

Medidata Rave Study Design and Build Essentials: Data Managers Course Agenda – Remote Version

Approximate Duration: 5 sessions

Time	Topic
Session 1	
15 minutes	Welcome & Introductions
90 minutes	<p>Goal: By the end of this session, you should know the basic concept of iMedidata and basic functionality of different Rave EDC roles.</p> <p>iMedidata Setting up an iMedidata account Navigating iMedidata as an end user eLearning</p> <p>EDC Module EDC Tasks The Subject Homepage Data Entry and Editing</p> <ul style="list-style-type: none"> • Add a New Subject • Standard Forms • All field types • Viewing the Audit History • Log Forms • Lab Forms/Lab Ranges¹
10 minutes	Break

¹ Lab forms and Lab ranges will only be covered for clients using the Medidata Rave Lab Administration Module.

90 minutes	<p>EDC continued</p> <p>Manual Queries</p> <p>Cleaning Data</p> <p>Subject Administration and Sharing</p> <p>Disabling Add Events</p> <p>Electronic Signatures</p>
Session 2	
15 minutes	Review
75 minutes	<p>Goal: By the end of this session, you should know how to view reports in EDC, set up a Study and basic concept Project development process and terminology</p> <p>Reports</p> <p>Accessing Reports in EDC</p> <p>Setting up a Study</p> <p>Setting up a study in Cloud Administration/iMedidata</p> <p>Assigning a Site to a Study</p> <p>Assigning a User to a Study Site</p> <p>Architect Module</p> <p>Project Development Process and Terminology</p>
10 minutes	Break
90 minutes	<p>Goal: By the end of this session, you should know how to build Draft and draft items.</p> <p>Architect Module: eCRF Configuration continued</p> <p>Creating a Draft and Draft Items</p> <p>Building Forms</p> <p>Building Fields</p>

Session 3	
15 minutes	Review
90 minutes	Architect Module: eCRF Configuration (continued) Creating Draft Items continued Building Dictionaries Building Unit Dictionaries Building Folders Building Matrices
10 minutes	Break
90 minutes	Architect Module: eCRF Configuration (continued) Restrictions Lab settings Draft Settings
Session 4	
15 minutes	Review
60 minutes	Goal: By the end of this session, you should know how to publish draft to version and push version to EDC , Subject fields config, and basic knowledge of Data validations. Architect Module: eCRF Configuration (continued) Publish, Push, and Test Subject Fields Configuration
15 minutes	Architect Module: Data Validations Introduction to Data Validations
10 minutes	Break
60 minutes	Architect Module: Data Validations (continued) Configuring an Edit Check

	<p>Configuring a Derivation Publish-in-Place Overview</p>
40 minutes	Extension Exercises *Time permitting
Session 5	
15 minutes	Review
75 minutes	<p>Goal: By the end of this session, you should know how to use Global Library and Architect Loader.</p> <p>Global Library Global Library Overview Defining Copy Sources Copying Forms Copying Fields Copying Data Dictionaries Copying Unit Dictionaries Copying Folders Copying Matrices 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</p>
10 minutes	Break
60 minutes	<p>Architect Loader Architect Loader Overview Downloading a Draft Creating a Form, Field, Data Dictionary in XML File</p>

	Uploading a Draft
60 minutes	Course Review Post Assessment
15 minutes	Course Wrap Up Questions and Answers Course Evaluation