus of this course includes the topics-Basic medical subjects Anatomy, Microbiology, Pathology, Biochemistry & Physiology; Pharmacology, Drug discovery & development, Pre-clinical models & Pharmacovigilance; Fundamentals of Clinical Trials (Trial Protocol, Project planning, Funding & ICH/GCP); Ethics in Human & Animal studies and Legal Considerations; Biostatistics & Epidemiological and Research methods; Clinical Trial operations (Trial management, Trial auditing, Data management & related topics); Pharmaceutical Chemistry and Quality assurance & Control in clinical research; Communication skills & Personality development, Business development & management and Health Economics.

Apart from the academic classes, students will have practical training in the planning, execution, data analysis and report writing of research projects in clinical trials. They will have clinical posting in the clinical Departments under the Principal investigators from 8.30 AM till afternoon for two years and Pharma company posting for a short period. They will also have to do individual research projects. At the end of the course they will have to submit separate reports on all these components—clinical posting, pharma company posting and individual projects.

There will be internal examinations in each paper at the end of each semester and a final University examination at the end of each year, followed by a viva-voce examination. In addition to the routine scheduled classes, students get opportunities to attend various Workshops / Seminars in Clinical Research sponsored and conducted by Pharmaceutical companies and Government organizations in collaboration with the Faculty at AIMS. A total of 30 Faculty members from various Clinical and Non-clinical Departments both from AIMS and outside AIMS are associated with the teaching / clinical programme of this course.