

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

Approximate Duration: 5 sessions

Time	Topic
<b>Session 1</b>	
15 minutes	<b>Welcome &amp; Introductions</b>
90 minutes	<p><b>iMedidata</b>            Setting up an iMedidata account            Navigating iMedidata as an end user            eLearning</p> <p><b>EDC Module</b>            EDC Tasks            The Subject Homepage            Data Entry and Editing</p> <ul style="list-style-type: none"> <li>● Add a New Subject</li> <li>● Standard Forms</li> <li>● All field types</li> <li>● Viewing the Audit History</li> <li>● Log Forms</li> <li>● Displaying Previous Visit Data</li> <li>● Lab Forms/Lab Ranges<sup>1</sup></li> </ul>
15 minutes	<b>Break</b>

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

90 minutes	<p><b>EDC continued</b></p> <p>Manual Queries</p> <p>Cleaning Data</p> <p>Subject Administration and Sharing</p> <p>Disabling Add Events</p> <p>Electronic Signatures</p>
<b>Session 2</b>	
15 minutes	<b>Review</b>
90 minutes	<p><b>Reports</b></p> <p>Accessing Reports in EDC</p> <p><b>Setting up a Study</b></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><b>Architect Module</b></p> <p>Project Development Process and Terminology</p>
15 minutes	<b>Break</b>
90 minutes	<p><b>Architect Module: eCRF Configuration continued</b></p> <p>Creating a Draft and Draft Items</p> <p>Building Forms</p> <p>Building Fields</p>
<b>Session 3</b>	
15 minutes	<b>Review</b>
90 minutes	<p><b>Architect Module: eCRF Configuration (continued)</b></p> <p>Creating Draft Items continued</p> <p>Building Dictionaries</p>

	Building Unit Dictionaries Building Folders Building Matrices
15 minutes	<b>Break</b>
90 minutes	<b>Architect Module: eCRF Configuration (continued)</b> Restrictions Lab settings Draft Settings
<b>Session 4</b>	
15 minutes	<b>Review</b>
60 minutes	<b>Architect Module: eCRF Configuration (continued)</b> Publish, Push, and Test Subject Fields Configuration
90 minutes	<b>Architect Module: Data Validations</b> Introduction to Data Validations Configuring an Edit Check Configuring a Derivation Publish-in-Place Overview
15 minutes	<b>Break</b>
60 minutes	<b>Extension Exercises</b> *Time permitting
<b>Session 5</b>	
90 minutes	<b>Global Library</b> Global Library Overview Defining Copy Sources Copying Forms Copying Fields

	<p>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>
<p>60 minutes</p>	<p><b>Architect Loader</b>                  Architect Loader Overview                  Downloading a Draft                  Creating a Form, Field, Data Dictionary in XML File                  Uploading a Draft</p>
<p>60 minutes</p>	<p><b>Course Review</b>   <b>Post Assessment</b></p>
<p>15 minutes</p>	<p><b>Course Wrap Up</b>                  Questions and Answers                  Course Evaluation</p>