

## **Advanced Post Graduate Diploma in Clinical Data Management**

**(3 Months Class Room + 3 Months Paid Industry Internship at CRO)**

<b>Mode</b>	:	Class Room – Weekend
<b>Duration</b>	:	6 Months (3 Months Class Room + 3 Months Paid Industry Internship at CRO)
<b>Eligibility</b>	:	MD, MS, MBBS, BDS, BHMS, BAMS, BUMS, BPT, B.Pharma, Graduate/Post Graduate Degree in Mathematics , Life Sciences, Pharmacology, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology and all professionals working with Pharmaceutical companies, CROs and hospitals.
<b>Methodology</b>	:	Weekend Classroom Contact Program; Printed Training Modules; Online E learning System and <b>Hands on training on CDM software's</b> in actual clinical research environment.
<b>Examination</b>	:	Classroom exams & Project work.
<b>Certificate</b>	:	Certificate would be awarded upon successful completion of the program. Program is certified & Accredited by the <b>Pharmaceutical Society of India</b>
<b>Job Assistance</b>	:	Placement support would be provided to the successful classroom candidates.
<b>Fee Payment</b>	:	Fee Payable by Cash, Cheque / Bank draft in the name of ' <b>TENET HEALTH EDUTECH PVT. LTD.</b> ' 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:

### **Module 1 (Theory)**

- Introduction to Data Management
- Study Set Up
- CRF Design Considerations
- Data Entry, Remote Data Entry
- Identifying and Managing Discrepancies
- Medical Coding
- Database Closure
- Clinical Database & Types
- Data Management Plan
- Electronic Data Capture
- Tracking CRF Data
- Managing Lab Data
- Collecting Adverse Event Data
- Creating Reports and Transferring Data
- Enterprise Clinical Data Management Tools

### **Module II (Practical)**

- Study set-up
- Introduction to Clinical Database
- Documents, guidelines used in CDM
- Data Entry
- Data Review/Data Validation, Query Management
- Database QC
- CRF Design (Introduction)
- Database Design (Introduction)
- Edit Check & Edit Check Testing
- UAT (User Acceptance Testing)
- SOPs
- Quality Assurance, Audits

### **Course Objectives**

- ❖ To provide a comprehensive introduction to the Clinical Data Management process.
- ❖ Learn the skills, knowledge and competencies of a candidate for the CDM.
- ❖ Become more familiar with roles/jobs as part of the study team.
- ❖ Understanding of Databases & management of clinical data.
- ❖ Understanding of key enterprise clinical data management tools.