EDC Inspection Readiness for Clinical Sites

eLearning Course Outline

Course Description: This course provides guidance to Investigators and Coordinators about what to potentially expect during a regulatory inspection, specifically focused on the use of Rave EDC. The course reviews many potential questions that could be asked by an inspector as well as guidance on the critical areas that are important from a regulatory point of view on how they use Rave EDC during the conduct of their study.

Approximate Duration[1]: ~30 min

Module	Topic
Clinical Research Using EDC (5 min)	Introduction
	Objectives
	Regulatory Requirements
	Regulatory Inspections
	Regulatory Inspector's Expectations
	Electronic Systems
	Q&A
	Summary
Clinical Trial Responsibilities (8 min)	Introduction
	Objectives
	Roles Within Rave EDC
	Data Integrity
	Scenario: PI Assuring Data Integrity
	Data Security
	Data Privacy in Rave
	Q&A

Module	Topic
	Summary
EDC Data Flow (6 min)	Introduction
	Objectives
	Traditional Paper Case Report Form (CRF)
	Electronic Data Capture (EDC)
	EDC Benefits
	Source Data
	Electronic Signatures
	Q&A
	Summary
Data Handling and Source Documents (3 min)	Introduction
	Objectives
	Investigator's Responsibilities
	Data Collection Considerations
	Scenario: PI Assuring Source Data Accuracy
	Q&A
	Summary
Working with Rave (5 min)	Introduction

Module	Topic
	Objectives
	Validation of Rave EDC
	Rave Security Access and Control
	Support System for Rave EDC
	Sponsor Roles
	Q&A
	Summary
Final Review (3 min)	Key Points
	Additional Points to Consider
	Question 1
	Question 2
	Question 3
	Question 4
	Conclusion
Post Assessment	Post Assessment

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