Information Brochure

DIPLOMA IN PHARMACOVIGILANCE

BioMed
Research & Analysis

BioMed Research & Analysis Pvt Ltd

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BioMed Research & Analysis Pvt. Ltd.

We are a Clinical Trial & Research company **specializing in providing high quality research** in all aspects of Healthcare. We pride ourselves in having international experts on our panel, having over **25 years of research experience** in world leading markets of US & Canada.

BioMed Research & Analysis strategically partners with Healthcare Organizations and supports them in value creation of their products. Our expertise lies in conducting **Clinical Trials & Management, Electronic Data Capture, Biostatistics and Medical Writing**. Ethical and Regulatory Compliance with strict adherence to GCP Guidelines form the core of our operations.

With our offices in US, Canada and India we are advantageously placed to cater to all research and clinical trial needs of different Healthcare Organizations. Our value proposition is to provide "**End to End Solution**" to our clients i.e. from "**Protocol Writing**" to "**Journal Publication**".

In our continuous endeavor to contribute to the field of research, BioMedRA provides world class "**Training**" to professionals in the related field, in order to build and hone their skills and make them job ready for clinical research.

Experienced Team

Our group has a collective experience of more than 30 years in US, Canada & India into numerous domains of healthcare & science, education and training hundreds of aspirants. Over these past years, we have persistently understood the gap amongst the industry requirements and lack in the opportunities and understanding of an applicant for a perkier future. Our vibrant training team and coordinators are passionate to bring a major makeover in your career by sharing their understanding, considerations and opportunities in form of training courses

Advantages

Our exclusive blend of understanding & experience, propositions an intrinsic gain to our candidate. Right from admission till employments we support them in following ways:

- Quality Curriculum designed by Industry Experts
- Smooth Enrolment & Completion
- 100% Placement Support
- Secured Payment routes
- Pay-in-Instalments Substitute
- Professionals Networking with Industry Gurus
- Economical Course Fee
- Employment Oriented Programs

Clinical Research Overview

The value of global clinical research business is assessed to US$ 65 billion with more than 160000 clinical trials being conducted till date (source: clinicaltrail.gov). As United States account 41% of the total studies, the attention is shifting to countries like India, Russia, Brazil, China due to greater patient pool & higher enrolment rate, low price, enhanced infrastructures, high number of hospital and medical specialists.

With numerous resource advantages and changing mind sets, India has emerged as the preferred destination for Clinical Trials. After India became a signatory of intellectual property regimen of WTO, Clinical Trials Industry has seen a multi-fold increase in the past 10 years or so. The charts & figures below give a snapshot of how this industry has progressed in India over a period of time.

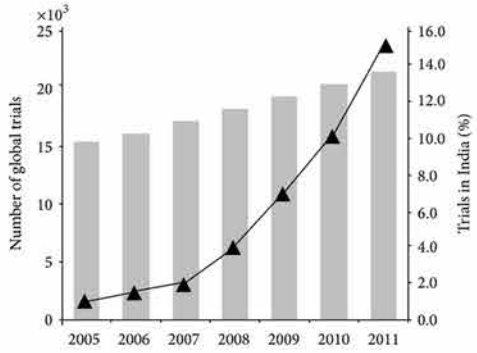

Fig 1. Number of global trials and the proportion in India. Source: The Boston Consulting Group and Business Communications Company data quoted in Mishra

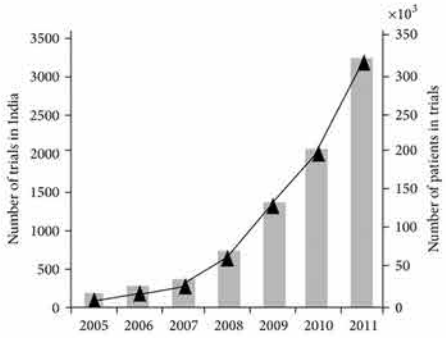

Figure 2: Number of trials and patients in India. The Boston Consulting Group and Business Communications Company data quoted in Mishra

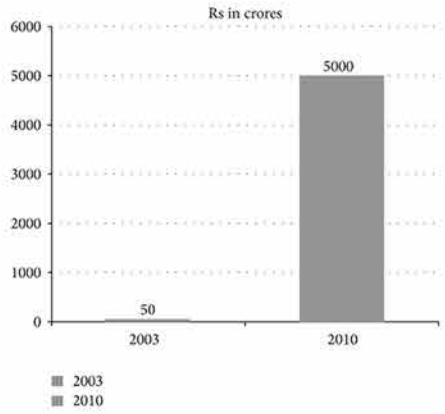

Figure 3: Financial growth of clinical trials industry in India. Source: Vasireddi

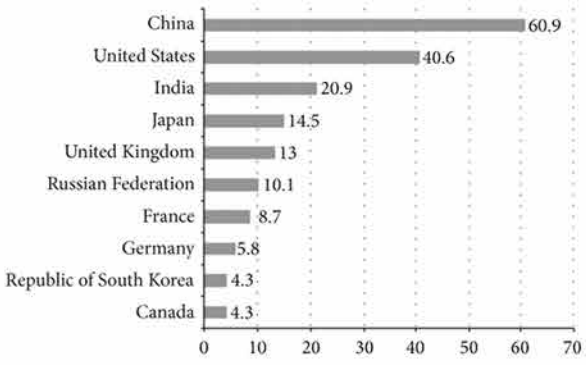

Figure 4: Most attractive locations for future foreign R & D in UNCTAD survey, 2005–2009 (percent of responses).

TABLE 1: INDIA - Resource advantages as destination for clinical trials.

Investigators	(i) Large no. of specialists in different therapy segments (ii) Medical training in English (iii) 600,000 English speaking physicians (iv) PG training from Europe/US (v) Treatment protocols in line with west (vi) Large no. of ICH/GCP complaint investigators/sites
Patient population	(i) Large, diverse, therapy-naïve (ii) Advantage of having 6 out of 7 genetic varieties (iii) Large pt. pool in acute/chronic disease segment (iv) Increasing no. of pts in life style disorders segment, HIV, oncology
Clinical research infrastructure	(i) Over 200 medical colleges (ii) Over 22,000 graduates per year (iii) 15,622 hosp., 903,952 hosp. beds >75% in urban area (iv) 14000 diagnostic labs (v) 700,000 scientists and engineering graduates/year (vi) World class medical/lab facilities at secondary/ tertiary care centres (vii) Skilled computer savvy biomedical work force
IT support	(i) Highly developed IT/ITES (ii) Motivated and committed personnel
Connectivity	(i) High quality digital connectivity (ii) Excellent air/surface transport facilities across country

Source: Surender Singh

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Diploma In Pharmacovigilance

Overview

To sustain the universal principles and prevent adverse events, Pharmacovigilance has driven the requirement for a comprehensive training in this field. The worth of international pharmacovigilance market is projected to reach US$ 2255 million by 2015. Being fourth major drug manufactures in world, India offers possibilities of an excellent career option for the aspirants from health sciences in Pharmacovigilance.

The course Diploma in Pharmacovigilance is designed by industry professionals having more than 30 years of experience in this domain, to impart a clear understanding on various vital topics of Pharmacovigilance. The course aims to prepare an aspirant competent to accomplish an entry level job profile such as Pharmacovigilance Associate (PVA) or Drug Safety Associate (DSA).

Syllabus

- Pharmacovigilance (PV) Terminology
- Overview to Pharmacovigilance
- International Outlook of PV & ADR Reporting
- Guidelines and Standards Governing PV
- Global AE Reporting System and Reporting Forms
- Individual Case Safety Reports (ICSRs)
- Public Safety Update Reports (PSURs)
- Signal Detection
- Medical Dictionary for Drug Regulatory Activities
- (MedDRA)
- Expedited Reporting and Requirements

Assignment

MCQs and Case Studies

Mode of Learning

Online (e-learning) and Offline (distance)

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Examination

Assignments Based Course Assessment

Duration

6 Months (can be completed before)

Eligibility Criteria

The minimum eligibility criteria for all Clinical Research Course would include either of the following:

- 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 last year of graduation for the above progressions can also apply.

Placement Support

- CV Preparation & Editing
- Interview Q&A Preparation
- Recent Updates & Job Broadcast
- Resume distribution to Industry Experts and applicable consultancies
- Networking with Industry Experts and Placement Coordinators
- Profile Distribution and References with industry associates
- Regular guidance via Industry Experts

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Fee Structure

Participants	Fees
Indian participants	9,500/-
Indian Participants Residing Overseas	9,500/- + 3,000 towards postal charges
Foreign Participants	US$ 200

Candidates are required to send their Application Form along with a copy of highest qualification proof and program fee through Demand Draft drawn in the favour of **"Biomed Research & Analysis Pvt Ltd"** payable at **Delhi**. The candidates are advised to write their name and address on the back of demand draft. The enrolment in the program is subject to the realization of Program fees.

Application Form Completed in all respect should be sent to:

Program Coordinator, BioMed Research & Analysis Pvt Ltd.
805 Satpura Tower, Kaushambi, Ghaziabad - 201010