

Getting Started with Issue Management eLearning Course Outline

Course Description: Issue Management allows organizations running clinical trials to streamline the process of capturing findings and managing resolutions as part of clinical operations. It facilitates clinical research organizations (or sponsors) and key study team members to log findings and potential problems using an intuitive interface. The interface provides a holistic view of issues, deviations, and preventive or corrective actions at the client division, study-environment, country, and site context levels, depending on role and level of access. This course focuses on basic configuration and navigation of the Issue Management module. Topics include:

- Issue Management Settings Overview
- Creating and Managing Issues
- Creating and Managing/Commenting on Actions

Approximate Duration: 15 min

Module	Topic
Welcome (0.5 min)	Objectives
Getting Started with Medidata Issue Management (14 min)	Accessing Issue Management
	Issue Management Settings Overview Issue Settings Action Settings Workflow Settings
	Managing Issues and Actions Managing Issues Managing Actions
	Creating Issues and Actions Creating Issues Creating Actions
Summary (0.5 min)	Summary