

Documenting Risks in Medidata Risk Management (RETIREMENT PENDING) eLearning Course Outline

Course Description: The Medidata Risk Management application allows study team members to identify, document, and monitor the risks of a study protocol and document activities within a Risk Plan Report. Risk Management supports the identification of Critical Data and Processes (Critical to Quality Factors), risk identification and evaluation, development of risk control strategies, cross-functional risk communication and review, and risk reporting. Risk Management also supports the capability to identify and track performance indicators, such as KRIs and QTLs, to assist with risk & mitigation oversight.

This course shows study end users of Risk Management how to add risks, as well as how to manage risks on an ongoing basis throughout the study.

Approximate Duration: 10 min

Module	Topic
Welcome (0.5 min)	Objectives
Documenting Risks in Medidata Risk Management (9 min)	Add Risks Add QTLs, KRIs, and Risk Mitigations Manage and Update Risks
Summary (0.5 min)	Summary