

Information Brochure
Advance Certificate Program (s) in Clinical Research (ACPCR™)



Catalyst Clinical Services Pvt. Ltd.
Unit No. 11, CSC-12, Block D1, Sector-16, Rohini, Delhi - 110089 (India)
M: +91 9818356273
Email: info@catalystclinicalservices.com

Program Objective

- To provide an in-depth training and opportunity for skills development on various specialized job functions of clinical research.
- 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.
- Competency development for the specialized field of Scientific/Medical Writing, Clinical Trials Project Management and Clinical Trial Monitoring

Program Highlights

- Optimal Duration: 6 months
- Ease of Training and Evaluation: Assignment based evaluation
- Optimal Course Fee
- Unique practical training component through 'mock hands-on training material'

Program Curriculum

Course # 1: Advance Certificate Program in Scientific Writing and Creation of Essential Trial Documents

- Introduction to Clinical Research
- Evolution of Ethical Research Principles, Regulations and Guidelines
- Clinical Study Process
- Development of Standard Operating Procedures (SOPs)
- Protocol
- Informed Consent Document (ICD)
- Clinical Report Form (CRF)
- Data Validation Plan (DVP)
- Clinical Study Report (CSR)
- Publication

Course # 2: Advance Certificate Program in Project Management

- Introduction to Clinical Research
- Evolution of Ethical Research Principles, Regulations and Guidelines
- 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.)

Course # 3: Advance Certificate Program in Clinical Trial Monitoring

- Introduction to Clinical Research
- Evolution of Ethical Research Principles, Regulations and Guidelines
- Clinical Study Process
- Investigator Site Selection/Assessment
- Development of Monitoring Plan
- Site Initiation, Review of Essential Trial Documents, Delegation of Duties
- Clinical Trial Monitoring
- 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

Duration

The duration for each of the above training program is 6 months. However it can be stretched to a maximum of 10 months (due to inability to qualify in the first attempt), failure of which would lead to cancellation of the candidature thereby requiring a fresh enrolment.

Eligibility

Candidates who are currently pursuing or have completed following curriculum are eligible for enrolment:

- B.Pharm, M. Pharm, Ph.D
- MBBS, MD, DNB, DM
- BDS, MDS
- BAMS, BHMS, BUMS
- BPT, MPT
- Life Sciences: B.Sc, M.Sc, Biotechnology
- Working Professionals

Application and Fee

The fee for each of the above Advance Certificate Program (s) in Clinical Research is as follows:

S. No	Participants	Total Fee
1.	Indian Participants	Rs. 15,000
2.	Indian Participants Residing Overseas	Rs. 15,000 + Rs. 3000 towards postal charges
3.	Foreign Nationals	US \$ 325

Candidates are required to send their Application Form along with a copy of highest qualification certificate and program fee either through **Demand Draft** drawn in the favor of “**Catalyst Clinical Services Pvt. Ltd.**” payable at Delhi or via direct bank transfer to the address mentioned in the footer of the Application Form. If the fee is paid via demand draft, the candidates are advised to write their name and address at the back of the 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

Catalyst Clinical Services Pvt. Ltd.

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Evaluation

The evaluation is based on grading of assignments. The assignments are required to be submitted to the Program Coordinator on or before the scheduled date. **Assignments reaching after the scheduled dates will not be considered for the evaluation.** The grading system for overall credits is as follows:

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

Participants are required to score an overall 60 (and above) cumulative credits for the successful completion of the training program. Participants unable to secure minimum qualifying credits would be given one more chance to attempt the assignments. A fee of Rs. 4000 would be applicable for all reappearing participants. If a participant 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 or seek prior management approval for further proceedings. 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 Duplicate Copy of Grade Card and Certificate

Request for issue of duplicate copy of grade card and certificate can be made to the program coordinator stating the reason thereof. A processing fee of Rs. 500 will be applicable for issue of duplicate copy of grade card and certificate.