

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>Navigating the EDC Homepage Using Cloud Navigation Reviewing Sites and Patient Page</p> <p>EDC Module 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 Ranges¹

	<ul style="list-style-type: none"> • Translations in Rave EDC
10 minutes	Break
90 minutes	<p>EDC continued</p> <p>Manual Queries</p> <p>Cleaning Data</p> <p>Patient 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	<p>Architect Module: eCRF Configuration (continued)</p> <p>Creating Draft Items continued</p> <p>Building Dictionaries</p> <p>Building Unit Dictionaries</p> <p>Building Folders</p> <p>Building Matrices</p>
10 minutes	Break
90 minutes	<p>Architect Module: eCRF Configuration (continued)</p> <p>Restrictions</p> <p>Lab settings</p> <p>Draft Settings</p>
Session 4	
15 minutes	Review
60 minutes	<p>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.</p> <p>Architect Module: eCRF Configuration (continued)</p> <p>Publish, Push, and Test</p> <p>Patient Fields Configuration</p>
15 minutes	<p>Architect Module: Data Validations</p> <p>Introduction to Data Validations</p>

10 minutes	Break
60 minutes	<p>Architect Module: Data Validations (continued)</p> <p>Configuring an Edit Check 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</p> <p>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	Architect Loader Architect Loader Overview Downloading a Draft Creating a Form, Field, Data Dictionary in XML File Uploading a Draft
60 minutes	Course Review Post Assessment
15 minutes	Course Wrap Up Questions and Answers Course Evaluation