Information Brochure

Oncology Clinical Trials Training (OCTT™)

Catalyst Clinical Services Pvt. Ltd.
Unit No. 11, CSC-12, Block D1, Sector-16, Rohini, Delhi - 110089 (India)
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Program Objective

It is estimated that of the total clinical trials conducted worldwide, oncology clinical trials tops the therapeutic area list. Management and monitoring of oncology clinical trials requires a specialized training at the level of Project Managers/ Clinical Research Associates/ Clinical Research Coordinators and an unmet need of structured training curriculum exists for individual stakeholder.

Oncology Clinical Trials Training (OCTT^{TM}) is a skills development program (through distance learning) 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 Curriculum

OCTT^{TM} program comprise of Three Training Modules with following components:

Module-1: Fundamentals of Oncology Clinical Trials

- 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)

Module-2: Oncology Clinical Trials Monitoring

- Development of Monitoring Plan
- Site Initiation Visit, Review of Essential Trial Documents, Delegation of Duties
- 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

Module-3: 'Dummy Clinical Trial Monitoring Kit'

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

Duration

The program duration is 12 weeks. However it can be stretched to a maximum of 20 weeks (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 is as follows:

S. No	Participants	Total Fee
1.	Indian Participants	Rs. 18,000
2.	Indian Participants Residing Overseas	Rs. 18,000 + Rs. 3000 towards postal charges
3.	Foreign Nationals	US $ 350

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

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.** 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 scoring D grade and above would be eligible to receive the Certificate of Completion. If a candidate fails to secure minimum "**D**" grade, he/she can avail another chance to resubmit a fresh set of assignments. The fresh set of assignments would be issued to the candidates on a written request. A fee of Rs. 4000 would be applicable for all reappearing participants. 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 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.