

**PROFESSIONAL DIPLOMA  
IN  
CLINICAL RESEARCH (PDCR®)  
(2010-11)**

**Information Brochure**  
Distance Learning Program

“India’s Largest Clinical Research Training Program”

**Catalyst Clinical Services Pvt. Ltd.**

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PDCR® is a registered trade mark of Catalyst Clinical Services Pvt. Ltd.

## Objective

PDCR® is skill development program (purely through correspondence) of 6 months duration with a primary focus on Drug discovery and clinical trial processes, Good Clinical Practices (GCP) guidelines, Drug regulatory affairs, Roles and responsibilities of various clinical trial stakeholders *etc.* The prime objective is to provide a high-end training thereby enhancing the employment prospects of the participants.

With a track record of running **34 successful batches** (over last 6 years), **3900 candidates** from **156 cities** across **8 countries** has already enrolled for PDCR® program, establishing itself as the largest clinical research training program of the country. Majority of successful PDCRians are working for leading Pharmaceutical Companies, Contract Research Organizations (CROs) and Research Institutions across 300+ organizations.

## Clinical Research and It's Potential

India became a member of WTO/GATT/TRIPS in 1995 and implemented the product patent regime in 2005. As part of WTO/GATT/TRIPS, Pharmaceutical Industry has the right to patent products as well as processes throughout the world including India. This has led to a significant growth in pharmaceutical industry and increased stakes of multi-national companies in Indian operations.

In light of these changes, Clinical Research has emerged as a leading knowledge based industry of the new millennium. Clinical research is carried out on healthy volunteers and patients with diseases to ensure that the drug, which is to be marketed, is safe and effective. It takes approximately 12 years and US \$900 million to introduce a new drug to the market.

Clinical Research industry in India is growing rapidly and the country is projected to conduct nearly 5% of all global clinical trials in next 5 years. Being a sunrise industry it is offering exciting career avenues as well as an accelerated growth path. Being a signatory of GATT/TRIPS, India is being looked upon as a favorable destination for conducting global clinical trials. India offers unique advantages for global clinical research that include:

- Lower drug development cost
- Abundance of patients with genetic diversity
- Wide spectrum of disease
- Trained medical professionals
- Skilled manpower and IT enabled infrastructure at a lower cost
- Proficiency in English language

An estimate of total market of clinical trial conduction either directly or through contract research organization in India by 2012 is projected at US \$ 2.0 billion by major Pharmaceutical companies. This in turn offers **enormous employment opportunities for the medicine/pharmacy/life sciences graduate and post-graduate students**. However, clinical research is highly specialized and regulated profession therefore it requires specific skill sets to carry out various operations, as per global norms.

We at **Catalyst Clinical Services Pvt. Ltd.** are committed towards developing **India** as a hub for global clinical research by catering to the ever-growing training and compliance needs of the profession, through specialized training courses and workshops.

## Job Prospects

Following positions are available to pursue a career in clinical research:

Positions	Minimum Entry Criteria
Site Coordinator	Fresher
Clinical Research Associate	Fresher or 1-2 year experience
Regulatory Affair Associate	Fresher
Business Development Associate	Fresher
Project Manager	>3 years experience
Manager-Clinical Research	>4 years experience
Auditors	>5 years experience
Medical Advisor	>5 years clinical experience
Data Manager	1-2 years experience
System Analyst	Fresher

### The Company Profile: Catalyst Clinical Services Pvt. Ltd.

Catalyst Clinical Services Pvt. Ltd. is a contract research organization with a prime focus on clinical research training and development activities. With regards to clinical research training *Catalyst* has made pioneering initiatives such as:

- Professional Diploma in Clinical Research (PDCR®);
- Advance Certificate in Clinical Research (ACCR®);
- Advance Certificate Program(s) in Clinical Research;
- GCP Training Workshop(s)
- Oncology Clinical Trials Training (OCTT™);
- 21 CFR Part 11 Training;
- Orientation lectures on clinical research;

### Program Director

Sanjay Gupta, Director-Clinical Operations with Catalyst Clinical Services Pvt. Ltd has over 12 years of exclusive clinical research experience. He has personally conducted and supervised several **clinical trials** (Global registration, Phase II CTNRs, IITs etc.) across a wide range of therapeutic areas including oncology, endocrinology, CNS, critical care, andrology etc.

He has authored 6 books including a quick reference guide "**All You Need To Know About Clinical Research™**". He has presented his research work in various International Journals and Conferences including **American Society of Clinical Oncology (ASCO)**, **British Journal of Cancer (BJC)**, **British Journal of Radiology (BJR)**, **Gastric and Breast Cancer (GBC)** and **Seminars in Oncology** etc.

He is the founder member of **Society for the Promotion of Ethical Clinical Trials (SPECT)** in India and also the Network Coordinator for a cancer trials network set-up by University of Oxford, London (India and UK).

## PDCR® Program Curriculum

All the students enrolled for PDCR® are committed to uphold the highest standards of personnel and professional ethics. The PDCR® program consists of four modules in all. The components of four modules are as follows:

### Module Components:

Module No.	Module Title and Components
1	<p><b>Introduction to Pharmaceutical Medicine</b></p> <ul style="list-style-type: none"> <li>• The Drug Development Process</li> <li>• New Drug Discovery</li> <li>• Clinical Development of Drug</li> <li>• Essential Clinical Trial Documents</li> <li>• Clinical Trials Terminology</li> </ul>
2	<p><b>Good Clinical Practice (GCP) Foundations</b></p> <ul style="list-style-type: none"> <li>• History of GCP - milestones in the evolution of GCP</li> <li>• Principles of GCP</li> <li>• Applicable GCP Guidelines</li> <li>• Declaration of Helsinki</li> <li>• Clinical Study Process</li> <li>• The Management of Clinical Studies (Sponsor)</li> <li>• Ethics in Clinical Research</li> <li>• Informed Consent</li> <li>• Serious Adverse Event (SAE)</li> <li>• Challenges in the Implementation of GCP Guidelines</li> <li>• Biostatistics</li> </ul>
3	<p><b>Drug Regulatory Affairs (Clinical Trials)</b></p> <ul style="list-style-type: none"> <li>• Overview of Regulatory Environment in USA, Australia, Europe and India</li> <li>• Clinical Trial Application Requirements in India</li> <li>• Import- Export of Clinical Trial Drugs in India</li> <li>• Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.</li> <li>• IND/ANDA/New Drug Application</li> </ul>
4	<p><b>Roles and Responsibilities of Clinical Trial Personnel</b></p> <ul style="list-style-type: none"> <li>• Roles and Responsibilities of Sponsor</li> <li>• Roles and Responsibilities of Investigator</li> <li>• Roles and Responsibilities of ERB/IRB/IEC</li> <li>• Roles and Responsibilities of CRA /Monitor</li> <li>• Roles and Responsibilities of Auditor</li> <li>• Roles and Responsibilities of Clinical Research Coordinator or Site Manager</li> <li>• Roles and Responsibilities of CRO's</li> <li>• Roles and Responsibilities of Regulatory Authorities</li> <li>• Roles and Responsibilities of Clinical Data Manager (CDM )</li> <li>• Roles and Responsibilities of Clinical Biostatistician</li> </ul>

## Duration

The program duration is 6 months. However; it can be stretched up to a maximum of 10 months, failure to which would lead to cancellation of the candidature requiring a fresh enrolment.

## Eligibility

- B.Pharm, M.Pharm, Ph.D
- M.B.B.S, M.D, M.S, D.N.B, D.M
- B.D.S, M.D.S, B.P.T, B.Tech
- B.A.M.S, B.H.M.S, B.U.M.S
- B.Sc, M.Sc, Ph.D
- Working Professionals

Third year students of above curriculums are also eligible for enrolment in the program.

## Application and Fee

The program fee for Indian Participants is **Rs. 8000**. The program fee includes cost of study material, assignments, evaluation and certification. Overseas students are also eligible to apply for the program.

Fee for Overseas Students		
1	Application Processing	US\$ 50
2	Program Fee: PDCR®	US\$ 430
<b>Total</b>		<b>US\$ 480</b>

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 favor of "Catalyst Clinical Services Pvt. Ltd." payable at Delhi). The candidates are advised to write their name and address on the back of demand draft.

The enrolment in PDCR® program is subject to the realization of Program fees.

## Last Date of Application:

**August 2010 Batch:** 10<sup>th</sup> August 2010

Applications complete in all respects should be sent to the:

**Course Coordinator- PDCR®**  
Catalyst Clinical Services Pvt. Ltd.  
119, State Bank Colony, G. T. Karnal Road, Delhi-110009 (India)  
**Tel:** 011-42384005, **Telefax:** 011-27466248  
**E-mail:** info@catalystclinicalservices.com

## Evaluation

The evaluation is based on grading of assignments. There will be one graded assignment for each module. These assignments are required to be submitted to the Course Coordinator on or before the scheduled date. **Assignments reaching after the scheduled dates will not be considered for the evaluation.**

Letter grade system is used for grading the assignments. These letter grades are:

<b>A</b>	<b>Excellent</b>	<b>80% and above</b>
<b>B</b>	<b>Very Good</b>	<b>≥ 60% and &lt; 80%</b>
<b>C</b>	<b>Good</b>	<b>≥ 50% and &lt; 60%</b>
<b>D</b>	<b>Satisfactory</b>	<b>≥ 40% and &lt; 50%</b>
<b>E</b>	<b>Unsatisfactory</b>	<b>&lt; 40%</b>

**Candidates securing D grade and above in all four modules would be eligible to receive Professional Diploma in Clinical Research (PDCR®).** If a candidate fails to secure minimum “D” grade in the assignment of any particular module, he/she would be given another chance to resubmit the fresh set of assignments in the next semester only. The fresh set of assignments would be issued to the candidates on request. If a candidate fails to pass his/her second attempt, he/she would be ineligible for the award of certificate. In that case the candidate has to apply for a fresh registration. There is no provision for the re-evaluation of assignments.

The decision of Catalyst Clinical Services Pvt. Ltd. would be final and binding to all the students. All legal disputes would be subject to New Delhi jurisdiction only. Catalyst Clinical Services Pvt. Ltd. reserves the right to change the rules and regulations from time to time in its sole and absolute discretion. If any such change is made, the latest amended rule/regulation would be applicable.

### Issue of Fresh set of Assignments

Candidates who are not able to qualify the program in the first attempt can make a written request for the issue of fresh set of assignments. For all such requests a processing fee of Rs.2000/- will be payable in the form of **bank draft** drawn in the favor of “**Catalyst Clinical Services Pvt. Ltd.**”. The same fee is applicable to those candidates also who are not able to submit the assignments within the stipulated time frame\*.

### Issue of Duplicate Copy of Grade Card and Certificate

Request for issue of duplicate copy of grade card and certificate can be made to the course coordinator stating the reason thereof. For issue of duplicate copy of grade card and certificate, a processing fee of Rs. 500/- will be payable in the form of **bank draft** drawn in the favor of “**Catalyst Clinical Services Pvt. Ltd.**”

### Class Room Training (Optional)

Classroom training for a period of about 16 hrs. (2 days) is available to Indian students for an extra charge of Rs. 3500/- at selected cities. The classroom training will be arranged if at least 25 students opt for it in the selected cities. The most probable location would be Delhi, Mumbai, Bangalore, and Chennai\*\*.

\* The total program duration can not exceed 10 months from the start date of a batch.

\*\* Venues are subject to change depending upon minimum registration of 25 participants per city.