USING ACTIVE LEARNING METHODS, ADULT LEARNING PRINCIPLES AND THE IDENTIFICATION OF CRITICAL TO QUALITY (CTQ) FACTORS TO CREATE EFFECTIVE SITE STAFF TRAINING PLANS AND IMPROVE QUALITY RISK MANAGEMENT

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Introduction

❖ 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.[1,2,3]

❖ Quality is defined as the absence of risks that matter.[4]

❖ Critical to Quality (CTQ) Factors include good protocol design, feasibility, study conduct, third-party engagement, study reporting, and patient safety.[4]

❖ An effective Quality Management Plan includes strategies to identify, evaluate, reduce and communicate risks related to study conduct, patient safety and data integrity.[2]

❖ High quality training of site staff is an effective risk reduction and quality enhancement method.[1,2,3,4]

Designing Effective Training Plans to Improve Quality Risk Management [4,5,6]

❖ 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.

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.[7]

Examples of Active Learning Methods[6]

❖ 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

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.

References: 1. US DHHS FDA. (2018). *E6(R2) Good Clinical Practice: Integrated addendum to ICH E6(R1): Guidance for industry.* 2. US DHHS FDA. (2006). *Guidance for industry: Q9 Quality Risk Management.* 3. US DHHS FDA. (2019). *A risk-based approach to monitoring clinical investigations. Questions and answers. Guidance for industry.* 4. Clinical Trials Transformation Initiative (CTTI). (n.d.). What is Quality by Design [Slide presentation]? Retrieved from https://www.ctti-clinicaltrials.org/toolkit/qbd/learn-about-qbd. 5. Merriam, S., & Bierema, L. (2013). Adult Learning: Linking Theory and Practice. San Francisco, CA: Jossey-Bass. 6. Berkeley Center for Teaching & Learning. (2019). Active learning strategies. Retrieved from https://teaching.berkeley.edu/active-learning-strategies. 7. Gewurtz, R. E., Coman, L., Dhillon, S., Jung, B., & Solomon, P. (2016). Problem-based learning and theories of teaching and learning in health professional education. *Journal of Perspectives in Applied Academic Practice, 4*(1), 59-70.