



The Pharma Daily

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Clinical Data Management Fundamentals Curriculum





Allow me to introduce myself, Mitali Jain, the Founder of ThePharmaDaily.

Throughout my professional journey, I have had the privilege of working with esteemed organizations such as **TCS (Tata Consultancy Services)** and **Syneos Health**, where I have gained invaluable experience in the pharmaceutical industry. These experiences have shaped me into a passionate and driven individual, dedicated to making a difference in the field.

In 2017, I achieved a remarkable milestone by securing an **All India Rank of 320** in the **Graduate Pharmacy Aptitude Test (GPAT)**. This accomplishment not only reflects my academic prowess but also highlights my unwavering commitment to excellence and continuous learning.

Currently, I am focusing my efforts on developing professional training programs in pharmacovigilance, medical coding, and other crucial pharmaceutical courses through my company, ThePharmaDaily. Recognizing the rapid advancements in the industry, I believe in equipping aspiring professionals with the skills and knowledge they need to thrive in their careers.

At ThePharmaDaily, we strive to provide comprehensive and industry-relevant courses that empower individuals to excel in various roles within the pharmaceutical sector. I am deeply passionate about cultivating a culture of excellence and fostering innovation in the field, and I am committed to ensuring that our students receive the highest quality education and training.

As the Founder of ThePharmaDaily, my mission is to make a lasting impact on the pharmaceutical industry by nurturing the next generation of professionals. I firmly believe that with the right education and guidance, individuals can reach their full potential and contribute to the advancement of the industry.

I am excited about the opportunities ahead and look forward to sharing my knowledge and expertise with aspiring pharmaceutical professionals through ThePharmaDaily. Together, let us embark on a journey of growth, learning, and success in the ever-evolving world of pharmaceuticals.

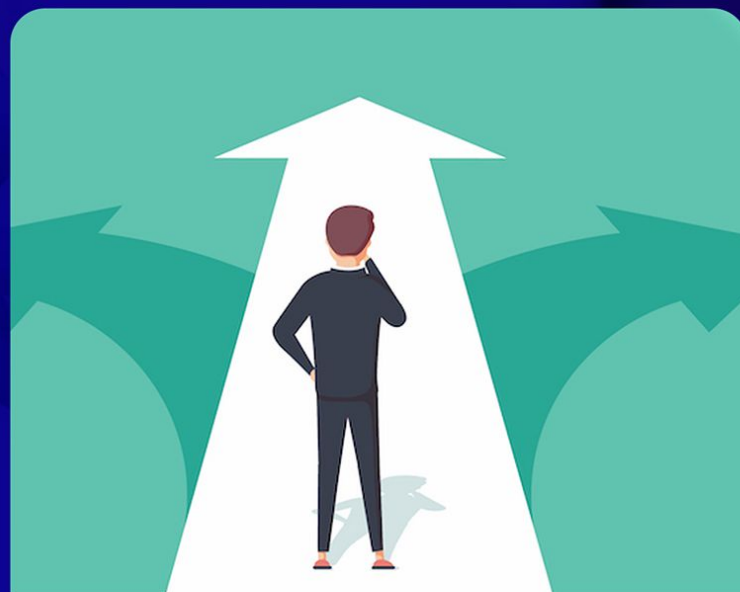
Who Can Join These Courses?



College Students



Industry Professionals



Career Changers

Training Methodology



INSTRUCTION

Live lectures with faculty & learning material on LMS

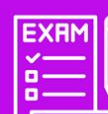
Live lectures with our expert faculty supplemented by additional learning material on LMS.

Benefits:

- > In-depth understanding of concepts
- > Real-time interaction and query resolution
- > Additional self-learning of your own convenience

Used for:

Live Instructions by expert faculty and additional self-learning opportunities.



ASSESSMENTS

Quizzes, Assignments & Exams

Work on quizzes and assignments to test your knowledge, along with mock interviews and exams.

Benefits:

- > Gauge your progress throughout the program
- > Identify areas of improvement and learning gaps
- > Build confidence for the placement phase

Used for:

Ensuring consistent progress over the course of the program and preparing for job opportunities

**We will also be working
with you to enhance your**

**Communication
skills**

**Corporate life
experiences**

**Email
etiquette**

**Interview
body
language**

**Telephonic
interview
gestures**

**Resume
building**

**Cover letter
fabrication**

Course Overview

The Clinical Data Management Certification Program is a comprehensive training course designed to equip participants with the knowledge and skills required for a successful career in clinical data management. This program covers essential concepts, practices, and tools in the field of clinical research data management, preparing students for roles in clinical trials, pharmaceutical companies, contract research organizations (CROs), and regulatory agencies.

Course Duration: 8 weeks

Module 1: Introduction to Clinical Data Management

- Understanding the Importance of Clinical Data Management
- Overview of Clinical Trials and Phases
- Role of Clinical Data Management in Drug Development

Module 2: Regulatory Guidelines and Standards

- Overview of Regulatory Requirements (ICH-GCP, FDA, EMA)
- GCP (Good Clinical Practice) Guidelines
- CDISC (Clinical Data Interchange Standards Consortium) Standards
- Data Management Plans and SOPs (Standard Operating Procedures)
- Data Privacy and Confidentiality (HIPAA, GDPR)
- Electronic Data Capture (EDC) Systems and 21 CFR Part 11 Compliance

Module 3: Data Collection and Entry

- Case Report Form (CRF) Design and Development
- Electronic Data Capture (EDC) Systems
- Source Data Verification (SDV)
- Data Entry Guidelines and Quality Control

Module 4: Data Cleaning and Quality Assurance

- Data Cleaning Processes and Procedures
- Data Reconciliation (Lab, Safety, etc.)
- Data Validation and Edit Checks
- Query Management and Resolving Data Discrepancies
- Data Review and Quality Control

Module 5: Data Management Plan (DMP)

- Components of a Data Management Plan
- Data Management Plan Development
- Implementation of the DMP throughout the Study

Module 6: Database Design and Maintenance

- Database Design Principles
- Database Setup and Maintenance
- Data Dictionary Creation and Management

Module 7: Coding and Data Transformation

- Overview of Data Standards (CDISC, SDTM, ADaM)
- Medical Coding (MedDRA, WHO Drug)
- AE/SAE Coding and Reconciliation
- Data Transformation and Standardization
- Lab Data Coding (LOINC, SNOMED)
- Implementation of Data Standards in Data Management

Module 8: Data Monitoring and Auditing

- Risk-Based Monitoring (RBM)
- Centralized Monitoring
- Clinical Data Auditing and Inspections

Module 9: Database Lock and Clinical Study Reports

- Database Lock Process and Procedures
- Preparation of Clinical Study Reports (CSR)
- Interim Analysis and Unblinding

Module 10: Ethical Considerations in Clinical Data Management

- Informed Consent and Data Privacy
- Handling of Sensitive Data
- Ethical Challenges and Decision-Making

Module 11: Emerging Trends and Technologies

- Artificial Intelligence (AI) and Machine Learning in Data Management
- Real-World Data and Real-World Evidence
- Future of Clinical Data Management

Module 12: Career Development in Clinical Data Management

- Roles and Responsibilities in Clinical Data Management
- Skills and Competencies for Data Management Professionals
- Career Paths and Opportunities

Module 13: Case Studies and Practical Exercises

- Real-Life Case Studies in Data Management
- Hands-on Exercises using EDC Systems
- Data Cleaning and Query Resolution Simulations

BUILD & DEFEND your Resume

Description: This is the week in which we will actually be focussing on every individual student in this classroom training helping them "BUILD' and also learn to 'DEFEND' their resumes effectively in front of the recruiters.

- Fabricating a resume
- Fabricating a Cover Letter
- RESUME DISCUSSION (individually)
- RESUME DISCUSSION (individually)
- RESUME DISCUSSION (individually)

Personal interviews for every individual

Description: As we approach to the finale week of our training program it is time to test the knowledge of our students in order to foresee any shortcomings in the technical/ HR/resume/cover letter so that all the errors can be curbed before you actually appear for the interviews, leaving no boundaries or hurdles in the path of cracking your desirable jobs as well as compensations/LPAs.

- Personal interview (including technical & HR rounds)
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- Personal interview (including technical & HR rounds)
- Analysis of shortcomings & Individual feedbacks
- Boosting Finale lecture by Subject matter experts

Group Discussion

Description: Bringing another step closer towards a Clinical Data Management job dream and excelling it from every arena ensuring you knock out all the rounds at once.

- Group discussion (Session IV)
- Group discussion (Session V)
- Preparing for personal interviews
- Body language, hand gestures, promptness
- Proactiveness

Interview Skill Development

Description: Advanced interview preparations along with resume building. learning do's and dont's and also how to face the shortcomings you face during an interview process.

- Telephonic interview gestures (Voice modulations)
- Skype call interviews (as per lockdown protocols)
- Introduction to Resume
- Resume-DO's and DON'Ts
- Importance of Cover letter



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