

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

Approximate Duration: 5 sessions

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
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 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</p> <p>EDC Tasks</p> <p>The Patient Homepage</p> <p>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 • 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 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 Creating a Draft and Draft Items Building Forms Building Fields</p>
Session 3	
15 minutes	Review
90 minutes	<p>Architect Module: eCRF Configuration (continued) Creating Draft Items continued Building Dictionaries Building Unit Dictionaries Building Folders Building Matrices</p>
10 minutes	Break
90 minutes	<p>Architect Module: eCRF Configuration (continued) Restrictions Lab settings 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) Publish, Push, and Test Patient Fields Configuration</p>
15 minutes	<p>Architect Module: Data Validations Introduction to Data Validations</p>
10 minutes	<p>Break</p>
60 minutes	<p>Architect Module: Data Validations (continued) Configuring an Edit Check Configuring a Derivation Publish-in-Place Overview</p>
40 minutes	<p>Extension Exercises (incl. Deriving Study Build Specifications using a Protocol activity) *Time permitting</p>
Session 5	
15 minutes	<p>Review</p>
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</p>

	<p>Copying Folders</p> <p>Copying Matrices</p> <p>Copying Objects into a Non-blank Draft</p> <p>The Difference Report</p> <p>The Edit Check/Derivation Filter for Retesting</p> <p>Building a Global Library Volume</p> <p>Proposing a Global Library Volume</p>
10 minutes	Break
60 minutes	<p>Architect Loader</p> <p>Architect Loader Overview</p> <p>Downloading a Draft</p> <p>Creating a Form, Field, Data Dictionary in XML File</p> <p>Uploading a Draft</p>
60 minutes	<p>Course Review</p> <p>Post Assessment</p>
15 minutes	<p>Course Wrap Up</p> <p>Questions and Answers</p> <p>Course Evaluation</p>