

RBQM: Identify and Mitigate Protocol Deviations

eLearning Course Outline

Course Description:

In this course, you will learn about:

- What is Protocol Deviation in Clinical Research
- Roles and Permissions
- Clinical Data Studio Protocol Deviation Workflow
- Tasks that Project Managers or Central Monitors can perform in the Plan documents, and
- How Data Managers, Clinical Research Associates (CRAs)/, or Medical Monitors can identify and mitigate protocol deviations

Approximate Duration: 30 min

Module	Topic
Welcome (1 min)	Objectives
Protocol Deviations Overview (3 min)	• Protocol Deviations Overview Overview • Roles and Permissions • Clinical Data Studio Protocol Deviation Workflow
Project Managers/Central Monitors- Configure the Protocol Deviation Assessment Plan (PDAP) (7 min)	• Objectives • Configure Protocol Deviation Assessment Plan (PDAP) • Download PDAP • Edit PDAP
Knowledge Check (3 min)	• Knowledge Check 3 Questions
Data Managers/ CRAs/ Medical Monitors- Identify, validate, confirm, review, and approve protocol deviations (10 min)	• Objectives • Overview • Protocol Deviation Workflow and Review Process • Create Listings for PD

	• EDC Queries • Manually Add Proposed Deviation • Protocol Integrity Report (PIR) • Review Proposed PD • Confirm Protocol Deviation • Approve Protocol Deviation
Knowledge Check (5 min)	• Knowledge Check 5 Questions
Summary (1 min)	Summary