

## **Post Graduate Diploma in Clinical Trials Management**

<b>Mode</b>	:	Classroom
<b>Duration</b>	:	Fulltime – 6 months
<b>Date of Commencement</b>	:	6 <sup>th</sup> January 2010
<b>Classroom Locations</b>	:	Kerala
<b>Eligibility</b>	:	MD, MS, MBBS, BDS, BHMS, BAMS, BUMS, BPT, B.Pharma, Graduate/Post Graduate Degree in Life Sciences, Pharmacology, Pharmacy, Biochemistry, Microbiology, Biotechnology and all professionals working with Pharmaceutical companies, CROs and hospitals.
<b>Selection Criteria</b>	:	Personal Interview
<b>Methodology</b>	:	Classroom Contact Program; Printed Training Modules; Subscription to Online Learning System and Workshops
<b>Examination</b>	:	Online MCQs, Exercises, Classroom exams & Project work.
<b>Certificate</b>	:	Certificate would be awarded upon successful completion of the program. Program is certified & Accredited by the Pharmaceutical Society of India.
<b>Job Assistance</b>	:	Extensive placement support would be provided to the successful classroom candidates.
<b>Fee</b>	:	Rs 125,000/-
<b>Fee Payment</b>	:	Fee Payable by Cash, Cheque / Bank draft in the name of 'TENET HEALTH EDUTECH PVT. LTD.', payable at Delhi. Fee can also be deposited in company bank account. We also accept Credit/Debit Cards.
<b>Loan Facility</b>	:	HDFC Bank.
<b>Program Details</b>	:	The program would cover: <ul style="list-style-type: none"><li>• Clinical Research Introduction ,ICH GCP Principles &amp; Terminology</li><li>• Healthcare Management Issues</li><li>• Introduction to Pharmaceutical Industry &amp; Global Challenges</li><li>• Ethical Consideration in Clinical Trials</li><li>• Global Clinical Research Environment &amp; Opportunities</li><li>• Regulatory Affairs</li><li>• Principles of Pharmacology &amp; Drug Discovery &amp; Development</li><li>• Roles &amp; Responsibilities of Key Stakeholders</li><li>• Preparations &amp; Planning for Clinical Trials</li><li>• Essential Documentation in Clinical Research &amp; Regulatory Submissions</li><li>• Clinical Trials Project Planning &amp; Management</li><li>• Study Start up Process</li><li>• Clinical Monitoring Essentials</li><li>• Compliance, Auditing &amp; Quality Control in Clinical Research</li><li>• Clinical Data Management, Biostatistics, Analysis &amp; Reporting</li><li>• Medical &amp; Scientific Content Writing</li><li>• Pharmacovigilance</li><li>• Bioavailability and Bioequivalence Studies</li><li>• Management of Cancer Clinical Trials</li></ul>

- Organizational Behavior & Human Resource Management
- Financial Management
- Personality Development
- Communication Skills
- Project

### **Course Objectives**

- ❖ To provide a comprehensive introduction to the clinical research process, conduct & management of clinical trials.
- ❖ Learn the skills, knowledge and competencies of a candidate for the Clinical Research Associate and other key positions.
- ❖ Become more familiar with roles/jobs as part of the study team.
- ❖ Extensive Knowledge & application in different aspects of Clinical Research.