According to Good Clinical Practice (GCP), sponsors are required to select investigators, site staff and monitors qualified by education, training and experience and implement a risk-based quality management system to ensure human subject protection and data integrity. Quality is defined as the absence of risks that matter. Critical to Quality (CTQ) Factors include good protocol design, feasibility, study conduct, third-party engagement, study reporting, and patient safety. An effective Quality Management Plan includes strategies to identify, evaluate, reduce and communicate risks related to study conduct, patient safety and data integrity. High quality training of site staff is an effective risk reduction and quality enhancement method.

Examples of Active Learning Methods

- Question and answer sessions
- Role playing
- Demonstrations
- Hands-on training
- Drills and dry runs
- Small group discussions
- Teach back method
- Teach others
- Think (alone) – pair (discuss with partner) – share (ideas with the group)
- Learner presentations
- Use case studies and real life examples to problem solve
- Polling
- Complete worksheets and share with group

Designing Effective Training Plans to Improve Quality Risk Management

- Identify and rank training needs based on the impact and likelihood they pose as a risk to CTQ Factors, human subject protection and/or data integrity.
- State the learning objectives in behavioral terms.
- Select and align learning methods and activities based on active learning and adult learning principles.
- Conduct pre, during and post assessments of the learning activities.
- Collect feedback from learners and document learning completion.
- Continuously monitor the effectiveness of the learning activities and improve if necessary.
- Continuously monitor all staff during the conduct of the trial and retrain if necessary.

Introduction

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- Critical to Quality (CTQ) Factors include good protocol design, feasibility, study conduct, third-party engagement, study reporting, and patient safety.
- An effective Quality Management Plan includes strategies to identify, evaluate, reduce and communicate risks related to study conduct, patient safety and data integrity.
- High quality training of site staff is an effective risk reduction and quality enhancement method.

Figure 1. Eight principles associated with active learning and adult learning principles. Adapted from “Problem-based Learning and Theories of Teaching and Learning in Health Professional Education” by R. E. Gewurtz et al., 2016. *Journal of Perspectives in Applied Academic Practice, 4*(1), p. 61.

Real-life Scenarios

Site receives the informed consent for a new study from Sponsor.
- Less active learning activity: Instruct staff to review the informed consent.

More active learning activities: After staff reviews the informed consent, work in pairs to role play consenting a participant and problem solve several real-life issues.

Site receives the protocol for a new study from Sponsor.
- Less active learning activity: Instruct staff to review the protocol.

More active learning activities: After staff reviews the protocol, convene a small group discussion with a Q & A session; conduct a dry run of an actual visit.

Site receives Lab Processing Manual from Sponsor.
- Less active learning activity: Instruct staff to review the manual.

More active learning activities: After staff reviews the manual, work together in small groups to do several hands-on trainings and demonstrations.