

# 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>Goal:</b> By the end of this session, you should know the basic concept of iMedidata and basic functionality of different Rave EDC roles.</p> <p><b>iMedidata</b>            Setting up an iMedidata account            Navigating iMedidata as an end user            eLearning</p> <p><b>Navigating the EDC Homepage</b>            Using Cloud Navigation            Reviewing Sites and Subject Page</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> </ul>

	<ul style="list-style-type: none"> <li>• Lab Forms/Lab Ranges<sup>1</sup></li> </ul>
10 minutes	<b>Break</b>
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>
75 minutes	<p><b>Goal:</b> 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><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>
10 minutes	<b>Break</b>
90 minutes	<p><b>Goal:</b> By the end of this session, you should know how to build Draft and draft items.</p>

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

	<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> <p>Building Unit Dictionaries</p> <p>Building Folders</p> <p>Building Matrices</p>
10 minutes	<b>Break</b>
90 minutes	<p><b>Architect Module: eCRF Configuration (continued)</b></p> <p>Restrictions</p> <p>Lab settings</p> <p>Draft Settings</p>
<b>Session 4</b>	
15 minutes	<b>Review</b>
60 minutes	<p><b>Goal:</b> 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><b>Architect Module: eCRF Configuration (continued)</b></p> <p>Publish, Push, and Test</p> <p>Subject Fields Configuration</p>
15 minutes	<p><b>Architect Module: Data Validations</b></p> <p>Introduction to Data Validations</p>

10 minutes	<b>Break</b>
60 minutes	<p><b>Architect Module: Data Validations (continued)</b></p> <p>Configuring an Edit Check                  Configuring a Derivation                  Publish-in-Place Overview</p>
40 minutes	<b>Extension Exercises</b> *Time permitting
<b>Session 5</b>	
15 minutes	<b>Review</b>
75 minutes	<p><b>Goal:</b> By the end of this session, you should know how to use Global Library and Architect Loader.</p> <p><b>Global Library</b></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	<b>Break</b>

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