



**CRA & CDM**

# FULL COURSE

## Course Features

Name of the Course

Duration

Training Days

Course Materials

Realtime Project Data

CRA & CDM full course

60 days/ 1Hr per day

Monday to Friday(EST)

Projects, Videos, Books

Life Time Access

## About Us.

Great online training is the best e-learning platform which is providing the top quality online courses at affordable prices. Our online training courses are provided by qualified and professional trainers. We offer self-paced online training course to job professionals to learn at their flexible time and from their gadgets. Our instructor-led training is also provided by professional trainers who are available 24/7 to candidates in training period to guide.

In 10 years of experience we trained over 0.25 million candidates. Our team has the ability to identify the skills and tasks that the emerging market requires and examine the weaknesses or gaps as well as determine what steps can be taken to elevate your capabilities. Our team has the ability to identify the skills and tasks that the emerging market requires and examine the weaknesses or gaps as well as determine what steps can be taken to elevate your capabilities.



## ENROLL TO INSTRUCTOR LED TRAINING

Registration  
at website

A Call from  
Training Co-Ordinator

Fee  
Payment



E-mail  
confirmation

SAS  
Free Demo

# About **CRA & CDM course.**

CRA & CDM plays a pivotal role in the health sector, overseeing clinical trials, ensuring compliance with regulations, monitoring data for accuracy, and liaising between different stakeholders. This challenging yet rewarding career involves meticulous attention to detail, strong analytical skills, and a deep understanding of clinical procedures.

## **Course Features:**

- Unlimited Training Attempts
- Daily Class Recordings
- 24/7 Support
- Resume & Interview Preparation

## **Training Modes:**

- Self-paced training
- Instructor-led training

## **Candidate Requirements:**

- Need to Have Some Basic Knowledge on Computer
- Person with good Internet Connectivity
- laptop

## **Who Is Eligible:**

- Any Graduates
- PHD Candidates
- Graduates
- Programming Enthusiasts
- Technical leads

# About **CRA & CDM course.**

## Training Course Includes:

### CRA

- ✓ CRA Base
- ✓CRA Advance
- ✓CRA certification Training
- ✓Resume
- ✓Mock Interview
- ✓Job Assistance
- ✓Clinical research and data base
- ✓Oracle clinical database
- ✓Various phases of clinical trails
- ✓INDA and NDA applications
- ✓ICH-GCP guidelines
- ✓CRF annotation
- ✓In Oracle clinical database subsystems, programs, projects, regions,
- ✓ creation of intervals and events, investigator site records and
- ✓assignments and more functions
- ✓In RDC data entry process, discrepancy management and CRFS.

## Professional Team Meet Our Trainers.



### **Chandrakala**

**CDM Trainer**

A magazine is a periodical publication, which can either be printed or published digitally. It is issued regularly, usually every week or every month, and it contains a variety of content. This can include articles, stories, photographs, and advertisements. To create your own, choose a topic that interests you.

# Course Curriculum

- Day 1: CT process, Designs, Phases, INDA and NDA applications
- Day 2: CRF contents with Example
- Day 3: Protocol contents with Example
- Day 4: Quality Assurance: Audits and Inspections
- Day 5: ICH GCP E6 (R2) and FDA Regulation
- Day 6: Essential documents
- Day 7: Managing the Investigational Medicinal Product
- Day 8: Investigator Responsibilities
- Day 9: Sponsor Responsibilities
- Day 10: Monitor Responsibilities
- Day 11: Ethics Committees-IRB/IEC
- Day 12: Standard operating procedures with example
- Day 13: IB contents and sample IB
- Day 14: Informed Consent process
- Day 15: Adverse Events: Types, Reporting and Timelines
- Day 16: Source Data, Source Data Verification
- Day 17: Data Collection: Process and Systems
- Day 18: Data Validation Process and Query Process
- Day 19: Site Selection Process (Site Qualification Visit)
- Day 20: Site Initiation Process (Site Initiation Visit)
- Day 21: Planning, Conducting, Documenting, and Reporting monitoring sites
- Day 22: Closing Investigational Sites-Organizing the Close-Out visit
- Day 23: TMFs (Trial Master Files)

# Course Curriculum

- Day 24: Hands-on Data Validation and Query management
- Day 25: Discussion on Interview Questions

# Course Curriculum

## CDM



### **Module1: Clinical Research and CDM**

- Introduction To Oracle Clinical Database
- Introduction To Clinical Research And CDM
- Different Phases Of Clinical Trials
- INDA, NDA Applications
- ICH-GCP Guidelines
- Responsibilities Of Clinical Trial Team
- Protocol And Informed Consent Forms
- Clinical Data Management Process And Life Cycle
- Data Management Plan
- Case Report Forms, Types Of CRFs
- Designing Of CRFs
- CRF Annotation
- Data Capture Methods And EDC
- Data Entry – First Pass And Second Pass Entry
- Edit Check Specifications
- Data Validation Procedures
- Discrepancy Management
- Data Clarification Forms (DCFs)
- Database Locking And Freezing
- Data Coding And Medical Dictionaries
- SAE Reconciliation

# Course Curriculum CDM

## Module2: Oracle Clinical Database

- Introduction To Oracle Clinical Database
- Introduction To OC Window
- Subsystems In OC
- Defining Programs And Projects
- Defining Organization Units
- Defining Regions
- Defining Planned Studies
- Easy Study Design
- Creating Intervals
- Creating Events
- Creating Investigator, Site Records And Assignments
- Creating Patient Positions And Assignments
- Creating Questions
- Creating Question Groups
- Creating And Maintaining DVG's
- Creating DCM's, DCI's & DCI Books
- Test A Study
- Test Data Entry
- Initial Login
- Key Changes
- First Pass Entry



# Course Curriculum

## CDM



### **Module2: Oracle Clinical Database**

- Second Pass Entry
- Comparison Reconciliation
- Update
- Browse
- Patient Enrollment
- Data Validation(Batch Validation)
- Discrepancy Management
- Data Clarification Forms (DCFs)
- Locking And Freezing

### **Module3: RDC (Remote Data Capture)**

- DATA ENTRY IN RDC
- DISCREPANCY MANAGEMENT IN RDC
- CRFS IN RDC



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## Get In Touch!



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# Thank You !