



BIOINFORMATICS INSTITUTE OF INDIA

Website: www.bii.in

**FAQ'S FOR ADVANCE PROGRAM IN CLINICAL TRIAL,
RESEARCH AND DATA MANAGEMENT.**

- ✓ **About The Institute**
- ✓ **About The Program**
- ✓ **Joining Procedure and Fee**
- ✓ **About Clinical Trial & its Career Opportunities**

About the Institute

Can you provide me further details about the Institute?

Established in 2002, BII is a reputed and pioneering institution for imparting quality education and training in emerging areas like Bioinformatics / Clinical Trial , Pharma Regulatory affairs, Drug Design and Discovery etc. The Institutes activities include classroom, distance learning and e-learning programs, student projects and thesis publications, multimedia training kits and corporate trainings.

What is Institute's experience in conducting Clinical Trial Courses?

BII has been successfully running Clinical Trial Programs since 2004. Till date more than 750 students and professionals have joined BII's Clinical Trial Programs. Past students of BII are now working in reputed companies like Lotus Labs, Vimta labs, Quintiles, Stride Acrolabs, Pfizer, Lambda therapeutic research etc.

To its credit BII conducts its Clinical Trial Programs via Classroom, Distance Learning and E-learning modes. It is the only Institute in the country with its own Clinical Trial Corporate Training Kit. BII also publishes its Clinical Trial Directory every year in the month of November. The Institute posses its own custom course material and electronic CDs in the field of Clinical Trials. The Institute has tied up several Clinical Trial Companies and Clinical Trial Recruitment Consultants for the placement of its student.

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Can you provide some details of ongoing Batch of the Program?

The ongoing batch of the program is quite successful and is pursued by many doctors, medical professionals, B.Pharm, B.Sc & other science graduates. The classes are taken up by experienced faculty from industry and academia at Institute's Noida centre on every Sunday. Students are also trained to work on "Open Clinica software" which is used in industry for Clinical Data Management

What are facilities available at BII?

The Institute is having the following facilities

- Well Equipped Classrooms
- Well Stocked Library
- Modern Computer Lab
- Specialized course material for Clinical Trials
- LCD, OHP and Multimedia Projectors
- Moodle E-learning Platform
- Clinical Trial Corporate Training Kits
- Clinical Trial Software Open Clinica™
- University Management System ERP AADYA-EDU™

Whether Hostel facility is available at the Institute?

Hostel facility is not available, however we can assist you obtain suitable accommodation.

How Can I Visit the Institute?

BII is located at C56A/28 Sector 62 Institutional Area at Noida (NCR New Delhi). The Institute is 20 Kilometers from New Delhi Railway station.

About the Program

What is Advance Program in Clinical Trial Research and Data Management?

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Conducted by BII, a pioneering and reputed institution in the area of Bioinformatics and Clinical Trials, Advance Program in Clinical Trial, Research and Administration is a 6 month weekend program which would endow the major areas of clinical trials (application, randomized controlled trials, use of placebo, blinding/masking and intention to treat analysis etc.) including its design, analysis, documentation & interpretation. The program is designed for working professionals and highly motivated students.

What is the Program Duration?

The program duration is 6 months. The classes will be conducted for 6 hours on every Sunday at Institute's Noida centre.

How is the Clinical Trial Weekend Program Conducted?

- ✚ Usual Faculty (Industry Professionals and Senior Academicians) Lectures through LCD/OHP on Sundays (10 AM to 4 PM)
- ✚ Special Invitation Lectures from the most reputed Industry Professionals
- ✚ Research Study and Seminar
- ✚ Submission of Assignments I and II
- ✚ Midterm and Final Examinations
- ✚ Site Visits
- ✚ Working on Clinical Trial Software Open Clinica

When will the new session for the program commence?

The forthcoming session of "Advance Program in Clinical Trial Research and Data Management" will commence from **15th December, 2008**.

What is the practical exposure during the program?

Practical exposure during the program will involve Site Visits, working on important Clinical Trial Software Open Clinica and assignment with Clinical Trial Industry professionals. Site visits will include visits to Clinical Trial Sites, CRO's, Clinical Trial Companies and Hospitals etc.

What is the timing of classes on weekend?

Classes will be conducted between 10 AM and 4 PM on Sundays

Who will award "Advance Program in Clinical Trial, Research and Data Management"?

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After completion of the program the students will be awarded completion for “**Advance Program in Clinical Trial Research and Data Management**” from BII. This is Institute’s autonomous program. This program is providing students a theoretical and practical understanding of the issues involved in the design, conduct, analysis and interpretation of clinical trials.

What about Program Faculty?

The faculty for the program will be a mix of experienced clinical trial industry professionals and senior academicians. Dr Kumud Sarin (PhD Delhi University) a renowned author is the Program Director, Dr Neena Valecha, Scientist F in National Institute of Malaria Research, Dr Anirban Das is PhD in computer science from Jamia Milia Islamia University, M.Tech from IIT (Delhi) MCA from JNU, Mr. G. K. Srivastava (Clinical Trial Specialist), M.Sc (Molecular Biology and Biotechnology & P.G. Dip in Clinical Research and Clinical Data Management and Industry advisor. Mr. Asif Khan, (M.Sc Statistics & Actuarial Sciences). Many more expert faculties from industry and academia would come and deliver the lectures.

Joining Procedure and Fee

What is the Program eligibility?

Graduates & Post graduates are eligible to apply for this program. The program is highly eligible for Graduates and Post Graduates in Science, Pharma, and Biotechnology etc. Among the medical professionals, Allopathic, Homeo and Ayurvedic Doctors are highly eligible to apply. Candidates in the profession of MLT, Medical writing, Medical Transcription are also eligible. The program is highly suitable for working professionals.

How Can I Join the Program?

Every student willing to enroll has to submit an application form along with a Demand Draft of Rs. 300 /- in favor of bioinformatics institute of India, payable at Delhi / Noida. The final selection is on the basis of Interview conducted at the Institute.

To download application form from our website www.bii.in

What is its fee structure for this program?

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Total program fee INR 35000/

Whether installment facility is available?

Payment in installment can be made.

- 1) 12000/- at the time of joining.
- 2) 12000/- after 2 months.
- 3) 12000/- after 4 months.

How can I obtain the prospectus?

Prospectus can be obtain from the website

On request through phone/sms/letter by submitting your details (name/address/academic background/contact)

You can take it directly from the institute.

About Clinical Trials & Career Opportunities

What is a Clinical Trial?

A Clinical trial is a comparison test of a medication or other medical treatment (such as medical devices), versus a placebo, other medication or devices or the standard medical treatment for a patient's condition. Clinical trial is investigation in human intended to discover or verify the effects of a drug, and / or to identify any adverse reactions to that investigational drug with the object of ascertaining its safety and /or efficacy.

What is the requirement of manpowers and professionals in the country?

It is certain that in future as the number of clinical projects expands, there will be demand for qualified personnel. According to a McKinsey report, the global clinical trial outsourcing opportunity in India in the pharmaceutical industry is estimated to be around \$2 billion by 2010 and there will be requirement

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of 50,000 clinical research professionals. Trained pharmacists and clinicians can plug this wide gap. They will be involved in the various aspects of clinical research starting from site-monitoring, site-management, clinical data management, data analysis, report writing, report submission, presentation and publication.

In the field of clinical research, there is an imbalance between demand and supply with the scales tipping in favor of demand. Thus, pharmaceutical houses are hunting for trained professionals and are using bulky pay packages to lure them .**According to the data from Express Pharma:**

Table 1: Projected figures in respect of revenue, human power and patient load for clinical research in India			
	2003	2008	2010
Value (million USD)	50	200	1000
Revenue (crore INR)	75	300	875
Full time staff requirement	800	4000	20,000
Site-staff requirement	1500	6000	30,000
Patient load	10,000	50,000	300,000
Source: McKinsey report			

What are the career opportunities?

Career prospects include a professional career in Clinical Research industry either as a clinical investigator, site coordinator in at a hospital conducting clinical investigations or CRO (Clinical Research Organization). Jobs are also available in pharmaceutical industry, drug development, medical writing, biostatistics or as a Manager of Clinical Project, Clinical Research Business Development, Clinical Operations, Data Management, Regulatory Affairs and Auditing of Clinical Trials. You can build up your carrier in clinical trials as:

- **Clinical Research Associate:** The main function of a clinical research associate is to monitor clinical trials. He or she may work directly with the sponsor company of a clinical trial, as an independent freelancer or for a Contract Research Organization (CRO). A clinical research associate ensures compliance with the clinical trial protocol, checks clinical site activities, makes on-site visits, reviews Case Report Forms (CRFs) and communicates with clinical research investigators.

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- **Clinical Research Investigator:** Conduct BA/BE studies as per cGCP guidelines, Writing/revising SOP for clinical operations. Review of protocols, Investigators Brochures, ICF and CRFs Protocol, CRF and ICF preparation Plan & conduct of BA/BEIEC/IRB affairs-GC.
- **Study Coordinator:** Study coordinators work directly with study volunteers, providing them safety and protection while collecting and managing the study data. They promote, advertise, and conduct telephone and face-to-face screenings to recruit volunteers. During the study process, they assess volunteer condition and coordinate ongoing clinical/laboratory testing and physical exams. Coordinators may assess vital signs (height, weight, blood pressure, pulse), and some are trained to collect blood/urine specimens and perform lung function testing. Study coordinators follow up with volunteers after the study and manage a great deal of paperwork, electronic correspondence and data.
- **Data Manager / Biostatistician:** Biostatisticians collaborate with researchers to design studies that may show the seriousness of a disease, predict a specific disease's seriousness, evaluate a new treatment, assess the safety and effectiveness of medications and increase knowledge of environmental issues. Additionally, biostatisticians participate in research design, data collection, choosing and implementing appropriate methodologies, and interpreting the results.
- **Regulatory Affairs Manager:** Responsible for review & registration of documents as per country specific guidelines for export. Evaluation of technical data & answer to various related queries as per regulated & semi - regulated requirements. Liaison with regulatory authorities.
- **Clinical Trials Auditor :** Conducts audits for the regulatory/QA function within the Clinical Trials Department in order to help assure compliance with GLP/GCP in accordance with established FDA regulations and company policies and standard operating procedures Job Requirements Normally B.A./B.S. in Science w/1-2 years of experience
- **Clinical Project Manager:** Responsible for ensuring compliance across projects to all applicable Clinical Trial regulations, guidelines, SOPs Protocols and procedures. Coordinate project start-up, project maintenance and project close-out activities, Serve as the primary contact for the Sponsor and all project team members, Direct supervisory responsibility for project Coordinators, project Assistants, CRAs, etc
- **Clinical Research Manager :** Manage interdisciplinary clinical research projects, as Project. Supervise, train, and mentor Clinical Research staff, Approve investigator study budgets and contracts, Review and approve regulatory and administrative documents, develop protocols and approve Case Report Forms (CRFs), Review Tables and Listings generated from study data. Author Clinical Study Reports. Train CRAs on monitoring, internal procedures, and query, resolution.

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- **Business Development Manager:** Identify potential clients & establish business relations & convert into real business. Responsible for all Business Development functions Meeting new clients, following up on leads, CRM. Continuously monitor the Competition and Global Market.
- **Drug Safety Associate :** Manage and relay drug safety information, maintain current knowledge of global drug safety regulations, summaries clinical safety data, participate in meetings with potential and actual study sponsors, write narratives with medical input from a physician, report SADR to the Regulatory Authorities, participate in the training of operational staff on drug safety issues, quality control work of other staff in the department, take on any other task as assigned by the manager or Medical Director within the capabilities of the Drug Safety Associate.
- **Medical Writer:** To prepare high quality documents, manuscripts, abstracts and other communication tools (slide presentations, posters etc.) for publishing in indexed scientific/medical journals or for presentation in scientific/Health Authority meetings.
- **Clinical Data Manager:** The Clinical Data Manager (CDM) ensures complete, accurate and consistent data for reporting to regulatory bodies. A CDM is involved in the setting up, running and reporting of clinical trials. The CDM processes data using a range of computer applications and database systems to support collection, cleaning and management of patient data.

Leading companies in Clinical Trials and Research:

- Asian clinical trials serene
- Bioserve
- Clin invent
- Clintec international
- Clinigene
- Dr Reddy's lab
- Elly Lilly
- Glaxo smithkline
- IGATE clinical research
- Intass biopharmaceuticals
- Johnson & Johnson
- Lambda therapeutic research
- Lupin limited
- Matrix laboratories ltd.
- Merck

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- **Novartis**
- **Novo Nordisk**
- **Pfizer**
- **Pharmanet**
- **Quintiles**
- **Ranbaxy**
- **Roche India**
- **Sristek**
- **Siro Clinpharma**
- **Synchron**
- **Sanofi Aventis**
- **Torrent pharma**
- **Vimta labs**
- **Zydus**
- **Reliance life science**
- **Amed**
- **Accutest**
- **Acebiomed**
- **Actimus**
- **Adroit insights**
- **Alembic**
- **Asian Clinical Trials**

Can you provide some information about the companies working in the area of Clinical Trial?

For obtaining details about the leading Clinical Trial Companies u can visit at this page

http://www.bii.in/page/about_institute/company.asp

Does the Institute provide Placement Assistance?

Placement assistance is provided to all the program participants. The Institute is in touch with several reputed Clinical Trial and Pharma companies where passing out students will be placed. The institute has also tied up with several reputed Recruitment Process Outsourcing Organizations.

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