Safety Gateway – Managing Safety Cases

eLearning Course Outline

Course Description: Rave 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[1]: 31 min

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

Module	Topic
	Accessing the Management Tool
	Summary
Working with Safety Cases (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
Overview of the Generated E2B File (5 mins)	Objectives
	Overview
	Data Included in the E2B File
	Sample Rave Safety Gateway Output File
	Summary
Next Steps (1 min)	What to do Next
Post Assessment	

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