

## Medidata Safety Gateway (Legacy) – Managing Safety Cases

### 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 Management Tool to help you effectively manage and transmit safety data extracted from Rave.

Approximate Duration<sup>1</sup>: 31 min

Module	Topic
<b>Welcome</b>  (1 Min)	Welcome
<b>Introduction to the Safety Gateway</b>  (6 mins)	Client Responsibilities Objectives What is Safety Gateway? Need for Safety Gateway The Safety Gateway Workflow The Safety Gateway Workflow Example Assessment - The Safety Gateway Workflow Summary
<b>Getting Familiar with the Management Tool</b>  (4 mins)	Objectives Transmission Modes Security Roles Assessment - Security Roles

<sup>1</sup> Duration listed is approximated, and does not reflect activities, simulations or assessments

Module	Topic
	Accessing the Management Tool
	Summary
<b>Working with Safety Cases</b> (14 mins)	Objectives
	Viewing Open Tasks
	Searching for Tasks
	Managing Cases
	Reviewing and Selecting Case Data
	Assessment - Managing Cases
	Case Review History
	Discarding Safety Cases
	Reinstating Safety Cases
	Forcing a Follow-up Transmission
	Assessment - Safety Gateway Actions
	Summary
<b>Overview of the Generated E2B File</b> (5 mins)	Objectives
	Overview
	Data Included in the E2B File
	Sample Safety Gateway Output File
	Summary
<b>Next Steps</b> (1 min)	What to do Next
<b>Post Assessment</b>	