EDC Inspection Readiness for Sponsors (and CROs)

eLearning Course Outline

Course Description: This course provides information and insight into the inspection process and will prepare sponsors and CROs for what to potentially expect during a regulatory inspection, specifically focused on the use of Rave EDC. By completing this course and carefully considering the points that are covered, participants will be better prepared to answer a Regulatory Inspector's questions in regards to Rave EDC.

Approximate Duration[1]: ~35 min

Module	Topic
EDC: Inspectional Impact (11 min)	Introduction
	Objectives
	Sponsor's Regulatory Requirements
	Additional GCP Requirements
	Regulatory Requirements: CRO/Partner Perspective
	Regulatory Requirements: Investigator's Perspective
	Inline Assessment
	Working with Medidata and Clinical Investigators
	Sponsor/CRO/Partner's Inspection
	Regulatory Inspectors' Expectations of EDC
	Summary
Working with Rave EDC (14 min)	Introduction
	Objectives
	Validation of Rave EDC
	Electronic Signatures
	Rave Security Access and Control
	Audit Trail

Module	Topic
	Support System for Rave EDC
	Disaster Recovery
	Roles Within Rave EDC
	Investigator's Responsibilities
	Sponsor Roles
	Inline Assessment
	Medidata's Roles
	Data Privacy
	Summary
EDC Data Flow (8 min)	Introduction
	Objectives
	EDC Data Collection
	Data Integrity
	EDC Benefits
	Linkages to Other e-Data Sources
	Study Closure Process
	Data Archiving
	Inline Assessment
	Summary
Post Assessment	Post Assessment

[1] Duration listed is approximated, and does not reflect activities, simulations or assessments