

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

Duration: 3 days

Time	Topic
DAY 1	
15 mins	Welcome & Introductions
6 hours 15 min ¹	<p>iMedidata</p> <p>Setting up an iMedidata account Navigating iMedidata as an end user eLearning</p> <p>Navigating the EDC Homepage</p> <p>Using Cloud Navigation Reviewing Sites and Patient Page</p> <p>EDC Module</p> <p>EDC Tasks The Patient Homepage Data Entry and Editing</p> <ul style="list-style-type: none"> • Add a New Patient • Standard Forms • All field types • Viewing the Audit History • Log Forms • Lab Forms/Lab Ranges <p>Translations in Rave EDC Manual Queries Cleaning Data</p>

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

² Durations listed are approximated.

	Patient Administration and Sharing Disabling Add Events Electronic Signatures
30mins	Reports Accessing Reports in EDC
3 hours	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

² A 1-hour lunch break is built into this section

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 hours ³	Global Library Global Library Overview Defining Copy Sources Copying Forms Copying Fields Copying Data Dictionaries Copying Unit Dictionaries 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

³ A 1-hour lunch break is built into this section

	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 are available if time permits.