

Medidata Rave Study Design and Build Essentials: Data Managers In-Person Course Agenda

Duration: 3 days

NOTE: For Private Classes only, we recommend that you complete the following eLearning courses in iMedidata, before enrolling for this course:

• Medidata Cloud Administration - Study Administration

• Medidata Rave EDC: Clinical Research Coordinators

• Medidata Rave EDC: Data Managers

Completing these eLearning courses are not mandatory, but will help accelerate your understanding of Rave EDC and the Medidata platform prior to the class.

Time	Topic	
DAY 1		
15 mins	Welcome & Introductions	
	iMedidata	
	Navigating iMedidata as an end user	
	eLearning	
	Navigating the EDC Homepage	
	Using Cloud Navigation	
	Reviewing Sites and Patient Page	
6 hours 15 min ¹		
	EDC Module	
	EDC Tasks	
	The Patient Homepage	
	Data Entry and Editing	
	Add a New Patient	
	Standard Forms	
	All field types	

¹ A 1-hour lunch break is built into this section.

² Durations listed are approximated.

	Viewing the Audit History	
	Log Forms	
	Lab Forms/Lab Ranges	
	Translations in Rave EDC	
	Manual Queries	
	Cleaning Data	
	Patient Administration and Sharing	
	Disabling Add Events	
	Electronic Signatures	
30mins	Reports	
3 hours	Accessing Reports in EDC	
	Setting up a Study	
	Setting up a study in Cloud Administration/iMedidata	
	Assigning a Site to a Study	
	Assigning a User to a Study Site	
	Architect Module	
	Project Development Process and Terminology	
	Architect Module: eCRF Configuration	
	Creating a Draft and Draft Items	
	Building Forms	
DAY 2		
15 mins	Review	

6 hours and 45 min ²	Architect Module: eCRF Configuration (cont'd)	
	Creating a Draft and Draft Items continued	
	Building Fields	
	Building Dictionaries	
	Building Unit Dictionaries	
	Building Folders	
	Building Matrices	
	Restrictions	
	Lab settings	
	Draft Settings	
DAY 3		
15 mins	Review	
60 mins	Architect Module: eCRF Configuration (cont'd)	
	Publish, Push, and Test	
	Patient Fields Configuration	
60 mins	Architect Module: Data Validations	
	Introduction to Data Validations	
	Configuring an Edit Check	
	Configuring a Derivation	
	Publish-in-Place Overview	
3 hours³	Global Library	
	Global Library Overview	
	Defining Copy Sources	
	Copying Forms	
	Copying Fields	
	Copying Data Dictionaries	
	Copying Unit Dictionaries	

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	Copying Folders
	Copying Matrices
	Restrictions
	Copying Objects into a Non-blank Draft
	The Difference Report
	The Edit Check/Derivation Filter for Retesting
	Building a Global Library Volume
	Proposing a Global Library Volume
15 mins	Architect Loader
	Architect Loader Overview
	Downloading and Editing a Draft
	Creating a Form, Field, Data Dictionary to XML File
	Uploading a Draft
75 mins	Course Review*
	Post Assessment
15 mins	Course Wrap Up
	Course Evaluation

^{*}Extension exercises (including protocol interpretation activity) are available if time permits.