

Medidata RACT: Conducting Risk Assessment eLearning Course Outline

Course Description: The Medidata Risk Assessment Categorization Tool (RACT) allows study team members to identify, document, measure, and monitor the risk of a study protocol and devise a risk monitoring plan. The plan incorporates critical processes, critical data, source data review strategies, and key risk indicators. This course focuses on conducting a Risk Assessment in RACT. Topics covered include:

- Accessing Medidata RACT
- Starting a Risk Plan
- Documenting the Risk Assessment
- Adding a New Risk Subcategory and Category
- Submitting, Reviewing, and Approving the Risk Assessment

Approximate Duration: 18 minutes

Module	Topic
Welcome (0.5 min)	Objectives
Medidata RACT: Conducting Risk Assessment (17 min)	Accessing Medidata RACT
	Starting a Risk Plan
	Documenting the Risk Assessment
	Adding a New Risk Subcategory and Category
	Submitting and Approving the Risk Assessment
Summary (0.5 min)	Summary