

# Advance Certificate Program(s) in Clinical Research

These Program(s) are aimed at imparting skills and competencies required for higher level Clinical job functions leading to a **faster career growth**.  
By participating and successfully completing these Program(s) one can get **hands-on training** on these highly specialized job functions in a structured environment.

"From India's Largest Clinical Research Training Provider"

## Program # 1

**Clinical Trial Monitoring (CTM)**  
Duration - 6 months, Fee - Rs. 10500\*

### PROGRAM CONTENT

- Introduction to Clinical Research, Guidelines and Standards Governing Clinical Research
- Site Initiation, Review of Essential Trial Documents, Delegation of Duties at Individual Site
- Inventory Planning and Tracking
- Clinical Trial Monitoring
- 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

- ✓ Hands on Training
- ✓ PDCR®+ CTM  $\xrightarrow[\text{Level}]{\text{Competency}}$  CRA
- ✓ Faster Career Growth

## Program # 2

**Project Management (PM)**  
Duration - 6 months, Fee - Rs. 10500\*

### PROGRAM CONTENT

- Introduction to Clinical Research, Guidelines and Standards Governing Clinical Research
- 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.)

- ✓ Hands on Training
- ✓ PDCR®+ CTM + PM  $\xrightarrow[\text{Level}]{\text{Competency}}$  Project Manager
- ✓ Faster Career Growth

## Program # 3

**Scientific Writing and Creation of Essential Documents (SW)**

### PROGRAM CONTENT

- Introduction to Clinical Research, Guidelines and Standards Governing Clinical Research
- Development of Standard Operating Procedures (SOPs)
- Development of Protocol
- Development of Informed Consent Document (ICD)
- Development of Case Report Form (CRF)
- Development of Data Validation Plan (DVP)
- Development of Clinical Study Report (CSR)

Duration - 6 months, Fee - Rs. 10500\*

- ✓ Hands on Training
- ✓ PDCR® + CTM + SW  $\xrightarrow[\text{Level}]{\text{Competency}}$  Scientific Writer
- ✓ Faster Career Growth

\*A Fee waiver of Rs. 2000 per program is applicable to all PDCR® Participants (Net Fee Rs. 8500 per Program)

Information Brochure and Application Form can be downloaded from the website [www.catalystclinicalservices.com](http://www.catalystclinicalservices.com)

For more information either mail at [contact@catalystclinicalservices.com](mailto:contact@catalystclinicalservices.com) or contact Program Director

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