

Oncology Clinical Trials Training (OCTT)

Information Brochure
Distance Learning Program

Catalyst Clinical Services Pvt. Ltd.
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About the Company

The first company to start clinical research education in India, Catalyst has made pioneering initiatives by virtue of its customized training program(s) and has established itself as **India's Largest Clinical Research Training Provider**. The specialized training program(s) of Catalyst include:

- 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
- Training Program for Clinical Investigators and Site Personnel
- Training Program for Ethics Committee Members
- 21 CFR Part 11 Training

Being a premier Contract Research Organization, the primary focus area of the company is Clinical Trial Management and Execution, Medical Writing, Clinical Trials Training and Independent Auditing. Catalyst's mission is to meet the ever growing knowledge, compliance and execution needs of clinical research profession thereby making Indian clinical research industry, a benchmark for global clinical research.

Program Objective

Oncology Clinical Trials Training is a skill development program (through correspondence) of 12 weeks duration with a primary focus on Management of Oncology Clinical Trials. The objectives of the training program are:

- To arm clinical research professionals with the knowledge and skills required for carrying out oncology clinical trials.
- To provide an in-depth training on monitoring and management of oncology clinical trials.
- To identify and answer the major challenges that is seemingly inherent to the oncology clinical trial process.

Program Director

Sanjay Gupta (M.Pharm, MBA) is a well-renowned clinical research expert of the country having more than 11 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 and Breast Cancer (GBC) and British Journal of Radiology (BJR)**. He has authored **5 books** and written thought provoking articles on clinical research field for periodicals Chronicle Pharmabiz and Express Pharma Pulse.

He is the Network Coordinator for a cancer trials network set-up by University of Oxford, London (India and UK) and holds following professional affiliations:

- **Director-Clinical Operations**, Catalyst Clinical Services Pvt. Ltd.
- **President**, SPECT
- **Member Secretary**, SPECT-ERB
- **Coordinator**, INDOX Clinical Trials Network
- **Advisory Board Member**, International Journal of Pharmaceutical Sciences and Nanotechnology

Program Curriculum

The Oncology Clinical Trials Training Program consists of Three Modules with following components:

1	Fundamentals of Oncology Clinical Trials <ul style="list-style-type: none"> • Introduction to Drug Discovery Process • Guidelines and Standards Governing Clinical Research • Essential Clinical Trial Documents • Ethics Committee/Ethics Review Board • Informed Consent Process • Overview of Cancer and Oncology Clinical Trials • Diagnosing Cancer (staging and disease assessment) • Safety Evaluation in Oncology Clinical Trials (WHO, CTC) • Efficacy Evaluation in Oncology Clinical Trials (WHO, SWOG, RECIST)
2	Oncology Clinical Trials Monitoring <ul style="list-style-type: none"> • Development of Monitoring Plan • Site Initiation Visit, Review of Essential Trial Documents, Delegation of Duties at Individual Site • Routine Monitoring Visit • Inventory Planning and Tracking • Source Document Verification (SDV) • CRF Review, Collection and Coordination 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
3	'Dummy Clinical Trial Monitoring Kit' <ul style="list-style-type: none"> • Protocol • Source Document • Informed Consent Document (ICD) • Case Report Form (CRF)

Duration

The program duration is 12 weeks. However; it can be stretched up to a maximum of 16 weeks, 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

Application and Fee

Sl. No.	Category	Fee
1.	Indian Nationals	Rs. 15000
2.	Foreign Nationals	US\$ 500

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 / banker’s cheque. The enrolment in **Oncology Clinical Trials Training Program** is subject to the realization of Program fees.

Applications complete in all respects should be sent to the:

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

Evaluation

The evaluation is based on the grading of Assignments and Case Study. The assignments and case study 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.**

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

A	Excellent	80% and above
B	Very Good	≥ 60% and < 80%
C	Good	≥ 50% and < 60%
D	Satisfactory	≥ 40% and < 50%
E	Unsatisfactory	< 40%

Candidates securing D grade and above would be eligible to receive certificate of Oncology Clinical Trials Training (OCTT). If a candidate fails to secure minimum “**D**” grade, he/she would be given another chance to resubmit the fresh set of assignments. 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 and case study.

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.**”

* The total program duration can not exceed 16 weeks.