

# CERTIFICATE COURSE IN CR PV CDM

## Clinical Research

The Clinical Research industry has grown around the World and India at an unparalleled rate. With the number of clinical trials conducted in India increasing and the government keen on planning and executing several initiatives to strengthen the industry, a world of opportunities exist. This certificate course in CR PV CDM is aimed at imparting core competencies and skill set essential for a fresher to make a career in Clinical Research, Pharmacovigilance & Clinical Data Management.

### Topics

1. Introduction to Clinical Research and Study Designs.
2. Interpreting Guidelines in Clinical research (CT rules 2019, ICH GCP etc.)
3. Study Start-up Process.

4. Essential Documents in Clinical Research and Storage of Clinical Documents.
5. Subject Retention Strategy.
6. Responsibility of the Study Team.
7. IP accountability (storage, handling, administration, discarding)

8. Adverse Events & Serious Adverse Events.  
(Differences, Timeline of Submission, Reporting, Compensation).
9. Clinical Trials Monitoring, Auditing and Regulatory Inspections
10. Introduction to Medical Devices.
11. Informed Consent Form.
12. Elements of Protocol Development.
13. Changes in Clinical Research During COVID 19.
14. Resume Preparation, Email Etiquette, How to Find a Job, How to Ace Interview.

### Also includes



Weekly assignments



Mock Interviews



Group Presentations



Evaluation exams

# PHARMACOVIGILANCE

## Topics

1. Introduction and History of Pharmacovigilance
2. Pharmacovigilance Basics
3. Case Processing
4. DiLi – Drug Induced Liver Injury and Risk Management
5. Signal Management
6. Pharmacovigilance Quality
7. Digital Initiatives
8. Pharmacogenomics in Pharmacovigilance

11. Clinical Safety Management and Clinical Trials
12. Medical Information
13. Hemovigilance / Blood Vigilance
14. Pharmacovigilance Requirements, Setting up Pharmacovigilance
15. Cosmeto Vigilance
16. Medical Device Vigilance
17. Career Opportunities in Pharmacovigilance and Interview Questions
18. Effective LinkedIn Profile, CV and Advertising

# CLINICAL DATA MANAGEMENT

## Topics

### Theme: Introduction to Clinical Research and Clinical Data Management

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1. Clinical Research Overview
2. Basics of CDM
3. CDM Overview stepwise
4. Data Entry in e-Case Report Form

### Theme: Roles & Responsibilities of CDM

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1. Project Initiation
2. Internal Testing
3. Data Review and Discrepancy Management
4. SAE Reconciliation
5. External Reconciliation
6. Protocol Deviation
7. CRF Completion Guidelines

### Theme: Fundamentals to Focus

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1. Clinical Research Stakeholders
2. Structure of Protocol: How to read

### Theme: Tools used for Clinical Data Management

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1. Rave
2. Inform

### Theme: Additional Skills to Excel

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#### Soft skills:

1. Proactive and timely communication.
2. Delivering first time quality
3. Teamwork
4. Time Management

#### Technical Skills

1. Protocol Interpretation Skills
2. Discrepancy Management Skills: Learning and Implementation
3. Query Writing Skills

## PLACEMENT FEEDBACKS

“ The knowledge I gained from Karthik sir and Vardhan sir has helped a lot in clearing the interview and helping me to be an efficient team member in the organization I'm working.

- **Dr. Kishore Kumar Ramoju**, Pharm D  
Operations Specialist, Regulatory Reporting  
IQVIA

“ The only thing I would like to say is " it's all about getting connected to the right people. For me Avenida is one such right choice to get connected with. Thank you!

- **Dr. Achanta Sivaprasad**, Pharm. D  
Junior Regulatory Affairs Associate  
Parexel

“ The beauty of our profession is we have a wide variety of opportunities and its upto us to choose the right ones depending upon our priorities and interests. Dr. Karthik Rakam sir is a guide, mentor and above all a big motivation for me both in his professional as well as in spiritual journey.

- **Dr. Jishnu**, Pharm. D  
Drug Safety Associate  
PPD

“ My journey being a part of Avenida helped me decide Clinical Research as my choice of interest. The module was very useful to crack the interview. Thank you, Dr. Karthik Rakam and Team Avenida.

- **Dr. T. Narmada**, Pharm. D  
Clinical Trial Coordinator  
PPD

“ Choosing the right mentor always plays a vital role in career path. My journey being part of Avenida, identifying CDM as my interest and getting guidance towards it, is one such classic example. Thank you, Dr.Karthik sir and Team Avenida.

- **Dr. P. S. K. Srikanth**, Pharm. D  
Clinical Data Analyst  
COVANCE

“ All the sessions were insightful and knowledgeable, it was during this program I was able to capture the sets of prerequisites in my career building and was able to enhance my skills and subject proficiency, which gradually helped me to get into Pharmacovigilance.  
Thank you, Team Avenida.

- **Dr. Indumathi H**, Pharm. D  
Drug Safety Associate- I  
Novo Nordisk

AND MANY MORE.....

