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Pharmacovigilance and Clinical Research

Introduction

**Pharmacovigilance** is a French term. It is a study of effects of medicines. It is used to identify side effects of drugs, their treatment, documentation and reportage. The regulatory decisions are based on them. This study is usually carried out by pharmaceutical industry to suggest warnings and recommendation for product withdrawal.

**Clinical research** is research work in all the clinical subjects of medical sciences. This includes drug research, material research, device or equipment research, genetic research, research related to diagnosis, treatment management, and public health issues.

Pharmacovigilance is basically only drug related and clinical research covers all areas of health issues. In their scope they are related and interdependent. To understand effects of any drug, they have to be widely researched on a variety of subjects and under variety of conditions.

Both these are new disciplines in India which provide newer and better opportunities to candidates across the country.

Clinical research is part of medical science devoted to the study of effects of medicines on patients. The clinical trials are done under direct monitoring of the pharma companies.

However, there is another group of clinical researchers who primarily work in hospitals. They are the doctors who actually treat patients. They work on new treatment patterns for existing diseases, but pharma companies might not be monitoring their work.

Information technology (IT) has transformed the world of health care and clinical medicine. Now the work of doctors and the care of patients gets along with better quality, efficiency and lower costs. Information technology has induced clinical safety practices and creation of worldwide Pharmacovigilance systems for safety standards.

The IT transformative force have fundamentally changed clinical research, practice of medicines, and medicinal safety monitoring. Regulators are demanding proactive surveillance programs that include comprehensive risk
management plans and signal detection /analysis throughout a clinical products’ life cycle.

Pharmacovigilance is still in its infancy in India. However, with more and more clinical trials and other clinical research activities being conducted in India, there is an immense need to understand the importance of Pharmacovigilance and how it impacts the life cycle of the product.

This will enable integration of good Pharmacovigilance practice in the processes and procedures to help ensure regulatory compliance and enhance clinical trial safety and post marketing surveillance.

What is Pharmacovigilance?

- Proactive monitoring and reporting on the quality, safety and efficacy of drugs
- Assessment of the risks and benefits of marketed medicines
- Monitoring the impact of any corrective actions taken
- Providing information to consumers, practitioners and regulators on the effective use of drugs
- Designing programs and procedures for collecting and analyzing reports from patients and clinicians

Why do you need Pharmacovigilance?

- Political and social pressures have increased in seeking out potential safety issues with marketed drugs.
- Litigation due to the lack of Pharmacovigilance can be devastating for all concerned
- Failure to practice Pharmacovigilance can lead to the suspension or withdrawal of license

National Pharmacovigilance Programme

India has more than half a million qualified Doctors and 15,000 hospitals having bed strength of 6,24,000. It is the fourth largest producer of pharmaceuticals in the world. It is emerging as an important Clinical trial hub in the world.

The Central Drugs Standard Control Organization (CDSCO) has initiated a well structured and highly participative National Pharmacovigilance Programme.
The conditions under which patients are studied during the pre-marketing phase do not necessarily reflect the way the medicine will be used in the hospital or in general practice once it is marketed.

Information about rare but serious adverse drug reactions, chronic toxicity, use in special groups (e.g. pregnant women, children, elderly) and drug interactions are often incomplete or not available. Certain adverse drug reactions may not be detected until a very large number of people have received the medicine. Pharmacovigilance is therefore one of the important post-marketing tools in ensuring the safety of pharmaceutical and related health products.

The specific aims of the Pharmacovigilance Programme are to:

- Contribute to the regulatory assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost effective) use.
- Improve patient care and safety in relation to use of medicines and all medical and paramedical interventions.
- Improve public health and safety in relation to use of medicines.
- Promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public.

NATIONAL PHARMACOVIGILANCE POLICY

There are considerable social and economic consequences of adverse drug reactions and the positive benefit/cost ratio of implementing appropriate risk management.

Hence this program was initiated to engage health-care professionals and the public at large, in a well structured programme for monitoring adverse drug reactions.

The purpose of the programme is to collate data, analyze it and use the inferences to recommend informed regulatory interventions, besides communicating risks to healthcare professionals and the public.

The National Pharmacovigilance Programme has the following objectives:

- **Short-term objectives**: To foster a culture of notification
Medium-term objectives: To engage several healthcare professionals and NGOs in the drug monitoring and information dissemination processes.

Long-term objectives: To achieve such operational efficiencies that would make Indian National Pharmacovigilance Programme a benchmark for global drug monitoring endeavors.

Scope for Jobs

Clinical Research is a Multinational, Multibillion, Multidisciplinary Industry.

According to industry estimates, India will need the services of 50,000 clinical research professionals by the year 2013 from the present 10,000.

India is fourth largest pharmaceutical market in terms of volume and 13th in value terms. Merrill Lynch valued global outsourcing market at US$ 44 billion in 2007, expected to touch US$ 73 billion 2011.

Globally, there are 2, 50,000 opportunities waiting now for clinical research professionals.

All major pharmaceutical companies and clinical research organizations will need the services of professionally trained clinical research professionals. All these factors indicate a huge demand for professionally well-trained clinical research professionals in India and abroad.

By 2012, 50,000 new professionals will be required in the clinical research sector, which is currently growing at 40% per annum. By 2012, Indian clinical research industry would be over $2 billion (Rs.9,000 crores). At present industry needs over 15,000 clinical trial professionals per annum.

At present there are over 150 companies involved in the clinical research business in India, including all leading multinational and Indian pharmaceutical and biotechnology companies, Contract Research Organisations and several hospitals.

In addition to the contribution which you will be making towards new drug development, Clinical research sector also offers attractive salaries, continuous growth in annual salaries and professional growth opportunities both internally.
and externally. Most employers offer continuous training opportunities within India and abroad for their employees.

Clinical Research today offers most attractive career opportunities to the graduates and post graduates of Science, Life Sciences, MBBS, BDS, BAMS, BHMS, Biochemistry, Biotechnology, Microbiology, Pharmacy, Pharmacology and other allied life sciences streams.

**Career Prospects**

The various career options available while pursuing the field of Clinical Research are:

**Clinical Research Associates (CRAs)**

CRAs play a very important role in clinical trials by participating in the research program. Clinical Research Associates (CRAs) can progress to become Clinical Research Managers (CRMs). Their role is usually within the clinical or medical departments of a Company or in a Contract Research Organization.

**Monitors**

Research Professionals - monitoring and overseeing the conduct of the clinical trials in order to meet international/national guidelines as also national regulatory requirements. The monitor is the principal communication link between the sponsor and the investigator and is appointed by the sponsor. They will assess the compliance of investigators to the protocol of study.

**Investigators**

Investigators are the ones who are directly responsible for recruitment and treatment of patients in a Hospital setting and are usually medically qualified personnel.

**Site Co-ordinators**

Site Co-ordinators play a role in a hospital setting, by co-ordinating the study with the Chief Investigator of one center with activities of other centers in multicentric studies.
Data Managers:
Data Managers collect Clinical Trials data and process them using specialized software. The function of Data Management and Biostatistics is an emerging area with large prospects in India.

Regulatory Managers
Most Companies and CROs have competent personnel in regulations to oversee the function of submitting regulatory documentation for clinical trial permission and later for marketing permission. Regulatory bodies like the Federal Drug Administration (FDA) of USA and the Drug Controller General of India (DCGI) have very competent people occupying these positions.

Auditors and Inspectors
Candidates with experience in Clinical Trial monitoring also look towards auditing as a career option as there are very few competent auditors in India today.

Pharmacovigilance practice
Students in this field can get jobs in various pharmaceutical companies and earn attractive and handsome salary packages.
Remunerations

Doctors qualified in Clinical Research can augment their income by participating in Clinical Trials as Clinical Research Investigators.

Pharmacy and Science Graduates can look forward to rewarding careers as Clinical Research Associates, Clinical Research Coordinators, Clinical Research Auditors, Business Development Managers and Project Managers etc.

Entry-level remunerations are expected to range from Rs. 35,000 - Rs. 50,000 per month, depending on basic qualifications and experience.

At 30 years one could be a Director-Operations/Regulatory Affairs, earning a salary of Rs.1 lakh per month.

A job holder in pharmacology can easily get the starting salary of Rs.3.5 lakh - Rs.8 Lakh per annum

Starting salaries for CRAs
Salaries start at Rs.180,000 to Rs.250,000. Some may receive a higher salary due to their background, experience and education. After one year of experience the candidate will usually be able to transition into a position earning over Rs.300,000/-. A CRA with 4 plus years experience can earn from Rs.350,000/- to over Rs.400,000. Experienced CRAs have many flexible employment options (work from home, part-time, independent consultant, etc.)
Eligibility

Pharmacovigilance

Minimum eligibility criteria for application to the course would be any of the following:
A postgraduate or graduate in Bioscience/Life Sciences (with any of the following subjects: Botany, Zoology, Biochemistry, Microbiology, Genetics, Biotech) with at least 50% marks in aggregate. A postgraduate or graduate with Chemistry as a subject with at least 50% marks in aggregate. A postgraduate or graduate in Pharmacy or Pharmaceutical Sciences. A postgraduate or graduate in Medicine.

Selection Procedure:
To maintain high academic standard, the Institute gives due importance to the quality of students enrolled. To ensure this, the selection of individual student will undergo the following procedure: Written examination, personal interview, screening and selection of students based on merit.

Clinical Trials

Students consists of MBBS, MD, Pharmacy, Pharmacology, Biotechnology, Biochemistry, Microbiology and other Science graduates and post graduates. Large number of personnel currently working with CROs and Lifesciences companies opt for these programs

Any candidate having any sorts of medical or paramedical qualification is preferred over other life sciences qualification. 60% of the clinical research professionals are from medical background.
Courses

General Notes
I have visited all the listed sites. These are all correct and working as on May 2011.

- There are several institutes in the country now offering different courses on these disciplines.
- There are more institutes with Clinical Research programs and some have short courses of Pharmacovigilance also.
- Most of these companies are also providing services in these areas, and training is part of their services.
- A student can pursue certificate and diploma courses, online, distance education and regular classes.
- Several Institutes have collaborated with different Universities, and some degrees are awarded through these.
- Most Institutes have several campuses, and you can look for the one nearer to you.
- Some institutes have a long list of courses. I have given the names of the course, and links to look for it. It is not possible in a document of this type to really critically look and evaluate all the courses. I have only quoted from the site literature.

This is a fairly expensive course; the fee quoted is from 30000 Rs to over a Lakh.

1. I would seriously advise you to evaluate the institute well before parting with any money. Look for and ask about their placement record.

2. Some Institutes have a provision for scholarship[s for deserving candidates. See if you qualify.

3. I understand you can bargain about the way of payment with some Institutes where you can pay in installments.

4. Some Institutes help you avail loans from the banks.

I have made all possible checks, but some information is only given to the candidate.
Institutes

MedHimalayas

http://www.medhimalayas.com/home.html

MedHimalayas is a technologically advanced, contract research organization (CRO) which has been set up with an aim to deliver services of highest quality in clinical research, pharmacovigilance, regulatory, medical writing and clinical data management.

Headquartered in UK, MedHimalayas has its operational centers in Hyderabad and Mumbai in India.

Hyderabad
Level 7, Maximus Towers,
Building 2A, Mindspace Complex,
Hi-Tech City, Hyderabad,
India – 500081
Tel No : +91 404 033 9842 +91 404 033 9842       Fax No: +91 404 033 9852
Email : info-hyd@medhimalayas.com

Mumbai
Raheja Towers, Level 8,
G Block C62,
Bandra East,
Mumbai, India – 400051
Tel No : +91 224 090 7249 +91 224 090 7249       Fax No: +91 224 090 7272
Email : info-mum@medhimalayas.com

http://www.medhimalayas.com/home.html

Course: Global Pharmacovigilance Education & Training
The course is aimed to provide candidates with in depth knowledge and practical training of the Global Pharmacovigilance practices, processing and reporting of the ADR's, regulatory framework, pharmacoepidemiology and risk management systems.
Eligibility

- Professional qualification in Medicine (MBBS, BAMS, Nursing), Dentistry or Veterinary science.
- Masters or PhD in clinical sciences, biosciences or pharmacy
- A first class honors degree in clinical sciences, biosciences or pharmacy
- Professionals working in drug safety, clinical research, medical device or pharmaceutical industry.

Duration 6 Sundays – 100 hrs

Course Fees

The total fee for this advanced course is INR 1,50,000 for Indian students and USD 4,000 for Overseas students.

Placements:

100% placement assistance will be provided in India and Overseas to the candidates completing this course. Candidates can also be absorbed in our organization in various roles according to candidates credentials and performance.

Registration:

You can register online by sending your CV and post DD of Rs 500/- in favor of:

MedHimalayas Solutions Pvt Ltd,
Level 7, Maximus Towers,
Building 2A, Mindspace Complex,
Hi-Tech City,
Hyderabad,
India - 500081
Tel No: +91 404 033 9842 / Fax No: +91 404 033 9852
Email: info-hyd@medhimalayas.com
ICRI Institute of Clinical Research India

Visit: www.icriindia.com

It is the Country's premier Clinical Research Institute which is exclusively focused on specialized Clinical Research Programs.

They have many Degree, Diploma and certificate courses. For each course info is given with it.

Eligibility

Minimum eligibility criteria for application to the course would be either of the following:

- A postgraduate or graduate in Bioscience/Life Sciences (with any of the following subjects: Botany, Zoology, Biochemistry, Microbiology, Genetics, Biotech) with at least 50% marks in aggregate
- A postgraduate or graduate with Chemistry as a subject with at least 50% marks in aggregate
- A postgraduate or graduate in Pharmacy or Pharmaceutical Sciences
- A postgraduate or graduate in Medicine
- A graduate or equivalent degree/diploma in Nursing

Selection Procedure

To maintain high academic standard the selection of individual student will undergo the following procedure:

- Written examination
- Personal interview
- Screening and selection of students based on merit

Scholarships

The Institute offers merit scholarship to five students every year. The Scholarship is offered on the overall performance of the students during the first year and these first five students are given a complete tuition fee waiver for the next year.
COURSES

Full time

1. MSc Clinical Research
The MSc Clinical Research is awarded by Cranfield University and delivered in partnership with ICRI.

   **Course Duration**  One year

   **Course Timings**  Monday – Friday, full-time

The MSc in Clinical Research is awarded by Cranfield University. The MSc may be undertaken at Mumbai, Delhi, Ahmedabad, Bangalore and Cranfield, UK.

**Entry Requirements**
Students must have the equivalent of a UK 1st or 2nd class honours degree (according to NARIC criteria) and who have a qualification in English such as an International English Language Testing System Score (IELTS) of 6.5 or Test of English as a Foreign Language (TOEFL) 580.

Students who do not meet the entry requirements may gain access to the course by successfully completing ICRI’s Foundation Year.

2. MSc Clinical Research
**(Entry via ICRI Foundation Year)**
Admissions Open for M.Sc. in Clinical Research (Entry via ICRI Foundation Year)

   **Course Duration**  ICRI Foundation Year – One year

   MSc Clinical Research – One year

   **Course Timings**  Monday – Friday, full-time

This Clinical Research Program starts in the month of August every year at Mumbai, Delhi, Ahmedabad, Bangalore and Hyderabad and comprises a Foundation Year study program undertaken in India by ICRI followed by the MSc in Clinical Research course awarded by Cranfield University. The MSc may be undertaken at Mumbai, Delhi, Ahmedabad, Bangalore and Cranfield (UK).
3. M.Sc. in Clinical Trials
Get a degree from IGNOU and join fast growing Clinical Research industry in India.

Duration 2 Years - Full Time
Start Date July 2011

Eligibility
B.Sc. in Life sciences (Biology, Zoology, Botany, Genetics, Microbiology, Biotechnology, Chemistry, Nursing, Biochemistry), B.Pharm, M.Pharm, MBBS, BDS, BAMS, BHMS

Can apply online

4. MS in Clinical Research (MSCR)
Awarded by Medical University of South Carolina

Course Duration ICRI Foundation Year – One year
MSc Clinical Research – One year

Course Timings Monday – Friday, full-time

Campuses Hyderabad and Dehradun only

5. Post Graduate Diploma in Clinical Research & Pharmacovigilance

Course Duration: 6 Months Full-time / 10 Months Part-time

Eligibility: MBBS, BDS, B Pharma, M Pharma, B.Sc.(Botany), B.Sc.(Zoology) graduates

Course Offered at: Delhi, Mumbai and Bangalore campuses
Contact Numbers

**Delhi Campus**
Email: delhi@icriindia.com  
Phone: 011 - 4065 1000

**Mumbai Campus**
Email: mumbai@icriindia.com  
Phone: 0091 022 – 42114949 / 4211 4910

**Bangalore Campus**
Email: bangalore@icriindia.com  
Phone: 080 - 43577200 / 201 / 214 / 220 / 221

6. Post Graduate Diploma in Advanced Clinical Research
   Course Duration 10 Months with 2 Months Dissertation. Timing Monday – Friday (4 hours per day)
   *(Course timings are subject to change)*

7. PG Diploma in Clinical Research
   To provide participants with a broad understanding of the basic principles employed within Clinical Research both domestically and internationally.
   - **Duration of course**: 10 months including 1 month dissertation
   - **Course timings**: 4 hours on every Saturday of the month

Part Time
- **PG Diploma in Clinical Research**
- **PG Diploma in Clinical Data Management**
- **PG Diploma in Clinical Trial Management**
- **PG Diploma in Pharmacovigilance**
- **PG Certificate in Clinical Research for Nurses**
- **Certificate in Clinical Research for Nurses**
- **PG Diploma in Clinical Research specialization in Business Development**
- **PG Diploma in Clinical Research Specialization in Quality Assurance and Audit**
These courses are from 9 – 12 months duration, and most of them are conducted during weekends.

You can apply online. They have not mentioned any fee.

**Address and locations**

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<tr>
<th>Campus</th>
<th>Contact person</th>
<th>Phone / email of contact</th>
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<tr>
<td><strong>Delhi Campus</strong></td>
<td>CHARU</td>
<td><a href="mailto:charusawhney@icriindia.com">charusawhney@icriindia.com</a></td>
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<td>A-201, Okhla Industrial Area, Phase I, New Delhi 110020</td>
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<td><strong>Phone</strong>: 011 - 4065 1000</td>
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<td><strong>Fax</strong>: 0091 - 011 - 40527053</td>
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<td><strong>Mumbai Campus</strong></td>
<td>SUKANYA</td>
<td><a href="mailto:sukanyassindgikar@icriindia.com">sukanyassindgikar@icriindia.com</a></td>
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<tr>
<td>C-9, Central Road No. 22, MIDC Industrial Area, Marol, Andheri (East), Mumbai 400093</td>
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<td>DR. BHARTI GARG</td>
<td><a href="mailto:bhartigarg@icriindia.com">bhartigarg@icriindia.com</a></td>
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<td>RAJINI CHANDRAN</td>
<td><a href="mailto:rajinichandran@icriindia.com">rajinichandran@icriindia.com</a> Phone: 09724326596</td>
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<td>Hyderabad Campus:</td>
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<td>Dehradun Campus</td>
<td>SAPNA KAPOOR</td>
<td><a href="mailto:sapna@icriindia.com">sapna@icriindia.com</a> Phone: 9719111106</td>
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International Institute of Clinical Research & Training (IICRT)
http://www.iicrt.com/courses.html

Since 2007 International Institute of Clinical Research & Training has provided Customized Training Courses and Programmers for customers across the World.

Courses

1. A.D in Clinical Data Management (AD-CDM)
   
   Course Duration : 6 Months

   Eligibility : Bachelor's, Masters, or a Ph.D. in a Science or Allied Health Field; OR Healthcare Professional Medical Technologist, B.sc, M.sc life sciences. Pharmacy, Biotech, Computer.

2. P.G Diploma in Clinical Research & Data Management (PGD-CRDM)
   
   Course Duration : 11 Months

   Eligibility : Bachelor's, Masters, or a Ph.D. in a Science or Allied Health Field; OR Healthcare Professional Medical Technologist, B.sc, M.sc life sciences. Pharmacy, Biotech, Computer.

3. P.G Diploma in Clinical Research Project Management (PGD-CRPM)
   
   Course Duration : 11 Months

   Eligibility : Bachelor's, Masters, or a Ph.D. in a Science or Allied Health Field; OR Healthcare Professional Medical Technologist, B.sc, M.sc life sciences. Pharmacy, Biotech, Computer.

4. P.G Diploma in Clinical Research Project Management (PGD-CRPM)
   
   Course Duration : 11 Months

   Eligibility : Bachelor's, Masters, or a Ph.D. in a Science or Allied Health Field; OR Healthcare Professional Medical Technologist, B.sc, M.sc life sciences. Pharmacy, Biotech, Computer.

5. P.G Diploma in Pharmacovigilance (PGD-P)
   
   Course Duration : 6 Months
Eligibility: Bachelor's, Masters, or a Ph.D. in a Science or Allied Health Field; OR Healthcare Professional Medical Technologist, B.sc, M.sc Life sciences, Pharmacy, Biotech, Computer.

Addresses and Locations
Office Hours: Weekdays: 10:00 AM - 7:30 PM
Saturdays & Sundays: 2:30 PM - 7:30 PM

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<th>Location</th>
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BioMed Informatics, Medwin Hospitals

http://www.biomedlifesciences.com/

It has been setup as a premier research centre for Clinical Research and Development, Advanced Training and Services for the promotion, growth and prosperity of Biosciences.

We Offer

- Job Oriented Training
- Live Project Experience Certification
- Placement Assistance
- Training with Project Experience
- Certification Live Projects for Final Semester Students
- Live Projects for Summer Training Students
- Corporate Training

Course: Clinical Research, Pharmacovigilance & Clinical Data Management - CDM

Eligibility:

- MBBS, MD, BDS, BHMS, BUMS, BAMS, BPT
- M.Sc., (Microbiology / Biochemistry / Biotechnology / Bio-informatics / Chemistry / Genetics / Botany / Zoology / Life Sciences / Biomedical Genetics / Molecular Biosciences / Statistics / Nursing)
- B.Pharmacy, M.Pharmacy, B.Tech.(Biotechnology)

OPPORTUNITIES:

Excellent Opportunities are available in Abroad / India in this emerging field. In India alone, the clinical trials market of $35 million is expected to grow to nearly $300 million shortly. Our candidates are employed in Satyam Computers, Global Hospitals, Apollo Hospitals, NIMS, Quintiles, Novartis, Glenmark Pharmaceuticals Ltd, Parexel International (India) Pvt Ltd, SMO Clinical Research (I) Pvt Ltd, Pioneer Corporate Services Inc-USA, Texas Woman’s University-USA and many more…

Interested candidates are kindly requested to fill the enquiry form in the website http://www.biomedlifesciences.com for further information.
Please note that we also provide separate hostel facility guidance for ladies as well as gents.

BioMed Informatics

Medwin Hospitals
B Block, First Floor,
Nampally, Hyderabad- 500 001, India.
Ph: +91-040-40209750 / 66821025

Website: www.biomedlifesciences.com
Email: ceo@biomedlifesciences.com
Email: hrprojects@biomedlifesciences.com

The Academy for Clinical Excellence (ACE)
http://aceindia.org/

It is the pioneering clinical research training institute in India established in February, 2002. ACE is an initiative of Pfizer India Ltd in partnership with Suven Life Sciences Ltd. and Bombay College of Pharmacy. The Academy is conceived as a one-stop-shop for the training needs of all clinical research professionals.

Courses

The following programs are offered by the Academy for Clinical Excellence:

- Diploma for a detailed training covering every aspect of Clinical Research.
- Certificate courses to cater continuing Clinical Research Training.
- Customized courses to suit the specific requirement of the customer.

1. DIPLOMA IN CLINICAL RESEARCH

Eligibility

Graduates in Life Sciences, Pharmacy and Medicine with 55% aggregate marks.
The Diploma Program is available in two modes

1. Campus Based

Classes are held on weekends (Saturday/Sunday). The curriculum is covered in course attendance of 8hrs X 28 days.

2. E-Learning

Fees : Rs. 45000

Address

Academy for Clinical Excellence

Bombay College of Pharmacy,
Kalina,Santacruz (E),
Mumbai 400 098

Tel:  +91 22 26664568 / 26671032
Fax:  +91 22 26671032

E-mail 1: cce@aceindia.org E-mail 2: acebcp@eth.net E-mail 3: acebcp@yahoo.com

Web: http://aceindia.org/

CREMA

http://www.cremaindia.org/CREMA-Website/about-crema.html

Clinical Research Education and Management Academy was launched in August 2007 as "Institute of Excellence" to educate and equip students and industry professionals by imparting advanced training in Clinical Research.

http://www.cremaindia.org/courses.html
Full Time Courses

1. Advanced Postgraduate Diploma in Clinical Research Management (APGDCRM)
   This first-of-its-kind programme in India is comprehensively-structured and internationally-styled to match academic standards with industry requirements. The course is accredited by the Jaipur National University (JNU). Hence making it the 1st of its kind 1 year state accredited Clinical Research course in India.

   The 1-year duration includes a pre-placement process after the 3rd quarter to ensure that students get a quick entry into the industry for faster career success.

   Students also would receive the training in Business Proficiency from ISIL & Speak First (UK) where in at the end of the course, the students would be given a certificate by ISIL & Speak First (UK).

   Duration: APGDCRM is a one-year full-time course with lectures held from Monday to Friday.

   Eligibility: Graduate or Postgraduate in Life Sciences / Microbiology / Biotechnology / Pharmacy / Medicine / Nursing / Physiotherapy / Dentistry / Homeopathy / Ayurvedic and Veterinary Science.

Part Time Courses

1. Post Graduate Diploma in Clinical Research (PGDCR)
   It is a one year weekend course. It focuses on the essential principles of Clinical Research and standard regulatory controls necessary to study the safety and efficacy of a drug. Students are not only trained in Clinical Research but there is a special focus given to Management & Soft Skill learning.

   CREMA offers Postgraduate diploma in Clinical Research (1 year - Part Time ) from Jaipur National University.

   Duration: PGDCR is a one year part-time course with lectures held every
Unusual Careers Pharmacovigilance and Clinical Research

Saturday.

**Eligibility:** Graduate or Postgraduate in Life sciences/ Microbiology/ Biotechnology/ Pharmacy/ Medicine/ Nursing/ Physiotherapy/ Dentistry/ Homoeopathy/ Ayurvedic and Veterinary Science.

2. **Post Graduate Diploma in Clinical Data Management (PGDCDM)**

Clinical Data Management is a branch of Clinical Research concerned with managing and processing the data gathered during clinical trials. This one year part-time course is one of the most comprehensive course on the subject.

The course is divided into two semesters which comprises both theory and practical sessions having workshops, case study assignments, and exercises. During all practical sessions, the students will get hands-on experience on Clinical Data Management software and its applications like Oracle Clinical and EDC Software.

**Duration:** PGDCDM is a one year part-time course with lectures held every Saturday.

**Eligibility:** Graduate or Postgraduate in Life sciences/ Microbiology/ Biotechnology/ Pharmacy/ Medicine/ Nursing/ Physiotherapy/ Dentistry/ Homoeopathy/ Ayurvedic/ Veterinary Science/ Statistics and IT

3. **Post Graduate Diploma in Pharmacovigilance (PGDPhV)**

This one year part time course is designed to impart the knowledge of regulatory requirements of drug safety monitoring for various countries, train the students on management of pharmacovigilance projects in an organization, drug safety data development during pre-clinical and clinical phases of drug development and during post approval period.

This course is divided into two semesters that comprises of both theory and practical sessions having exercises and clinical case assignments. During practical sessions, the students will get hands on experience on pharmacovigilance databases, information resources, coding systems and their applications.

**Duration:** PGDPhV is a one year part-time course with lectures held every...
Saturday.

**Eligibility:** Graduate or Postgraduate in Life sciences/ Microbiology/ Biotechnology/ Pharmacy/ Medicine/ Nursing/ Physiotherapy/ Dentistry/ Homoeopathy/ Ayurvedic/ Veterinary Science/ Statistics and IT.

**Address**

**HEAD OFFICE**  
Silver Astra Building  
Wing A, 2nd Floor,  
J.B.Nagar, Andheri(East)  
Mumbai 400 059..

**Phone:** +91 022 66715491/92 ,  
**Toll Free:** 1800 2093731  
**Mobile:** +91 99877 70761/62/63/64  
**Email:** mumenquiry@cremaindia.org  
**Tele Fax:** +91 022 66715490

For more information on Courses in Clinical Research SMS “CREMA” to 57333
## Other Campuses

<table>
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<th>Address</th>
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<td>BANGALORE</td>
<td>465/A, 22nd Cross Road, 3rd Block, Jayanagar, Opp NMKRV College</td>
<td>Phone: 080-4142 5578/79 Mobile: +91 9632319877 / 9972361942 / 69 Email: <a href="mailto:bglrenquiry@cremaindia.org">bglrenquiry@cremaindia.org</a></td>
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<tr>
<td></td>
<td>Bengaluru 560 011.</td>
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<tr>
<td>DELHI</td>
<td>632 Lane No.3 West End Marg, Near Saket Metro Station GATE No. 2</td>
<td>Phone: 011-40678801/02/04/05 Mobile: +91 97170 94112/13/14/15/16 Email: <a href="mailto:delenquiry@cremaindia.org">delenquiry@cremaindia.org</a></td>
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<td>Saidulajab New Delhi -110030</td>
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<tr>
<td>HYDERABAD</td>
<td>Plot No.8A, MLA Colony, Road No.12, Banjara Hills, Hyderabad 500 034</td>
<td>Phone: 040-4454 9999 Mobile: +91 - 90008 83363, 99639 92084/2579 Email: <a href="mailto:hydenquiry@cremaindia.org">hydenquiry@cremaindia.org</a></td>
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</table>
Cliniminds

http://www.cliniminds.com/presentation/Home.aspx

Cliniminds was established in year 2004, by a group of professionals from Clinical Research, Pharmaceutical industry and Healthcare industry. Cliniminds today is one of the best clinical research training institutes.

Cliniminds Online Programs are popular amongst the students from India, USA, Mexico, U.K., Canada, Europe, Africa, Asia and Middle East. Cliniminds today is the leader in the clinical research education and training domain.

MAIN FEATURES OF THE PROGRAMS

- High Quality Courses Offered through Classroom; Online; Distance Learning & E-Learning.
- Cost Effective.
- Professional Faculty.
- Convenient 24x7 format using Learning Management System.
- Placement Support.

List Of all courses

Total 37 courses offered.

Many are online, 6 months to 1 year duration.

Add 10.3% service tax on fee.

I have captured the Info for 30 courses from the site. For details contact the Institute.
## List of All Courses

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<th>S.No.</th>
<th>Course</th>
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DELHI CENTRE HEAD OFFICE

**Medical Director Cliniminds**

Unit of Tenet Health Edutech Pvt. Ltd.
C-55, 1st Floor, Preet Vihar, Main Vikas Marg, Delhi 110092 (India)

Tel : +91-11-30287800 - 04
Mobile No. : +91-9311166940, 9311168241, 9311188671
Fax : +91-11-30287802
Email : info@cliniminds.com
Website : www.cliniminds.com
**List of other centers**

- Hyderabad
- Kerala
- Bangalore
- Bhopal
- Gujarat
- Vijayvada
- Kolkata
- Mumbai
- Pune
- Coimbatore
- Lucknow
- Chennai

[http://www.cliniminds.com/presentation/ContactUs.aspx](http://www.cliniminds.com/presentation/ContactUs.aspx)

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**Focus Institute of Clinical Research (FICR)**


The Focus Institute of Clinical Research offers following courses

1. **Advanced Post Graduate Program in Clinical Research (APGPCR)**

   APGPCR is an unique and in-depth programme in India which is comprehensively structured to match the academic standards with industry requirements for clinical research. The mix of extensive theory and live projects in the curriculum, along with personality development and management training, ensures a head start, enabling you to move up the corporate ladder fast, whether your interest is in research, or management.

   **Eligibility**

   **Health science:** MBBS, BDS, BAMS, BUMS, BVSc, BSSM

   **Allied Health Science:** BMLT, BSc-MLT, BPT, BMIT, BSc-MIT, BSc-HIA, BSc-HIA, BOT, BSc-SP & HG, BASLP, BSc-Opt, B.Pharma, Bsc-Nursing.

   **Duration** 1 year (weekdays)
2. Post Graduate Certificate in Clinical Research (PGCCCR)

This is an Online course

PGCCCR is an unique and in-depth programme in India which is comprehensively structured to match the academic standards with industry requirements for clinical research.

Eligibility

Health science: MBBS, BDS, BAMS, BUMS, BVSc, BSSM

Allied Health Science: BMLT, BSc-MLT, BPT, BMIT, BSc-MIT, BSc-HIA, BSc-HIA, BOT, BSc-SP&HG, BASLP, BSc-Opt, B.Pharma, BSc-Nursing.

3. Post Graduate Program in Clinical Research (PGPCR)

PGPCR is an unique and in-depth programme in India which is comprehensively structured to match the academic standards with industry requirements for clinical research.

Eligibility

Health science: MBBS, BDS, BAMS, BUMS, BVSc, BSSM

Allied Health Science:
BMLT, BSc-MLT, BPT, BMIT, BSc-MIT, BSc-HIA, BSc-HIA, BOT, BSc-SP & HG, BASLP, BSc-Opt, B.Pharma, BSc-Nursing.

Duration 1 year (weekdays)

4. Post Graduate Program in Pharmacovigilance (PGPP)

PGPP is an unique and in-depth programme in India.

Eligibility

Health science: MBBS, BDS, BAMS, BUMS, BVSc, BSSM

Allied Health Science:
Unusual Careers
Pharmacovigilance and Clinical Research

BMLT, BSc-MLT, BPT, BMIT, BSc-MIT, BSc-HIA, BSc-HIA, BOT, BSc-SP & HG, BASLP, BSc-Opt, B.Pharma, BSc-Nursing.

Duration 1 year (weekdays)

Contact Us

Corporate Office
Focus Educare Pvt Ltd
119/1, 2nd Floor, Srinidhi Complex,
11th Cross, Off Sampige Road,
Malleswaram, Bangalore-560003,
India.
Phone: +91 80 23345566, 23469099
Toll Free Number: 1800 425 1221
E-Mail: enquiry@focuseducare.com

Our Branch Offices

<table>
<thead>
<tr>
<th>AHMEDABAD</th>
<th>BANGALORE</th>
<th>CHENNAI</th>
</tr>
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<tbody>
<tr>
<td>#405 &amp; 406, Swapneel 5, Commerce Six Roads, Navrangpura, Ahmedabad-9</td>
<td>#119/1, 2nd FLOOR, Srinidhi Complex, 11th Cross, Off Sampige Road, Malleswaram, Bangalore-560003</td>
<td>Old No-142, New No-211, 2nd floor, Sivemegam Towers, Valluvarkottam High Road, Nungambakkam, Chennai - 600034</td>
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<tr>
<td>Ph: 079-64500166</td>
<td>Phone: 080-23345566, 23469099</td>
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<td>Classic House, W-86, Greater Kailash-II, New Delhi- 110048.</td>
<td>#3-6-770/2, 2nd Floor, Ala Citadel Complex, Himayatnagar, Hyderabad-29</td>
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James Lind Institute

http://www.jli.edu.in/jli_global_courses.php

James Lind Institute (JLI) is an educational division of Clinexa Life Sciences Pvt. Ltd. Clinexa is a Contract Research Organization (CRO) making its mark in niche areas of clinical research.

Courses

- Post-Graduate Diploma in Clinical Research
- Advanced Post-Graduate Diploma in Clinical Research and Pharmacovigilance
- Advanced Post-Graduate Diploma in Clinical Research and Medical Writing
- Advanced Post-Graduate Diploma in Clinical Research and Business Development
- Advanced Post-Graduate Diploma in Clinical Research and Regulatory Affairs
- Professional Diploma in Pharmacovigilance and Pharmacoepidemiology
- Advanced Certificate in Clinical Research for Physician Investigators - ACCRP (Clinical Research Investigative Site Set-up Program)
- Professional Diploma in Medical Writing
- Professional Diploma in Medical Journalism
ONLINE COURSES

- **Post-Graduate Diploma in Clinical Research (CR-01)**
- **Advanced Post-Graduate Diploma in Clinical Research & Pharmacovigilance (CR-02)**
- **Advanced Post-Graduate Diploma in Clinical Research and Medical Writing (CR-03)**
- **Advanced Post-Graduate Diploma in Clinical Research and Business Development (CR-04)**
- **Advanced Post-Graduate Diploma in Clinical Research and Regulatory Affairs (CR-05)**
- **Advanced Post-Graduate Diploma in Clinical Research and Quality Assurance (CR-15)**
- **Professional Diploma in Pharmacovigilance & Pharmacoepidemiology (CR-06)**
- **Advanced Post-Graduate Diploma in Scientific Writing & Medical Journalism (CR-07)**
- **Professional Diploma in Medical Writing (CR-08)**
- **Professional Diploma in Medical Journalism (CR-09)**
- **Advanced Post-Graduate Diploma in Healthcare & Hospital Management (CR-10)**
- **Certificate in Healthcare Risk Management (CR-11)**
- **Certificate in Pharmaceutical Event Management (CR-12)**
- **Advanced Certificate in Medical Law & Bioethics (CR-13)**
- **Advanced Certificate in Clinical Research for Physician Investigators- ACCRP (Clinical Research Investigative Site Set-up Program)(CR-14)**

**Eligibility**

- MBBS/BHMS/BAMS/BPT/MPT/BDS/BMLT/Bachelor in Naturopathy & Veterinary Science /MD/MS.
- Graduate/Postgraduate degree in Pharmacy/ Pharmaceutical Sciences.
- Graduate/Postgraduate degree in Life Sciences (Botany, Zoology, Biochemistry, Microbiology, Genetics, Biotechnology).
- Graduate/Postgraduate degree in Chemistry/Biostatistics/ Bioinformatics.
- Graduate or equivalent degree in Nursing/Allied Health.
- Students in their final year of graduation for the above courses may also apply.

**Course duration**

Self Paced 6 - 8 months
A student enrolled in the Post-Graduate Diploma in Clinical Research Course (PGDCR) is expected to study online for a minimum of fifteen hours per week.

FULL TIME COURSES

- Post-Graduate Diploma in Clinical Research & Other Advanced Courses
- Six Month Internship

Tuition

James Lind Institutes approved tuition rates vary by course.

Please send an email to academics@jli.edu.in or admissions@jli.edu.in

or chat with our counselor online to know the approved tuition rates applicable to you for 2010-2011.

Financial Options:

Education is an investment in your future, and at JLI we understand that financing it can sometimes prove to be a challenge. For students opting for multiple courses and tuition fee of more than INR 50,000/-, we have partnered with HDFC Bank, one of the premier private banks in the country, to provide you with student loan for our courses.

Scholarships

James Lind Institute recognizes the fact that academic excellence achieved by hard work must get rewarded. If you have been a meritorious student in your field of study, you may be eligible for a scholarship of up to 50 percent of the course fees which will be paid to you in the form of a reimbursement. All scholarship requests must be accompanied by the student’s relevant marks sheets. Scholarships for each year are limited, and the final decision of granting scholarship remains with JLI. Please feel free to contact the student success team coordinator if you have any questions about scholarship after you have enrolled in any JLI course.
Address

James Lind Institute
501, 5th Floor
V.V.Vintage Boulevard
Raj Bhavan Road, Somajiguda
Hyderabad-500082
Andhra Pradesh, India
Phone: +91-40-42023318
+91-40-42023319
Fax: +91-40-42208247
Email: info@jli.edu.in
admissions@jli.edu.in

Mir-IFCR India
http://mirifcr.com/

With the headquarters in Kerala Mir-IFCR India has grown into the leading educator of US, EU, Australian, and US standard clinical research specialists in India.

Courses

Master's Programs - 2 years (1 ½ yrs training + 6 months internship)

1. M.Sc. in Clinical Research
2. MBA in Healthcare

P.G. Diploma Programs - 1 year (6 months training + 6 months internship)

1. PGDCR - Post Graduate Diploma in Clinical Research
2. Post Graduate Diploma in Regulatory Affairs
3. Post Graduate Diploma in Clinical Data Management
4. Post Graduate Diploma in Pharmacovigilance
Work & Study Programs - 1 year (6 months training + 6 months internship)

1. APGDCR - Advanced Post Graduate Diploma in Clinical Research and Regulatory Affairs
2. Advanced Post Graduate Diploma in Clinical Research and Pharmacovigilance
3. Advanced Post Graduate Diploma in Clinical Research and Clinical Data Management

Certificate Programs - 6 months (3 months training + 3 months internship)

1. CPCR - Certificate Program in Clinical Research
2. Certificate Program in Clinical Data Management
3. Certificate Program in Pharmacovigilance
4. Certificate Program in Medical Writing
5. Certificate Program in Drug Discovery and Pre-Clinical Studies
7. Certificate Program in Clinical Research for Medical Practitioners
8. Certificate Program in Clinical Research for Nurses

Application Procedure
For Indian Nationals, enquiries about the program and requests for Application Forms and Prospectus should be made directly to Mir-IFCR India through mail or online to
The Registrar  
Mir-IFCR India  
Little Flower Campus  
CC 37/715, S.A.Road, Kadavanthara,  
Cochin-682 020, Kerala, India  

Completed Applications must be submitted at least 15 days prior to the commencement of the program. Students applying after the commencement date will not be considered for training for the ongoing intake. However conditional admission may be offered for a subsequent intake commencing either in March/June/September/December.

Completed Applications should be submitted to the Administrative Department of Mir-IFCR India and should include:

- Biodata
- The signed Application Form
- 4 passport size and 2 stamp size color photographs.
- Attested copies of all official academic transcripts/marks lists from Secondary School onwards (Originals to be submitted upon admission)
- Synopsis of research or project work done (if any)
- Two references (work / academic related)
- Application fee of Rs. 300/- (DD Favouring Mir-IFCR-India, payable at Kochi)

Eligibility

- All Graduates and Post Graduates
- M.Sc / M.Sc Nursing
- MBBS / MD
- BAMS / MD Ayurveda
- BHMS
- B.Pharm / M.Pharm
• BDS / MDS
• BPT / MPT
• BVMS
• BCA / MCA
• BE (All Fields)
• B.Pharm / M.Pharm
• M.Sc (Biostatistics, Biotechnology, Molecular Biology, Microbiology, Biochemistry, Genetics & all life sciences)
• Ph.D in Basic Health Science

Selection Procedure
Final selection of scholars will be made based on overall evaluation of academic credentials, Research Aptitude Test, personal interview with the Interview Board, work experience and submission of application document.

All short listed candidates will be duly informed of the result within one week of the interview.
Decisions made by the Academic Board of Mir-IFCR on selection of the candidates will be final. Further re-consideration of application will not be entertained once admission decisions are made.

Intakes and Deadlines
There will be four intakes in a year as follows:

| Intake 01  | March |
| Intake 02  | June  |
| Intake 03  | September |
| Intake 04  | December |

Application Deadlines
For March intake   First week of March
For June intake    First week of June
For September intake First week of September
Mitcon India

http://www.mitconindia.com/Pages/tabstrip_biotech.html

Diploma Course in Clinical Research

Eligibility:
Science, Pharmacy, Medicine, Nursing, Management undergraduates, Graduates and Post Graduates, Doctors.

Duration: 6 Months (Weekend Batches)

CERTIFICATION:
Candidates who complete the course will be awarded Diploma in “Pharmacovigilance & Clinical Data Management” from MITCON BIOPHARMA, Pune.

FEES
The total fees for this 6 month course will be Rs 33,090 for students, working professionals. It will cover all course materials and examinations. There will also be provision for tea / coffee on teaching days.

For any information you may contact on 9011042629 / 020 - 66289452.

Symogen
www.symogen.net

This is one site which is referred by all searches, hence I am including this. But their site does not seem to be updated for two years. They also do not have a proper Address. Before proceeding further please make proper inquiries.
Course

Certificate Course in Pharmacovigilance & Pharmacoepidemiology
It is designed to cover all aspects of Pharmacovigilance and Drug safety Management. This course is the first of its kind in India.

The Course is designed as 12 modules spread over 4 months to cover all aspects of Pharmacovigilance,

Eligibility
Doctors/Physicians of all disciplines, Post Graduates in Pharmacy and Biosciences, Graduates in Pharmacy/Life sciences with work experience, and Junior professionals in Pharmaceuticals and IT Industry, Clinical Research Organizations, BPOs, Academia and Regulatory Agencies.

Admission will be based on Candidates’ merit, a genuine interest in this area and a short interview with the panel of Symogen India.

Candidates wishing to join the course need to submit their CVs to Symogen India at info@symogen.net

Duration and Venue of the Courses:
The next batch of the course will be start in May, 2009. Number of seats is limited to 30, so that personal attention can be paid to each student and this will also facilitate effective discussions, practical hands on training and in conducting mini-workshops during the course of study.

Fees
The total fees for this 4 month course will be Rs 95,000 for working Indian Professionals and SAARC countries and 5000 USD for other International students. The fees for Indian students pursuing higher Education will be Rs 65,000.
It will cover all course materials and examinations. There will also be provision for coffee and lunch on teaching days.

Examination
At the end of each four month course students will be assessed on the knowledge of Pharmacovigilance. The exams will consists of:
A written component of two hours duration consisting of 2 Long Questions and 4 Short Questions.

Viva: Thirty (30) minutes with two examiners.

A short Project to be submitted at the end of the course on the topics to be given by the Faculty on Pharmacovigilance.

**Certification**

Candidates who complete the course will be awarded Certification in "Pharmacovigilance & Pharmacoepidemiology" from SYMOGEN India for participation in the course. This course is supported by WHO-Uppsala Monitoring Centre, Sweden and The International Society of Pharmacovigilance.

90 Credits (7.5 Credits per module CME/CPD) approved for the Certificate course in Pharmacovigilance and Pharmacoepidemiology by Faculty of Pharmaceutical Medicine of The Royal College of Physicians, London, UK.

**Address**

SYMOGEN India

New Delhi
Tel No: +91-11-65805451
Fax No: +91-11-26882891
Email: info@symogen.net

**DIA (Drug Information Association)**

http://www.diahome.org/en/AboutDIA/Overview/DIAOverview

It is a neutral, nonprofit, global, professional association of nearly 18,000 members who work in every facet of the discovery, development, and life cycle management of pharmaceuticals, medical devices, and related products.

First-rate instructors and quality content highlight DIA’s best-in-class training program. Our instructor-led courses, in-company training, certificate programs, EudraVigilance, and online training and e learning offer a variety of courses in regulatory affairs, clinical research/development, risk management, clinical data management, project management, safety, and much more.
DIA offers certificate programs in:

► Project Management
► Clinical Research
► Clinical Safety and Pharmacovigilance
► Regulatory Affairs

eLearning

• DIA eLearning is Internet-based courseware that can be accessed 24 hours a day, 7 days a week. Modules do not have to be taken in one sitting; users can start/stop at any time and begin where they left off. After a module is completed, users will be able to review the module for one year from the date of purchase.

• Continuing Education credits are offered for some modules. To obtain Continuing Education credit (if applicable) for a module, you must receive a passing score on the exam and complete the evaluation within one month of completing the module.

• DIA’s Clinical Investigator eLearning Program provides a unique opportunity for clinical research professionals to learn the regulations, process, and best practices of conducting safe and effective clinical trials

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mumbai 400 059
India
Tel. +91.22.67653226
Fax. +91.22.28594762
diaindia@diaindia.org

http://www.diahome.org/en/eduofferings/AboutEduOfferings/AboutEducationalOfferings

Pharmaceutical Training International
http://www.informaglobalevents.com/event/pharmacowc
10 week self study course for ALL regulatory professionals
Not much information on site without registering.

WHO
WHO Medicines Safety division periodically organizes training courses for capacity building in pharmacovigilance, to help Member States establish pharmacovigilance centres for adverse drug reactions (ADR) monitoring; these courses are offered in collaboration with the WHO Collaborating Centre for International Drug Monitoring (the UMC) in Sweden, the details of which are available on the collaborating centre’s website. Lately, the Medicines Safety division has also been engaged in organizing training workshops to promote ADR monitoring in Public Health Programmes.

To know about any current program, please visit:

Other related sites

Bioinformatics India
Bioinformatics-India.com is the leading source of bioinformatics news, jobs, seminars, and training programs in India.

http://www.bioinformatics-india.com/new/?q=node/807

The International Society of Pharmacovigilance
The International Society of Pharmacovigilance (ISoP) is an international non-profit scientific organisation, which aims to foster Pharmacovigilance both scientifically and educationally, and enhance all aspects of the safe and proper use of medicines, in all countries...

Announce various training programs from time to time
http://www.isoponline.org/

**The ISoP Administration address is:**

ISoP Secretariat Ltd  
140 Emmanuel Road  
London SW12 0HS, United Kingdom  
Tel/Fax: +44 (0) 203 256 0027  
E-mail: administration@isoponline.org

**Clinical research forum**

Enjoy the best clinical research discussion platform on the internet! Learn about clinical research jobs and training courses. Discuss clinical research questions and stay updated with the latest clinical research news.