

**ADVANCE CERTIFICATE
IN
CLINICAL RESEARCH (ACCR™)
(2009-10)**

Information Brochure
Week-end Training Program

'From India's Largest Clinical Research Training Providers'



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Clinical Research and It's Potential

Clinical Research is an indispensable part of drug discovery process to ensure the safety and efficacy of a new drug. Typically it takes 10-12 years and millions of dollars to bring one new drug to the market with a very limited success rate. In the present IPR regime, patent for a drug is valid for 20 years of which a significant amount of time is spent in development alone. This, in turn, is posing a big challenge to the pharmaceutical/biotech companies (Sponsor) worldwide and they have started adopting outsourcing strategies to optimize their innovations.

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.

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 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.

The need and complexity of the specific training at the level of CRA(s)/Monitor(s)/QA Auditor(s) increases as they move up the professional ladder thereby shifting the focus from 'trouble shooting' to 'planning and forecasting'. ACCR™ is aimed at imparting basic to advance level skills on various clinical research topics (such as Drug development and clinical trial process, GCP guidelines, Clinical trial monitoring, Drug regulatory affairs *etc.*) in order to train and develop clinical research professionals by imparting quality education to them.

ACCR™ Program Objective(s)

- To provide an in-depth training and opportunity for skills development on Clinical Trial Processes.
- To uncover the hidden pitfalls of clinical study process for a sound milestone planning and execution of the study in a time bound and flawless manner.
- To nurture the culture of 100% GCP and regulatory compliance at any time-point.
- Competency development.

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 and has established itself as India's largest clinical research training providers through specialized training programs such as:

- Professional Diploma in Clinical Research (PDCR®)
- Advance Certificate Program(s) in Clinical Research
- GCP Training Workshop(s)
- Oncology Clinical Trials Training
- Training Program for Clinical Investigators, Site Personnel and Ethics Committee Members
- 21 CFR Part 11 Training

Program Director: Sanjay Gupta 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 and 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.**

Program Overview

ACCR™ consists of multi-disciplinary approach of skills enhancement including Induction, Class room training, Self-reading, Training Workshops, Assignments, Project Work and Examination.

Program Element	Duration	Description
Induction	1 day	Interaction between the faculty and the participants to provide the program overview and intensity of training followed by a clinical trial site visit.
Class Room Training	12 weeks	3 hrs. class at each week-end for 12 weeks.
Self-Reading Modules	Through-out	Customized study material holistically covering the entire program curriculum.
Training Workshops	4 weeks	Training workshops of 8hrs. each conducted by experts to provide in-depth understanding of the industry practice with in-built team exercises.
Assignments	8 weeks	Participant's perception and opinion on pre-designed case studies.
Examination	1 day	Written examination followed by viva-voice.
Award of Credits	2 weeks	Evaluation of project work by experts, compilation of credits and certification.

Curriculum:**Module – 1 Foundation to Clinical Research and GCP Guidelines**

- Introduction to Drug Discovery Process
- Guidelines and Standards Governing Clinical Research
- Clinical Development of a Drug
- Essential Clinical Trial Documents
- Ethics in Clinical Research
- Overview of HIPAA Regulations
- Roles and Responsibilities of Clinical Trial Stakeholders
- Challenges in Implementation of GCP Guidelines
- Clinical Trials Terminology *etc.*

Module – 2 Regulatory and Clinical Trial Processes

- Overview of Regulatory Environment
- Schedule-Y of Drugs and Cosmetics Act (India)
- Import/Export Authorization
- Investigator Site Evaluation/Selection Process
- Creation of Trial Master File(s)
- Organization of Investigator Training Meeting
- Informed Consent Process
- Serious Adverse Event Reporting
- Audits and Quality Assurance *etc.*

Module – 3 Clinical Trial Monitoring

- Development of Monitoring Plan
- Site Initiation Visit, Review of Essential Trial Documents, Delegation of Duties and Responsibilities at Individual Site
- Routine Monitoring Visit
- Inventory Planning and Tracking
- Source Document Verification (SDV)
- CRF Review, Collection and Co-ordination of Data Management Activities
- Serious Adverse Event (SAE) Review and Regulatory Compliance
- Investigational Product Accountability and Management
- Escalation, Management and Prevention of Violations/Deviations
- Tracking of Enrolments, Payments and Ongoing Correspondence
- Site Closure Monitoring Visit *etc.*

Module – 4 'Dummy' Clinical Trial Monitoring Kit™

- Protocol
- Source Document
- Informed Consent Document
- Case Report Form (CRF)

Each participant will get an opportunity to perform Dummy Clinical Trial Monitoring thereby getting hands on experience of this important activity. This is a unique feature of ACCR™ Program and no other training program in the country provides the opportunity of developing the monitoring skills in this manner.

Duration

The program duration is 6 months however; it can be stretched up to a maximum of 9 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 with relevant qualifications

Application and Fee

The program fee for ACCR™ is Rs.50,000 (Rupees Fifty Thousand Only). Foreign students studying/working in India are also eligible to apply for the program. Candidates are required to send their applications along with program fee through **Demand Draft** drawn in the favor of “**Catalyst Clinical Services Pvt. Ltd.**” payable at **Delhi**. The candidates should write their name and address on the back of demand draft. The enrolment in ACCR™ program is subject to the realization of Program fees.

Completed Application should be sent to:

Program Director: ACCR™
 Catalyst Clinical Services Pvt. Ltd.,
 119, State Bank Colony,
 G.T. Karnal Road, Delhi – 110 009 (India).
Ph: 011-42384005, **Telefax:** 011-27466248
Email: info@catalystclinicalservices.com

Job Prospects

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

Positions	Minimum Entry Criteria
Clinical Research Coordinator (CRC)	Fresher
Clinical Research Associate (CRA)	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

Evaluation System

ACCR™ Program follows a credit system. Credits would be awarded at three levels:

Level	Total Credits	Minimum Qualifying Credits
Assignments	30	18
Examination	50	30
Viva-voice	20	12

The grading system for overall credits is as follows:

≥ 80 credits	70-79 credits	60-69 credits	< 60 credits
Excellent	Good	Satisfactory	Unsatisfactory

Participants are required to secure minimum qualifying credits at individual level and an overall 60 (and above) cumulative credits for the successful completion of the ACCR™ program. Participants unable to secure minimum qualifying credits at individual level would be given one more chance to attempt the individual level. A fee of Rs.5000/ for each level would be applicable to reappearing participants. Failure to qualify the repeat chance would require a fresh enrolment (if desired by the participant).

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