

## Medidata Strategic Monitoring Overview eLearning Course Outline

**Course Description:** The Medidata Strategic Monitoring Suite is the only end-to-end comprehensive suite that combines risk assessment and anomaly detection with centralized issue management and streamlined site monitoring reporting, enabling users to identify risks and document actions in real-time. This course will give you an overview of the functionality of the various components of the suite, including:

- Introduction to Strategic Monitoring
- Overview of Risk Assessment and Key Risk Indicators
- Overview of Centralized Monitoring
- Overview of Targeted Monitoring
- Overview of Site Monitoring
- Overview of Issue Management and Action Items

Approximate Duration: 15 minutes

Module	Topic
<b>Welcome</b> (0.5 min)	Objectives
<b>Medidata Strategic Monitoring Overview</b> (14 min)	<b>Introduction to Strategic Monitoring</b> Complying with New Risk Based Monitoring Guidelines End-to-End Risk Management Smart, Collaborative, and Streamlined ICH E6 (R2) GCP Compliance The Medidata Strategic Monitoring Suite
	<b>Risk Assessment Categorization Tool (RACT) Overview</b> RACT - Risk Assessment Template RACT Functionality Risk Assessment Key Risk Indicators Study Procedures
	<b>Centralized Monitoring Overview</b> Centralized Statistical Analytics (CSA)

	<p><b>Targeted Monitoring Overview</b></p> <p>Study Procedures and SDR Strategy</p> <p>Targeted Source Data Verification (TSDV)</p>
	<p><b>Site Monitoring Overview</b></p> <p>SiM Functionality</p> <p>SiM Visits</p> <p>SiM Settings</p>
	<p><b>Issue Management Overview</b></p> <p>Issue Management</p> <p>Action Items</p>
<p><b>Summary</b> (0.5 min)</p>	<p>Summary</p>