

# **ADVANCED DIPLOMA IN CLINICAL RESEARCH AND PHARMA REGULATORY AFFAIRS**

*From the pioneers in the Clinical Research Industry*



*Enhance your skills for a dream career in Clinical Research organization*



**Innovative Center for Biosciences**  
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## About US

**Innovative Centre for Biosciences**, the academic wing of ICBio Clinical Research Pvt. Ltd., Bangalore, was established in 2006 by likeminded, elite professionals and academicians from various segments of the society and is presently the leading research and customized education provider in the field of Clinical Research and Healthcare.

ICBio is collaborated with University of Mysore to offer globally recognized regular certificate courses in Health Care and Clinical Research with specialization in Clinical Research, Data Management, Pharmacovigilance, and Pharma Regulatory Affairs. ICBio uses high-quality and innovative approaches, methodologies and fulltime staff members, in research & teaching, to improve the job prospects for learners and aspirants of Life sciences thereby enabling them to meet the growing demand of skilled manpower for the Pharma, Healthcare, Life Sciences, and Biomedical industries.

ICBio provide quality training to all its students and ensures optimum utilization of its training resources by adhering to ISO 9001:2008 standards.

## ADVANCED DIPLOMA IN CLINICAL RESEARCH AND PHARMA REGULATORY AFFAIRS

### Course Details

|             |   |
|-------------|---|
| Certificate | Advanced Diploma in Clinical Research and Pharma Regulatory Affairs |
| Duration    | 3 months  |
| Classes     | Weekly 5 days   |
| Timings     | 10 a.m - 2 p.m  |

|             |   |
|-------------|---|
| Certificate | Advanced Diploma in Clinical Research and Pharma Regulatory Affairs |
| Duration    | 6 months  |
| Classes     | Sat & Sun   |
| Timings     | 10 a.m - 4 p.m  |

### Course Objective

- ▶ To impart knowledge about Clinical Research and services offered by ICBio.
- ▶ To make our students "Ready to be absorbed Clinical Research Professionals."
- ▶ To create awareness about Clinical Research and the latest techniques and trends in the industry.
- ▶ To create awareness about the potential of the Clinical Research industry.
- ▶ To create awareness about Career Prospects in the Clinical Research industry.

### Eligibility

Graduates from the following stream are eligible to join

- ▶ Life sciences
- ▶ Pharmacy
- ▶ Nursing
- ▶ Dental
- ▶ Medicine
- ▶ Biotechnology
- ▶ Bio medical Engineering

### Course Curriculum

| PAPER | SUBJECT   | MARKS |
|-------|---|-------|
| I     | Clinical Research and Clinical Pharmacology”            | 100   |
| II    | Ethics, Guidelines and Regulations in Clinical Research | 100   |
| III   | Clinical Trial Management and Quality Management        | 100   |
| IV    | Pharma Regulatory Affairs                               | 100   |
| V     | Internal Assessment                                     | 100   |
| VI    | Viva  | 100   |

### Admission

- ▶ Send your updated CV (your 10<sup>th</sup>, 12<sup>th</sup>, B.Sc. and / or M.Sc. results)
- ▶ Selection Process
- ▶ Selection letter
- ▶ Registration.

For Registration submit the duly filled application form along with copies of your 10<sup>th</sup>, 12<sup>th</sup> and graduation certificates and two passport size photographs, personally/post at our campus along with the prescribed registration fees.

### Examination and Certification

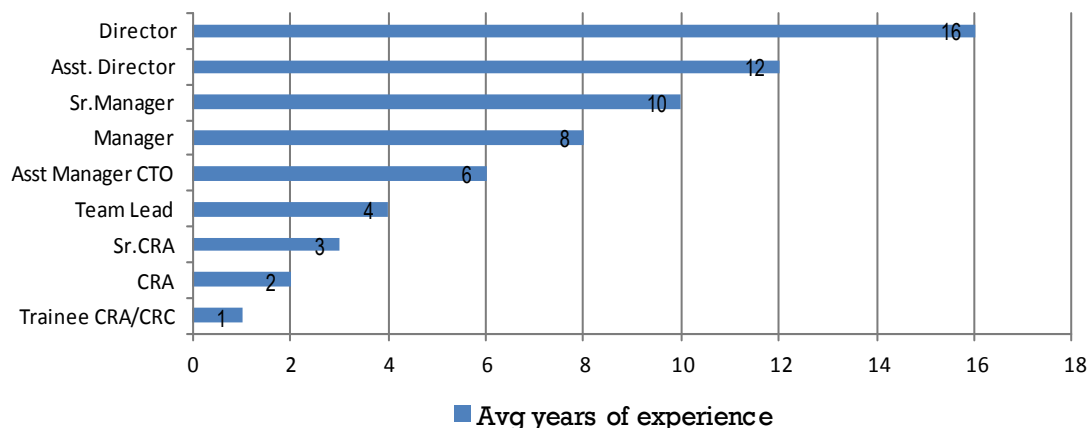
ICBio has introduced the online exam pattern in which a student can give his/her exam from a place and at the time of his/ her convenience. Every Paper will have 100 questions each and the time allotted is 1 hour. Each question carries 1 mark and there is no negative marking. A maximum 35 marks is required for passing the exam. Result can be viewed and printed out immediately after the exam by clicking on ‘Show Results’.

The student would be awarded the marks cards and certificate from the institute.

### Market Potential: Clinical Research

Clinical Research sector is booming day by day and in this perspective of globalization the demand of Clinical Research Professional has increased tremendously. A profession in Clinical Research is among the top ten millennium professions according to a recent US survey. The size of the Clinical Research market in India is growing at 40% and is estimated to grow to around US\$4.5 billion by 2015. According to a Survey the country would needs around 2, 00,000 professionals in the Clinical Research industry in the coming years. In order to cater to the need, an **Advance Diploma Certificate in Clinical Research and Pharma Regulatory Affairs** is a skill development program which is primarily targeted towards executing all the job functions of a Contract/Clinical Research Organization.

**Career prospects**



**Placement Cell**

The Placement Cell at ICBio serves as a bridge between the students and the Corporate to help the students find their dream careers. Apart from bringing a varied list of Recruiters to the campus, the Placement Cell also organizes talks, internship opportunities and workshops for the collective student body. As an added feature skill building workshops such as workshops for Personal Interviews and Group Discussions and Personality Development are conducted to help the students enhance their chances for a smooth transition from a student to an executive. The placement cell has been successful in bringing the best of organizations to the campus head hunting and is a fact of pride for ICBio. To provide world class industry and practical exposure to students, ICBio has collaborated with the companies like Quintiles, Accenture, Indegene, etc to place their students as interns during their course for duration of 3 to 6 months with paid stipend.

**Facilities**



## Course Highlights

- ▶ Globally recognized certificate
- ▶ Flexible Learning Schedule (Regular , Part Time)
- ▶ Globally Validated Curriculum developed by industry experts.
- ▶ Free comprehensive study material.
- ▶ Classroom/ Practical training by industry experts.
- ▶ In-house Central Lab & BA/BE training.
- ▶ 100% Placement Assurance\*.
- ▶ Outstanding placement record

## FAQs

- 1) Is your institution recognized by AICTE/UGC or any state govt.?  
A. Yes it is recognized by University of Mysore
- 2) Does your institute provide any placement assistance or guarantee?  
A. Yes, we provide 100% placement assurance to the students doing their Full time and Part time classroom programmes, and placement assistance will be given to Distance Learning.
- 3) Why Life Science graduates/Postgraduates are preferred for this course?  
A. Because of the domain experience and the terminologies associated with it.
- 4) How much will be the initial or start up salary for a Clinical Research professional?  
A. Somewhere around Rs.2 Lakh per annum
- 5) I have heard people in this industry need Hands-on-experience, could you please explain this?  
A. Yes it's true, that's why we will provide hands on experience and the 2nd semester would have practical sessions. Regular assessment would be done to monitor the students.
- 6) Where will the students be placed for internship and project work?  
A. During internship students will be placed directly in the CRO industry and at the investigator sites so they can have a practical approach/exposure to Clinical Research Methodologies and Processes.
- 7) Can I pay the fee in installments?  
A. Yes, an applicant can pay the fee in 2 installments.
- 8) What are the job prospects after doing Diploma in Clinical Research and Pharma Regulatory Affairs from your Institute?  
A. There is huge demand for trained & qualified Clinical Research professionals in the Industry. Jobs are available in Contract Research Organizations, Pharmaceutical Companies and Research Sites. Salaries are according to qualification & experience ranging from Rs. 2, 00,000 to Rs. 18, 00,000 annually. Our programs are totally job oriented and the course curriculum is developed as per the industry requirements with Specializations in Clinical Research, Data Management, Pharmacovigilance and Pharma Regulatory Affairs. Your future employers are our faculty members. We provide 100% placement assurance\* by campus interviews. We also have in -house placement opportunities. During On Job Training (OJT /internship), students will be placed directly in the investigator site and in the industry, this will definitely give them a very good opportunity to prove their skills.
- 9) What are the different job profiles in the Clinical Research Industry?  
A. The Clinical Research industry is an integrated industry where job profiles varies from Clinical Research Associate, Clinical Research Coordinator, Clinical Trial Assistant, Clinical Research Investigator, Study Coordinator, Data Manager ,Regulatory Affairs Manager, Clinical Project Manager, Clinical Research Manager, Clinical Data Coordinator, Clinical Data Associate , Clinical Data Validator, Clinical Data Reviewer, SAS programmer, Biostatistician ,Business Development Manager ,Drug Safety Associate, Regulatory Affairs Associate ,Scientific Medical Writer ,QA/QC Associate .....
- 10) I need further details, who do I contact?  
A. We understand that choosing a course to study is an important decision and we would like to be able to provide you with as much information as we can to assist you. Please call us Monday-Saturday from 9 am to 6.30 pm at 080 23641042/43. Or you can email us anytime at [course@icbio.org](mailto:course@icbio.org) or [info@icbio.org](mailto:info@icbio.org) or visit [www.icbio.org](http://www.icbio.org)