



## Clinical Research (CR), Clinical Data Management (CDM) & Medidata RAVE Content

**Duration:** 25 Hrs

**Training Fee:** 50K + GST (18%)

S. no	Contents	Sub topics	Hrs
1	<b>Introduction To Drug Development Process</b>		1
2	Introduction to Clinical Trials- Phases		1
3	Clinical Research Functions and Responsibilities	inform consent	1
4	Protocol	Clinical Trial Design	1
5	Introduction CDM	Regulatory Agencies	1
6	Terminology & Definitions		2
7	Guidelines	ICH GCP	1
		CFR Part 11, CDISC- Models	1
8	Data Management Plan	Definition	1
		Over view and Elements	
9	CRF and Elements of CRF.	CRF Definition	1
		Elements of CRF	
		Standard CRFs	
		Poorly designed CRFs	
		Properly designed CRFs	
10	Annotated CRFs (db specs)	Definition	1
		Purpose, Examples	
11	Edit checks	Definition, Types	2
		Exercise	1
12	SAE Reconciliation	Definition	1

### **Covalent Trainings**

Flat.No; 401, Nandini Residency, Addagutta Society, Western Hills, JNTU circle, Kphb, Hyderabad-072

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13	Medical Coding	Concepts	1
		Classification	1
		Types	
14	GCDMP		1
15	Clinical Data Management Systems		
16	<b>Medidata Rave</b>		
		Understanding EDC	
		Introduction to Tool RAVE	1
		Main Menus-Functions	1
		User Role	1
		Browsing in the toll	1
		Query management	1
		Other roles and resources	1
17	SOP		1
18	<b>Mock interview</b>		1
	<b>Total</b>		25

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