

Medidata Site Monitoring and Issue Management End User Training ILT Course Outline

Course Description: Site Monitoring provides efficient monitoring of clinical studies with integrated workflows to improve the site monitor experience, aid proactive decision making, and reduce risk and costs to ultimately increase study performance, patient safety, and time to market for the drug or device.

This course gives attendees in depth training for the entire end user workflow in Site Monitoring, from planning the site visit all the way through finalizing the follow up letter. Management of issues and action items with Issue Management will also be covered in the course.

Approximate Duration: 8 hours

Module	Topic
Welcome (0.5 hours)	Course Overview
Medidata Site Monitoring: Submit, Review, and Approve Visit Reports (5.5 hours)	For Your Consideration... Things to Keep in Mind Configuration Considerations
	Overview of Site Monitoring Workflow Site Monitoring Workflow Best Practices Utilizing the Automatic Visit Schedule vs. Manually Scheduling Site Visits
	Plan the Visit Plan the Visit Overview Access the Site Navigating the Visit Listings Page Add A Visit
	Approve Visit Reports Confirm the Visit Overview Mark the Visit As Confirmed
	Edit and Finalize the Confirmation Letter

	Conduct the Visit Conduct the Visit Overview Begin Visit Conduct Document a Multi-Select Question with a Required Comment Document a Yes/No Question with a Required Comment Document a Yes/No Question with a Required Issue Mark a Question as Not Applicable
	View the Visit Record View the Visit Record Overview View the Draft Visit Report
	Complete the Visit Conduct Complete Conduct Overview Mark the Visit as Conducted
	Submit the Visit Report for Review Submit Report Overview Submit the Visit Report
	Visit Report Approval Process Review the Visit Report Overview Review and Reject the Visit Report Review Report Comments and Perform Post Conduct Review on the Visit Review and Approve the Report & Mark the Visit as Complete
	Edit and Finalize the Follow Up Letter
	Manage Issues and Action Items Manage Issues and Action Items Overview Manage Issues and Action Items Open and Issue Not Connected to a Visit
Final Assessment (2 hours)	Final Assessment