

Safety Gateway (Legacy) – Administration and Setup

eLearning Course Outline

Course Description: Safety Gateway is a configurable interface for passing information on Serious Adverse Events (SAEs) from Medidata Rave to E2B-compatible external safety systems. This course will provide you with a thorough understanding of the Mapping Tool to help you identify the Rave fields for extraction when SAEs are triggered or updated. You will also learn how to configure the Management Tool for your projects.

Approximate Duration¹: 49 min

Module	Topic
Welcome (1 min)	Welcome
Getting Familiar with the Mapping Tool (9 mins)	Objectives The Mapping Tool Process Data Extraction from Rave Data Extraction Errors Assessment - Data Extraction from Rave The E2B Tags Security Roles Accessing the Mapping Tool Summary
Implementing Rave Fields to E2B Mappings (14 mins)	Objectives What are Mappings?

¹ Duration listed is approximated, and does not reflect activities, simulations or assessments

Module	Topic
	E2B Sections for Mapping
	What is a Project Configuration?
	The Project Configurations Page
	Assessment - Project Configuration Status
	Adding a New Project Configuration
	The Mapping Tabs
	Creating Your Mappings
	Mapping Dictionary Items
	Adding a Form to a Mapping Tab
	Assessment - Map the Past Drugs Tab
	Case ID and Highlighted Terms
	Drug/Reaction Pairs
	Fixing Mapping Errors
	Publishing and Activating Your Configuration
	Assessment - Publishing a Configuration
	Summary
<p>Managing Project Configurations</p> <p>(8 mins)</p>	Objectives
	Cloning Your Configuration
	Assessment - Cloning Your Configuration
	Editing a Configuration
	Deactivating a Configuration
	Assessment - Editing a Configuration
	Reviewing Your Mappings
	Specifying Relevant Fields

Module	Topic
	Assessment – Data Transfer Threshold
	Summary
Safety Gateway Administration (18 mins)	Objectives
	Selecting Required Fields for Mapping
	Adding and Removing E2B Plus Tags
	Setting Up Error Notifications
	Assessment - Error Notifications
	Global Project Settings
	Configuring Selection Rules
	Configuring Email Notifications
	Copying Project Settings
	Data Transfer History
	Dual Output/Input Paths Option
	Empty EDI Output Paths
	Assessment - Admin Tools
	Summary
Next Steps (1min)	What to do Next
Post Assessment	