

**ADVANCE CERTIFICATE PROGRAM(S)
IN
CLINICAL RESEARCH
(2010-11)**

Information Brochure
Distance Learning Program

“India’s Largest Clinical Research Training Providers”



Catalyst Clinical Services Pvt. Ltd.
119, State Bank Colony,
G. T. Karnal Road, Delhi-110 009
Ph: 011-27466248, 42384005
Email: contact@catalystclinicalservices.com
Web: www.catalystclinicalservices.com

Clinical Research Training: An Unmet Need

Clinical Research is an indispensable part of drug discovery process to ensure the safety and efficacy of a new drug. Clinical trials are the mainstay for bringing out new drugs to the market and constitute approximately 70% of the total time and money spent in overall drug development. India is fast emerging as a preferred destination for the conduct of global clinical trials due to the availability of large patient populations, skilled manpower, cost effectiveness, favorable economic and IP environment etc.

Clinical research is a highly specialized field that requires specific training to carry out various job functions. 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'.

Advance Certificate Program(s) in clinical research are 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.

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.

Target Audience

- Students from Pharmacy, Medicine and Life-sciences disciplines.
- Clinical research professionals employed in Pharmaceutical companies, Contract research organizations (CROs), Research and Academic Institutions etc.
- Allied professionals with basic level knowledge on clinical trial processes who aspire to pursue active clinical research stream.
- Clinical study coordinators employed at investigator sites.

About the Company

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 it has made pioneering initiatives in terms of,

- Professional Diploma in Clinical Research (PDCR[®]);
- Advance Certificate in Clinical Research (ACCR[®])
- Workshop(s) on Clinical Trials Management;
- Oncology Clinical Trials Training (OCTT[™]);
- Training Program for Clinical Investigator and Site Personnel;
- Training Program for Ethics Committee Members;
- Training Program on 21 CFR Part 11;
- Orientation lectures on clinical research etc.

Till date more than 4000 personnel (individual and corporate) from 156 cities across 7 countries have participated in various training programs offered by Catalyst

Program Director

Sanjay Gupta (M.Pharm, MBA) is a well-renowned clinical research expert of the country having more than 12 years of extensive clinical research experience. He has personally conducted and supervised over **80 clinical trials** (Global registration trials, Exploratory Phase-II trials, Phase-I trials, Investigators initiated trials etc.) across a wide range of therapeutic areas including Oncology, Endocrinology, Psychiatry, Critical Care, Infectious Diseases, Andrology, Ophthalmology etc.

He has presented his research work in various International Journals and Conferences including **American Society of Clinical Oncology (ASCO)**, **Seminars in Oncology**, **British Journal of Cancer (BJC)**, **Gastric & Breast Cancer (GBC)** and **British Journal of Radiology (BJR)**. He has authored **6 books** and written thought provoking articles on clinical research field for periodicals Chronicle Pharmabiz and Express Pharma Pulse.

He has been instrumental in taking various clinical research-training initiatives in India such as:

- **Chief Editor:** Clinical Quest®
- **Content Writer and Course Director:** Professional Diploma in Clinical Research (PDCR®)
- **Content Writer and Course Director:** Advance Certificate in Clinical Research (ACCR®)
- **Content Writer and Course Director:** Oncology Clinical Trials Training (OCTT™)
- **Convener:** Workshop(s) on Clinical Trials Methodology and Management
- **Mentor:** Orientation Lectures on Clinical Research across the Country

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).

He has been appointed as Independent Auditor/Co-monitor for auditing the work of Investigator sites as well as Contract Research Organizations in India by International sponsors and Dept. of Biotechnology, Govt. of India. He has served as a consultant to many clinical research organizations for setting-up and streamlining their processes and operations. Before joining Catalyst, Sanjay has worked with Eli Lilly and Co. (India) Pvt. Ltd., a U.S. based, research driven, pharmaceutical company at various positions over a period of 6 years.

Advance Certificate Program(s) Overview

Advance Certificate Program(s) consists of multi-disciplinary approach of skills enhancement including Induction, Self-reading, Assignment, Project Work and Award of Credits.

Program Element	Duration	Mode	Description
Induction (optional)	1 hour	Telephone	1:1 interaction between the program director and the participant in order to ascertain the developmental needs, focus area and intensity of training, if desired by the participant.
Self-Reading	80 days	Study Material	Customized study material holistically covering the program curriculum.
Assignment	10 days	Paper Based	Participant's perception and opinion on pre-designed case studies
Project Work	60 days	Dissertation	Dissertation submission on a relevant topic that has been mutually agreed between the participant and the program coordinator.
Award of Credits	30 days	Certification	Evaluation of project work by experts, compilation of credits and certification.

Curriculum

Course # 1	Advance Certificate in Clinical Trial Project Management; Duration: 6 months, Fee: Rs. 10,500/-
-------------------	--

Program Elements:

- Introduction to Clinical Research, Guidelines and Standards Governing Clinical Research
- Project Milestones Planning and Forecasting
- Cost Estimate and Financial Planning
- Logistics Planning, Vendor Selection and Management
- Clinical Study Process (multi-centric) and Creation of Trial Master File(s)
- Management of Regulatory Document Submission
- Co-ordination of Individual Site Set-up Activities
- Import/ Export Authorization
- Organization of Investigator Training Meeting
- Study Initiation, Conduct and Milestones Tracking
- Audit(s) and Quality Assurance
- Study Closeout (trial completion, suspension, termination etc.)
- Hands on training utilizing 'Dummy Clinical Trial Monitoring Kit TM'

Course # 2	Advance Certificate in Clinical Trial Monitoring; Duration: 6 months, Fee: Rs. 10,500/-
-------------------	--

Program Elements:

- Introduction to Clinical Research, Guidelines and Standards Governing Clinical Research
- Site Initiation, Review of Essential Trial Documents, Delegation of Duties and Responsibilities
- Inventory Planning and Tracking
- Clinical Trial Monitoring
- 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

Course # 3	Advance Certificate in Scientific Writing and Creation of Essential Documents; 6 months, Rs. 10,500/-
-------------------	--

Program Elements:

- Introduction to Clinical Research, Guidelines and Standards Governing Clinical Research
- Development of Standard Operating Procedures (SOPs)
- Protocol
- Informed Consent Document (ICD)
- Clinical Report Form (CRF)
- Data Validation Plan (DVP)
- Clinical Study Report (CSR)

'Enrolment to Advance Certificate Program(s) is offered throughout the year'

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

Candidates are required to send their completed applications along with a Demand Draft of 'requisite program fee' drawn in favor of "**Catalyst Clinical Services Pvt. Ltd.**" payable at **Delhi**.

Evaluation System

Advance Certificate Program(s) follows a credit system. Credits would be awarded at two levels:

Level	Total Credits	Minimum Qualifying Credits
Assignment	60	36
Project Work	40	24

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 respective program. Participants unable to secure minimum qualifying credits would be given one more chance to attempt the assignment and/or project work. A fee of Rs.5000/ would be applicable for all reappearing participants. Failure to qualify the repeat chance would require a fresh enrolment (if desired by the participant).

Applications completed in all respects should be sent to

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