



Career in Clinical Research

Academy for Clinical Research Training &
Management

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What is a Clinical Trial?

- ❖ A clinical trial (also clinical research) is a research study in human volunteers to answer specific health questions.
- ❖ Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people and ways to improve health.
- ❖ Interventional trials determine whether experimental treatments or new ways of using known therapies are safe and effective under controlled environments.
- ❖ Observational trials address health issues in large groups of people or populations in natural settings.

International Conference on Harmonisation

- ✦ Agreement between the United States, European Union and Japan.
- ✦ Describes Good Clinical Practices (GCPs).
- ✦ The ICH GCP guideline E6 describes the mutually agreed-upon standards by which clinical trials must be conducted in order to
 - protect human subjects
 - ensure credibility of data
- ✦ Data collected from studies in compliance with the ICH GCP guidelines are acceptable to regulatory authorities in the U.S., European Union and Japan.

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What Are the Basis for GCP?

GCP is based on international standards and guidelines, and national laws and regulations.

Important Regulations & Guidelines

- ⊕ ICH GCP – E6
- ⊕ USFDA CFR 21
- ⊕ Schedule Y – Drugs & Cosmetics Act, 2005
- ⊕ EMEA Guidelines – European Agency for the Evaluation of Medicinal Products

Key Stakeholders

- ⊕ Study sponsors
- ⊕ Investigators and site personnel
- ⊕ Monitors
- ⊕ IRB/IEC
- ⊕ Study subjects
- ⊕ Hospital Administration
- ⊕ Regulator

Phases of Drug Development

Steps prior to human trials:

- ⊕ Preclinical (nonclinical).
 - Animal and in vitro studies.
- ⊕ Investigational New Drug (IND) application or Investigational Device Exemption (IDE) for the FDA.

Phases of Drug Development

Phase 1:

- First studies in human.
- Usually involve small groups of healthy volunteers or patients with particular disease – 20 - 80.
- Short duration.
- Provide preliminary safety and tolerability evaluation.

Phases of Drug Development

Phase 2:

- Evaluate efficacy and short-term safety of the drug.
- Determine dosing.
- Usually conducted in fairly small groups of patients with disease under study.
- Have well-defined eligibility criteria.
- Comparison with placebo or active control.

Phases of Drug Development

Phase 3

- Larger, well-controlled trials with larger groups of subjects.
- Eligibility criteria usually broader.
- Simulates actual treatment conditions.
- Establishes safety and efficacy profile in broad sample.
- Results used in marketing application and official product labeling.

Phases of Drug Development

Phase 4:

- Conducted after marketing approval of drug.
- Postmarketing studies sometimes designed to differentiate the drug from competitors and demonstrate health economic benefits.
- Include post registration usage studies and post-marketing surveillance studies.
- Outcomes Research:
 - ◆ Study of the clinical, economic, and quality of life value of medical treatments to society, providers, and patients.

Clinical Trials for Devices

Device development and testing does not require the same developmental research phases as drugs or biologics.

Key Facts

- ⊕ It takes 10 – 12 years to develop new drug
- ⊕ It costs US\$1 billion to develop new compound
- ⊕ After 1500 compounds screened only 1 makes to the market

Indian Market For Clinical Research – Some Key Statistics

- ⊕ 2002 Industry Spending on CRO Services and Investigator Grants \$30 million
- ⊕ Market Size in 2005-06 \$200 million
- ⊕ Estimated Market Size in 2007 \$450 million
- ⊕ Estimated Market Size in 2008 \$600 million
- ⊕ ***2012 Projected Industry Spending on CRO Services and Investigator Grants \$2 billion***
- ⊕ Number of CROs - current 75

◆ Number of MNC & Indian Pharmacos in Clinical Research	60
◆ Clinical Research Market Growth (CAGR)	40%
◆ Full time & Site Staff Required in 2008	15,000
◆ New Protocols received by Indian Regulator everyday	20
◆ Patients / Subjects Required in 2008	120,000
◆ Over 3,000 new Certified Investigators will be required in 2008 and over 10,000 by 2010	

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India – Hub of Global Clinical Research?

- ✦ India is one of the top 3 countries where companies plan to spend the most R&D dollars over the next 3 years.
- ✦ Favoured destination ahead of countries like Israel, Philippines, Canada, China, Ireland & Russia in terms of Overall Climate (*Gartner Report, January 2003*)
- ✦ Powerhouse in R&D (*e.g. GVK Wyeth R&D Deal*)
- ✦ Over 30 CROs offer Phase I to IV trials complying with ICH-GCP guidelines.
- ✦ Over US\$500 million FDI expected in the next 18 months
- ✦ With 100 hospitals serving as sites for clinical trials, India is emerging as one of the fastest recruiter of subjects across the world.
- ✦ Some of the top medical/technical universities in Asia

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India Becoming Hub for Global Clinical Research – India Advantage

- ✦ The clinical community is populated with English speaking, western-trained graduates
- ✦ Sophisticated technological infrastructure
- ✦ 100 million plus English speaking people (Largest outside US)
- ✦ Over 2 million science post graduates
- ✦ Large pool of treatment naïve patients from multiethnic and multiracial backgrounds
- ✦ Better patient recruitment, retention and compliance
- ✦ Participants generally benefit, as the trials conducted in India, mostly in phase II - IV, provide improved care and cost savings as procedures and drugs are provided at no charge

- ✦ Cost effective operations
- ✦ Higher GMP/GLP/GCP Compliance
- ✦ Maximum number of approved GMP plants outside USA
- ✦ Excellent quality management, Technology and infrastructure
- ✦ Increasing presence of all Pharma majors, CROs & also in-house CROs set up by leading pharma companies
- ✦ Strong IT industry availability of IT skilled manpower

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India's Vital Clinical Statistics

- ✦ Cancer: 3 million
- ✦ Diabetes: 34 million
- ✦ HIV: 8-10 million
- ✦ Epilepsy: 8 million
- ✦ Hypertension: 150 million
- ✦ Schizophrenia: 1 million
- ✦ Asthma: 40 million
- ✦ Alzheimer's: 1.5 million
- ✦ Cardiac-Related Deaths: 2 million
- ✦ Recruits for genetic studies
- ✦ 600,000 practicing physicians
- ✦ 14,000 hospitals
- ✦ 700,000 beds
- ✦ 17,000 medical graduates per year

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Regulatory Framework & Reforms

- ⊕ Positive Regulatory Environment – Protocols Approved by DCGI / Schedule Y
- ⊕ CDSCO (Central Drugs Standard Control Organisation) to regulate Clinical Research
- ⊕ Further strengthening of environment by setting up National Drug Authority
- ⊕ Intellectual property protection
 - As of January 2005, recognize product patents from 1995 to present
- ⊕ Clinical Trial Protocol Approval Time is reducing
- ⊕ Duty Free Import of Clinical Trial Supplies
- ⊕ Easier Drug Importation Procedure
- ⊕ ICMR Guidelines on the Safety of Human Subjects

Key Pharma Companies in Clinical Research

- ◆ *Abbott, Mumbai*
- ◆ *Chiron, Mumbai*
- ◆ *Astra Zeneca Pharma India Ltd, Bangalore*
- ◆ *Astra Zeneca Foundation, Bangalore*
- ◆ *AventisPasteur, Delhi*
- ◆ *Pfizer Ltd, Mumbai*
- ◆ *Pfizer Biometrics, Mumbai*
- ◆ *Altana(Zydus), Mumbai*
- ◆ *Eli Lilly, Delhi*
- ◆ *Boston Scientific, Delhi*
- ◆ *Hospira, Delhi*
- ◆ *Merck ,Delhi*
- ◆ *Sanofi Aventis Syntho Lab, Mumbai*
- ◆ *GSK, Glaxo SmithKline Pharmaceuticals Ltd,Mumbai*
- ◆ *Novartis International Clinical Development Center, Mumbai*
- ◆ *Novartis Pharma, Mumbai*
- ◆ *Roche,Mumbai*
- ◆ *Sandoz, Mumbai*
- ◆ *Wyeth, Mumbai*
- ◆ *BMS, Mumbai*
- ◆ *Novo Nordisk, Bangalore*
- ◆ *Lundbeck, Bangalore*
- ◆ *Eisai Pharmaceuticals, Mumbai*

Key Pharma Companies in Clinical Research

- ◆ *LG Life Sciences, Delhi*
- ◆ *Bayer, Mumbai*
- ◆ *GE, Delhi*
- ◆ *Johnson & Johnson, Jansenn Cilag, Mumbai,*
- ◆ *Cordi Baxter, Delhi*
- ◆ *BD Biosciences, Delhi*
- ◆ *Bharat Biotech, Hyderabad*
- ◆ *Bharat Serum, Mumbai*
- ◆ *Cadila Pharmaceuticals*
- ◆ *Cipla, Mumbai*
- ◆ *Emcure, Pune*
- ◆ *Fulford India Mumbai*
- ◆ *Indus Biotherapeutics, Ahmedabad*
- ◆ *IPCA, Mumbai*
- ◆ *Shreya Biotech, Pune*
- ◆ *Shantha Biotechnics Pvt. Ltd. Hyderabad*
- ◆ *Sun Pharma, Mumbai*
- ◆ *Torrent Pharmaceutical Ltd, Gandhi nagar,*
- ◆ *USV Ltd. Mumbai*
- ◆ *Wockhardt, Mumbai*
- ◆ *Zydus Cadilla, Ahmedabad*

- ◆ *Biocon, Bangalore*
- ◆ *Cadila Pharmaceuticals, Ahmedabad*
- ◆ *Intas Pharmaceuticals Ltd., Ahmedabad*

Key Pharma Companies in Clinical Research

- ◆ *Glenmark Pharmaceuticals Ltd., Mumbai*
- ◆ *Himalaya Drugs ,Bangalore*
- ◆ *Lupin Ltd., Pune*
- ◆ *Nicholas Piramal,Mumbai*
- ◆ *Panacea Biotech, Delhi*
- ◆ *Ranbaxy Research Laboratories, Delhi*
- ◆ *Ranbaxy Research Laboratories, Gurgaon*
- ◆ *Serum Institute of India, Pune*
- ◆ *Torrent, Ahmedabad*

Key CROs in India

Quintiles	Ahmadabad / Bangalore
Synchron	Ahmedabad /Bangalore
Lambda	Ahmedabad
Genpact	Delhi/Bangalore
Siro Clinpharm	Mumbai
I-Gate	Mumbai
Reliance Clinical Services	Mumbai
PPD	Mumbai
Onmnicare	Bangalore
ICON	Bangalore
Clin Trac	Bangalore
PharmaNet	Bangalore
Pharm-Olam	Bangalore
Lotus Labs	Bangalore
Vimta	Hyderabad
GVK	Hyderabad
BioServe Clinical Research	Hyderabad
Apothecaries	Delhi
Kendle	Delhi/Gurgaon
Bioassay	Baroda
Clinworld	Bangalore
Perinclinical	Mumbai
Quest Life Sciences	

Key CROs in India

Quintiles	Ahmadabad / Bangalore
Synchron	Ahmedabad /Bangalore
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ICON	Bangalore
Clin Trac	Bangalore
PharmaNet	Bangalore
Pharm-Olam	Bangalore
Lotus Labs	Bangalore
Vimta	Hyderabad
GVK	Hyderabad
BioServe Clinical Research	Hyderabad
Apothecaries	Delhi
Kendle	Delhi/Gurgaon
Bioassay	Baroda
Clinworld	Bangalore
Perinclinical	Mumbai
Quest Life Sciences	

Why Career in Clinical Research?

- ✦ Fastest growing segment in the healthcare / pharmaceutical industry
- ✦ Excellent Opportunity to Develop Combination of Technical and Management Skill Development
- ✦ Part of the Global Growth Opportunity
- ✦ Wider Job Horizon
- ✦ Rapidly Growing Opportunities...and growing (internal and external)
- ✦ Attractive Compensation and future growth
- ✦ Higher Job Satisfaction
- ✦ Continuous Training Opportunities
- ✦ International Opportunities

Types of Jobs/Positions

- ✦ Clinical Monitors / CRAs
- ✦ Clinical Research Coordinators / Site Coordinators
- ✦ Drug Safety Personnel
- ✦ Project Personnel
- ✦ Medical Monitors
- ✦ Regulatory Affairs Monitors
- ✦ Medical Writers
- ✦ Quality Control / Assurance Personnel
- ✦ Data Management Personnel
- ✦ Statisticians
- ✦ Scientists
- ✦ Lab Personnel
- ✦ Management & Support Personnel

Types of Employers

- ✦ Pharmaceutical companies
- ✦ Contract Research Organizations
- ✦ Hospitals
- ✦ Non Governmental Organizations
- ✦ WHO

Key Cities in India for Clinical Research

- ✦ Delhi & NCR Region
- ✦ Mumbai
- ✦ Pune
- ✦ Ahmedabad
- ✦ Vadodara
- ✦ Hyderabad
- ✦ Bangalore
- ✦ Chennai

Background

- ✦ Tops in the 'Hot Jobs' segment in the healthcare industry with over 35% new hot job offerings
- ✦ Major gap in Demand & Supply of trained manpower – An unmet need
- ✦ With the shift of work to India; expected market size of \$2 billion and entry of new players, over 50,000 professionals will be required each year from 2012.
- ✦ Current demand is over 10,000 professionals per year.

- ⊕ The current facilities are able to train only 2,000 professionals.
- ⊕ Employers required well trained professionals.
- ⊕ Attractive Salaries Offered & High Annual Salary Growth.

Challenges From HR Perspective

- ⊕ Very rapid growth in number and size of companies
- ⊕ Spectrum of skills required in scarcity
- ⊕ Lack of specialization
- ⊕ Limited pool of experienced people
- ⊕ Employee Retention
- ⊕ Continuous Training

About Our Company

- Cliniminds was established in the year 2004 by a group of Senior Professionals from Pharmaceutical, Clinical Research & Healthcare industry.
- Two brands – Cliniminds & Mediminds were established to provide vocational and professional education and training in the clinical research, healthcare & pharmaceutical areas.
- To provide opportunities to fresh graduates or working executives aspiring to build career in the booming Clinical Research / Healthcare/ Pharmaceutical industry.
- To provide continuing education, Professional development, and vocational skills enhancement Programs for Clinical Research / Healthcare / Pharmaceutical professionals

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Cliniminds Key Team Members

1. **Kamal Shahani – Consultant/Industry expert/Trainer**
2. **Dr. Harpreet Singh, Director Operations - Cliniminds**
3. **Dr. Srinkant Tadipatri, Clinical Research Specialist from United States, ex Pfizer**
4. **Dr. Arun Gupta, Senior Clinical Research Manager**
5. **Dr. Suneet Sood, Professor of Surgery, leading international medical school – eminent clinical research professional**
6. **Dr. Sumbul Siddiqui, Clinical Investigator**
7. **Dr. U. Kapoor, Senior Manager, Clinical Research, MNC**
8. **Dr. Deepak Bungler, Clinical Investigator, PGI**
9. **Dr. Amit Bhatt, CEO, Nexus CRO**
10. **Mr. Imran Mubashir, Senior Team Leader, BMS**
11. **Mr. Vatsal Acharya, Industry Specialist from leading MNC**
12. **Dr. G.S. Arora, Industry Specialist from leading MNC & Former Professor of Clinical Research**
13. **Dr. Ramesh C, Principal, Pharmacy College, Hyderabad**
14. **Ms Pooja Saxena, Senior CRA, leading CRA**

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Our Core Areas

- ✦ Clinical Research/Medical/Healthcare Educational & Training Programs
- ✦ Course Content Development
- ✦ Management Development Programs
- ✦ Business & Consulting Services
- ✦ Placement Services

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Current Offerings

- ◆ Cliniminds has class room training programs in Clinical Research with different variants. All Programs Accredited by the Pharmaceutical Society of India
- ◆ The fresh classroom batch is starting from February 08 and August 08
- ◆ Online Programs and E-Learning Modules are ongoing
- ◆ 1 – 3 days training programs – corporate sponsored & independent events on Clinical Trial issues
- ◆ Course Content designed by the Senior Indian Academicians & Industry Experts from India and overseas
- ◆ Certificates would be awarded by Cliniminds and Pharmaceutical Society of India jointly.

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Main Programs

Classroom Programs, Distance & Online

- Post Graduate Diploma in Clinical Trial Management
- Advanced Postgraduate Program in Clinical Research: (Classroom; distance & e-learning)
- Post Graduate Program in Clinical Data Management

Specialised Distance & E-Learning Programs

- Certificate Program in Pharmacovigilance
- Certificate Program in Conducting & Managing Bioequivalence & Bioavailability studies
- Certificate Program in Quality Assurance in Clinical Research
- Certificate Program in Conducting & Managing Clinical Trials for Cancer Patients
- Certificate Program in Clinical Research : 3 months (distance & e-learning)
- Post Graduate Program for Investigators & Site Personnel
- Post Graduate Program for CRAs/Monitors
- Certificate Program in Clinical Research for Nurses

Post Graduate Diploma in Clinical Trials Management

Mode: Class Room – Fulltime

Duration: One Year

Selection: **Personal** Interview & Academic Record

Eligibility: MD, MBBS, BHMS, BAMS, BDS; Graduate/Post Graduate Degree in Science, Pharmacy, Nursing, Biochemistry, Microbiology, Biotechnology

Methodology: Regular classes, Printed Training Modules; Multimedia CD ROM; Workshops, Web based testing and examinations, onsite training

Certification: Diploma would be jointly awarded by Cliniminds & Pharmaceutical Society of India

Placement Support : Successful students would be offered attractive placement opportunities in life sciences companies; CROs, hospitals and clinical research related organizations.

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Post Graduate Diploma in Clinical Trials Management

- Clinical Research Introduction & Terminology
- Healthcare Management Issues
- Introduction to Pharmaceutical Industry & Global Challenges
- Global Clinical Research Environment & Opportunities
- Clinical Trials Management
- Principles of Pharmacology & Drug Discovery & Development
- Roles & Responsibilities of Key Stakeholders
- Preparations & Planning for Clinical Trials
- Essential Documentation in Clinical Research & Regulatory Submissions
- Clinical Trials Project Planning & Management
- Study Start up Process
- Clinical Monitoring Essentials
- Compliance, Auditing & Quality Control in Clinical Research
- Clinical Data Management, Biostatistics, Analysis & Reporting
- Pharmacovigilance
- Bioavailability and Bioequivalence Studies
- Management of Cancer Clinical Trials
- Organizational Behavior & Human Resource Management
- Financial Management
- Key Management Skills – Presentation, Communication; Time Management & Teamwork
- Hands on Training on Clinical Trials

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Advanced PG Diploma Program in Clinical Research

Mode : Distance Learning, E-Learning & Class Room

Duration : 6 Months (250 hours program) – Weekend (Sat/Sun)

Eligibility : MD, MBBS, BHMS, BAMS, Graduate/Post Graduate Degree in Science, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology

Methodology : Classroom Printed Training Modules; Multimedia CD ROM; Workshops, Web based testing and examination

Certificate :Certificate would be awarded at the end of the program

Job Assistance : Placement assistance would be provided to the successful candidates. CVs of successful candidates would be forwarded to the CROs and Pharmaceutical companies.

Program Details : A comprehensive interactive Advanced Certificate Program provides detailed orientation on the GCP Guidelines and management of the clinical trials. The Program is fully job oriented, and includes Multimedia, self-study modules and Class Room teaching.

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Advanced PG Diploma Program in Clinical Research

- Group 1** Clinical Research Introduction
- Group 2** Principles of Pharmacology & Drug Discovery & Development
- Group 3** Roles & Responsibilities of Key Stakeholders
- Group 4** Preparations & Planning for Clinical Trials
- Group 5** Essential Documentation in Clinical Research & Regulatory Submissions
- Group 6** Clinical Trials Project Planning & Management
- Group 7** Study Start Up Process
- Group 8** Clinical Monitoring Essentials
- Group 9** Compliance, Auditing & Quality Control in Clinical Research
- Group 10** Clinical Data Management, Biostatistics, Analysis & Reporting

Post Graduate Diploma in Clinical Data Management

Mode: Class Room – Part time – Weekend (Saturday & Sunday)

Duration: One Year

Selection: Personal Interview & Academic Record

Eligibility: MD, MBBS, BHMS, BAMS, BDS; Graduate/Post Graduate Degree in Science, Pharmacy, Nursing, Biochemistry, Microbiology, Biotechnology

Methodology: Regular classes, Hands on Training on Enterprise software's, Printed Training Modules; Multimedia CD ROM; Workshops, onsite training

Certification: Diploma would be jointly awarded by Cliniminds & Pharmaceutical Society of India

Placement Support : Successful students would be offered attractive placement opportunities in life sciences companies; CROs, hospitals and clinical research related organizations.

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Post Graduate Diploma in Clinical Data Management

- Introduction to Databases
- Clinical Database & Types
- Management of Clinical Data using MS Access
- Data Management Plan
- Study Set Up
- Electronic Data Capture
- CRF Design Considerations
- Tracking CRF Data
- Data Entry, Remote Data Entry
- Managing Lab Data
- Identifying and Managing Discrepancies
- Collecting Adverse Event Data
- Medical Coding
- Creating Reports and Transferring Data
- Database Closure
- Enterprise Clinical Data Management Tools

Post Graduate Program in Pharmacovigilance

Mode: Distance Learning & Online

Duration: 6 Months

Eligibility: MD, MBBS, BHMS, BAMS, Graduate/Post Graduate Degree in Science, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology

Methodology: Printed Training Modules; Multimedia CD ROM; Workshops, Web based testing and examination

Certificate: Certificate would be awarded at the end of the program

Job Assistance: Full placement support would be provided to the successful classroom candidates. CVs of successful candidates would be forwarded to the CROs and Pharmaceutical companies, Interviews would be organized.

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Post Graduate Program in Pharmacovigilance

Program Details: This is a continuing training / educational program designed to provide a practical knowledge for the, investigators, clinical research professionals, other pharmaceutical industry professionals, including sales and marketing personnel and the students of pharmacy and other life science stream.

The program would cover:

- Introduction to Clinical Research & Phases in Clinical Research
- Principles of Good Clinical Practices - ICH GCP
- Ethical Considerations in Clinical Trials
- Indian GCP Guidelines, Schedule Y & ICMR Guidelines
- Drug Discovery & Development

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Post Graduate Program in Pharmacovigilance

The program would cover:

- General Overview of Pharmacovigilance
- Medical Dictionary for Drug Regulatory Activities MedDRA
- Medical Evaluation of Adverse Events
- Expedited Reporting Requirements
- Periodic Safety Update Reports (PSUR,s) For Marketed Drugs (ICH E2C)

Post Graduate Program in Pharmacovigilance

Course Objectives:

- To provide a comprehensive introduction to the clinical research process.
- Learn the skills, knowledge and competencies of a candidate for the Clinical Research Associate / Clinical Research Coordinator position.
- Become more familiar with roles/jobs as part of the study team.

Post Graduate Program in Bioequivalence & Bioavailability Studies

Mode: Distance Learning & Online

Duration: 6 Months

Eligibility: MD, MBBS, BHMS, BAMS, Graduate/Post Graduate Degree in Science, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology

Methodology: Printed Training Modules; Multimedia CD ROM; Workshops, Web based testing and examination

Certificate: Certificate would be awarded at the end of the program

Job Assistance: Full placement support would be provided to the successful classroom candidates. CVs of successful candidates would be forwarded to the CROs and Pharmaceutical companies, Interviews would be organized.

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Post Graduate Program in Bioequivalence & Bioavailability Studies

Program Details: This is a continuing training / educational program designed to provide a practical knowledge for the clinical research professionals, potential staff for the BA/BE centers or CROs, other pharmaceutical industry professionals and fresh science graduates & post graduates including sales and marketing personnel and the students of pharmacy and other life science stream.

The program would cover:

- Introduction
- Basics of Pharmacokinetics
- The concept of Bioavailability and Bioequivalence-Regulatory Terminology
- Regulatory aspects of BE studies

Post Graduate Program in Bioequivalence & Bioavailability Studies

The program would cover:

- Need of Bioequivalence Studies- NCEs & Generic Drugs
- Intellectual Property Rights & TRIPs agreement
- Generic Drugs· ANDA approval, Reference List of Drugs & Orange book
- Approaches to Bioequivalence studies
- Types of BA/BE studies
- Design and Conduct of Bioequivalence Studies
- Study personnel required for conduct of BE studies and their role and responsibility
- Facilities for conducting BA/BE studies (CRO checklist)
- Departments – Clinical, Bio-Analytical and Quality Assurance
- Managing BE Studies
- Measurement Methodology
- Analysis of BE Studies
- Food effect BE studies
- Biowaivers

Post Graduate Program in Bioequivalence & Bioavailability Studies

Course Objectives:

- Distinguish the differences between bioequivalence and bioavailability
- Understanding the management and conduct of bioequivalence and bioavailability studies
- Understand how factors related to the dosage form and patient variables affect drug stability, dissolution capacity, and absorption properties
- Recognize problems that arise with bioequivalence and generic substitution
- Learn which critical patient and disease factors require special consideration
- Understand the process of approval of generic drugs in USA , Europe and India.

Certificate Program Quality Assurance in Clinical Trials

Mode: Distance Learning & Online

Duration: 6 Months

Eligibility: MD, MBBS, BHMS, BAMS, Graduate/Post Graduate Degree in Science, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology

Methodology: Printed Training Modules; Multimedia CD ROM; Workshops, Web based testing and examination

Certificate: Certificate would be awarded at the end of the program

Job Assistance: CVs of successful candidates would be forwarded to the CROs and Pharmaceutical companies.

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Certificate Program Quality Assurance in Clinical Trials

Program Details: This is a foundation educational program, designed for all the candidates aspiring to work in the field of clinical research or allied professions like central labs. The program provides complete overview and practical environment in the field of clinical research. The program would candidates to upgrade their knowledge about ICH GCP Guidelines, regulatory issues and other major aspects of clinical trials management. Select important topics from the following groups would be covered in the program:

- Introduction and role of QA in CRO
- Understanding the difference between QA & QC and other terms related to quality assurance
- Quality Planning
- Operational QC

Certificate Program Quality Assurance in Clinical Trials

- QA activities
- Site Management metrics and study site audits
- Internal audits types - inprocess and retrospective data audits, system and process audits (a) -Data management metrics, (b) Statistical analysis metrics
- Corrective and preventive action
- Continual improvement process
- An overview of different regulatory agencies-FDA, EU and DCGI

Certificate Program Quality Assurance in Clinical Trials

Course Objectives:

- To provide a comprehensive introduction to the clinical research process.
- Learn the skills, knowledge and competencies of a candidate for the Clinical Research Associate / Clinical Research Coordinator position.
- Become more familiar with roles/jobs as part of the study team.

Post Graduate Program in the Conduct & Management of Cancer Clinical Trials

Mode: Distance Learning & Online

Duration: 6 Months

Eligibility: MD, MBBS, BHMS, BAMS, Graduate/Post Graduate Degree in Science, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology

Methodology: Printed Training Modules; Multimedia CD ROM; Workshops, Web based testing and examination

Certificate: Certificate would be awarded at the end of the program

Job Assistance: Full placement support would be provided to the successful classroom candidates. CVs of successful candidates would be forwarded to the CROs and Pharmaceutical companies, Interviews would be organized.

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Post Graduate Program in the Conduct & Management of Cancer Clinical Trials

Program Details: This is a continuing training / educational program designed to provide a practical knowledge for conducting and managing cancer clinical trials. The program is targeted towards clinical professionals, potential staff for the BA/BE centers or CROs, other pharmaceutical industry professionals and fresh science graduates & post graduates including sales and marketing personnel and the students of pharmacy and other life science stream. The program would cover:

- Introduction
- Drug development "From molecule to medicine"
- Drug approval for clinical trials
- Components of cancer clinical trials
- Clinical Trial Designs

Post Graduate Program in the Conduct & Management of Cancer Clinical Trials

- Requirements
- Conducting clinical trials
- Interpretation of results
- Drug approval
- Understanding barriers:
- How to overcome barriers?
- Benefits
- Risks
- Education and development

Post Graduate Program in the Conduct & Management of Cancer Clinical Trials

Course Objectives:

- Increases the understanding of cancer drugs development process.
- Increases the understanding of international regulatory issues and guidelines.
- Increases the knowledge of designing cancer clinical trials.
- The course would assist in the overall understanding of cancer clinical research process.

Certificate Program in Clinical Research

Mode: Distance Learning & Online

Duration: 3 Months

Eligibility: MD, MBBS, BHMS, BAMS, Graduate/Post Graduate Degree in Science, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology

Methodology: Printed Training Modules; Multimedia CD ROM; Workshops, Web based testing and examination

Certificate: Certificate would be awarded at the end of the program

Job Assistance: CVs of successful candidates would be forwarded to the CROs and Pharmaceutical companies.

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Certificate Program in Clinical Research

Program Details: This is a foundation educational program, designed for all the candidates aspiring to work in the field of clinical research or allied professions like central labs. The program provides complete overview and practical environment in the field of clinical research. The program would candidates to upgrade their knowledge about ICH GCP Guidelines, regulatory issues and other major aspects of clinical trials management. Select important topics from the following groups would be covered in the program:

Group 1 Clinical Research Introduction

Group 2 Roles & Responsibilities of Key Stakeholders

Group 3 Preparations & Planning for Clinical Trials

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Certificate Program in Clinical Research

Group 4 Essential Documentation in Clinical Research & Regulatory Submissions

Group 5 Clinical Trials Project Planning & Management

Group 6 Study Start Up Process

Group 7 Clinical Monitoring Essentials

Group 8 Compliance, Auditing & Quality Control in Clinical Research

Certificate Program in Clinical Research

Course Objectives:

- To provide a comprehensive introduction to the clinical research process.
- Learn the skills, knowledge and competencies of a candidate for the Clinical Research Associate / Clinical Research Coordinator position.
- Become more familiar with roles/jobs as part of the study team.

Post Graduate Program For Investigators & Site Personnel

Mode: Distance Learning & Online

Duration: 6 Months

Eligibility: MD, MBBS, BHMS, BAMS, Graduate/Post Graduate Degree in Science, Life sciences, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology, Employees currently working for CROs and Pharmaceutical companies.

Methodology: Printed Training Modules; Multimedia CD ROM; Workshops, Web based testing and examination

Certificate: Certificate would be awarded at the end of the program

Job Assistance: Full placement support would be provided to the successful classroom candidates. CVs of successful candidates would be forwarded to the CROs and Pharmaceutical companies, Interviews would be organized.

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Post Graduate Program For Investigators & Site Personnel

Program Details: This program consists of modules on topics related to Good Clinical Practice (GCP), applicable to clinical research. This course is intended to provide the necessary training for investigators and other senior site personnel, to better understand the regulations regarding clinical research in human subjects, and a better understanding of roles and responsibilities in planning and conducting clinical trials. The program also covers the regulatory aspects as well.

Key topics covered in the program are :

- Introduction to Clinical Research
- Introduction to ICH GCP / Schedule Y
- Ethical Considerations in Clinical Research

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Post Graduate Program For Investigators & Site Personnel

Key topics covered in the program are :

- Investigator Roles & Responsibilities
- Informed Consent Process & Documentation
- Safety Reporting
- Study Drug Accountability
- Site Selection Process and Pre-Study Visits
- Routine Site Monitoring Visits
- Site Audits
- Site Close Out

Post Graduate Program in the Conduct & Management of Cancer Clinical Trials

Course Objectives:

- Increases the understanding of cancer drugs development process.
- Increases the understanding of international regulatory issues and guidelines.
- Increases the knowledge of designing cancer clinical trials.
- The course would assist in the overall understanding of cancer clinical research process.

Certificate Program in Clinical Research for Nurses

Mode: Distance Learning & Online

Duration: 6 Months

Eligibility: MD, MBBS, BHMS, BAMS, Graduate/Post Graduate Degree in Science, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology

Methodology: Printed Training Modules; Multimedia CD ROM; Workshops, Web based testing and examination

Certificate: Certificate would be awarded at the end of the program

Job Assistance: CVs of successful candidates would be forwarded to the CROs and Pharmaceutical companies.

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Certificate Program in Clinical Research for Nurses

Program Details: This is a foundation educational program, designed for all the candidates aspiring to work in the field of clinical research or allied professions like central labs. The program provides complete overview and practical environment in the field of clinical research. The program would candidates to upgrade their knowledge about ICH GCP Guidelines, regulatory issues and other major aspects of clinical trials management. Select important topics from the following groups would be covered in the program:

Group 1 Clinical Research Introduction

Group 2 Roles & Responsibilities of Key Stakeholders

Group 3 Study Start Up Process

Group 4 Clinical Monitoring Essentials

Certificate Program in Clinical Research for Nurses

Course Objectives:

- To provide a comprehensive introduction to the clinical research process.
- Learn the skills, knowledge and competencies of a candidate for the Clinical Research Associate / Clinical Research Coordinator position.
- Become more familiar with roles/jobs as part of the study team.

Placement & Training

Placements : 100% Placement program in place. The current batch has been placed with companies like :

- **LG Lifesciences**
- **Neeman International**
- **Nexus CRO**
- **Auroprobe Laboratories**
- **Excel Lifesciences**

Companies like Dabur, Pfizer and BMS and other CROs and pharma companies are currently interviewing candidates.

Training : Practical Training support is provided to the students in CROs and pharmaceutical companies.

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THANK YOU FOR YOUR TIME
AND PATIENT HEARING

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