

QbD Workshop – Facilitator Role

Introduction

The workshop provides an opportunity to educate attendees about clinical QbD, its intent, and regulatory support for the approach and to apply the QbD principles through hands-on exercises during breakout sessions. A sample agenda and facilitator slide deck are available for download on the QbD Toolkit website at: <https://ctti-clinicaltrials.org/our-work/quality/qbd-quality-by-design-toolkit/>.

Facilitator Key Characteristics

Ideally, the workshop facilitator will be a QbD champion from within the organization. Workshop facilitators should be well-versed in the background and principles of quality by design, as well as in clinical trial methodology, implementation, and proactive management of risks.

He/she will also need facilitation skills to be able to maintain an active and productive dialogue with participants, particularly during the read-out of breakout sessions, and to ensure that the diversity of participants is leveraged. He/she must encourage “thinking” vs. a traditional box-checking approach to clinical trial quality.

Workshop Attendees

The workshops will be most effective when participants are exposed to diverse viewpoints from within (and if feasible, external to) the company. Representatives from all functional lines engaged in trial design, conduct, analysis, and reporting should be included (see table of QbD workshop participants).

Materials

To facilitate active attendee engagement, the CTTI Principles Document, case study/ies to be used and relevant publications related to clinical QbD should be circulated to all attendees 1-2 weeks prior to the workshop with a request to review the documents in advance.

Duration

Depending on the time available for attendees, the workshop can be shortened (for example, through changing breakout session 1 into a group discussion vs. small group breakouts) or it may be split over multiple days.

QbD Workshop – Breakout Group Facilitator Role

Introduction

The breakout sessions are designed to allow small groups of diverse stakeholders to identify and discuss specific recommendations of aspects of a trial that are “critical to quality.”

Workgroup sessions will have specific, pre-assigned hypothetical protocol case studies and principles document that are meant to guide the discussions. Facilitators are asked to encourage the group to stay within the scope of the theme during this time.

Facilitator Key Characteristics

Breakout facilitators should be comfortable leading cross-functional, scientific dialogue. They should be well-versed in clinical trial design, implementation, and clinical risk management to be able to guide/re-direct participants where necessary identifying elements that are critical to quality for a particular trial and to provide feedback on strategies proposed by groups for mitigating risks.

Breakout Group Members and Other Breakout Group Roles

During breakout sessions, groups should ideally be pre-assigned to ensure a mix of different disciplines and backgrounds and a robust discussion. Each group should be limited to 8-10 people to allow for meaningful individual contributions.

Each facilitator should ensure the team identifies a **spokesperson** for the report-out who will be responsible for capturing and conveying the group’s discussion. The facilitator should also take high-level notes of the discussion, or assign a **note-taker** as needed. The facilitator’s notes will be used to produce a list of the key topics to discuss during the workshop wrap-up (what was easy or challenging for participants, what approaches they took to working together as a group, insights that came out of the discussions).

Materials

For breakout groups, make sure each group has a copy of the Principles Document, the case study, and flip charts to capture group discussion for the report outs. Consider whether groups require separate breakout rooms to work productively.

Duration

Allow 1-1.5 hours for each break out session so there is ample time for discussion.

Case Study Preparation

The workshop and breakout group facilitators should prospectively review case studies to be used and identify any key messages / points to be highlighted during the workshop.

Suggested Breakout Group Agenda

<p>Breakout Facilitator Role: Session 1</p>	<p>Break out session I objectives:</p> <ul style="list-style-type: none"> • Working in groups, participants will apply QbD principles to their hypothetical protocol outline, taking into account the concerns of key stakeholders. • Characterize the applicability of the QbD factors as high, medium, or low. • Select the top 5 factors that are critical to the success and quality of the trial protocol and why they are important. • Develop 3 priority recommendations to assure a successful and efficient trial. <p>In the principles document, there are:</p> <ul style="list-style-type: none"> • Over 20 Factors • Over 40 Description/Rationale Statements • Over 130 Examples of Issues for Consideration <p>Have the teams categorize each “Factor” as High, Medium, or Low and to select top 5 and why. Remind participants of the \$100 rule (If you only had \$100 to spend, what factors would you prioritize?).</p> <p>Given the amount of time to prioritize, select, and develop recommendations, we might want to suggest, as a guideline, an approach which could look like:</p> <ol style="list-style-type: none"> 1. Review objective of workshop and expected deliverables – 5 minutes 2. Review structure of principles document – 5 minutes 3. Agree approach to be taken in achieving objectives – 5 minutes (basically reviewing this list of tasks) 4. Overview case example – 5 minutes 5. Review each factor and designate H, M or L – 15 minutes (quicker than 1 per minute) 6. From the Highs, select and rank top 5. If this proves to be difficult, ask group members to cast their votes on a flipchart – 10 minutes 7. Develop a recommendation for top 3 factors by reviewing “Examples of Issues for Consideration” that would prevent such issues from occurring “by design”. – 30 minutes
<p>Breakout Facilitator Role: Session II</p>	<p>Break out session II objectives:</p> <ul style="list-style-type: none"> • Explore the role of risk management in clinical trial design and oversight • Take the one most important critical to quality (CTQ) parameter identified in Part I of the case study and address the following: <ul style="list-style-type: none"> ○ What proactive steps can be taken to avoid problems (mitigation plan)? ○ What ongoing checks can be performed to detect

	<p>problems?</p> <ul style="list-style-type: none"> ○ What type of error will trigger corrective actions? • Promote continuous improvement. Consider: <ul style="list-style-type: none"> ○ What steps can be taken to ensure that corrective and preventive actions remain focused on CTQ aspects of a trial, are sustainable, and efficient? (avoid the need to add additional activity for the sake of adding activity and making more complex and the complexity leads to inability to implement and sustain) ○ What steps can be taken to ensure the corrective action stays focused on addressing errors that matter? ○ How will lessons learned be captured and communicated? <p>Focus the team on opportunities to eliminate the potential for “errors that matter” through design or implementation changes.</p> <p>Encourage the team to focus on mitigating for errors that do actually matter in terms of impact on data reliability and / or patient safety.</p> <p>Re-assure the team that they may be uncomfortable with the process, but that being uncomfortable can generate good discussion and debate.</p> <p>Encourage open dialogue make sure that participants are not simply focusing on general GCP elements that are already well-controlled but looking for errors that matter based on the specific trial design.</p> <p>Ensure that teams discuss thresholds for action when errors are detected. Play devil’s advocate so that teams have to clearly articulate their rationale for a particular threshold.</p> <p>For quality control (QC), sense check that the group is not simply codifying existing clinical monitoring practices but is leveraging the functional expertise in the group.</p> <p>Have the team sense-check whether their planned mitigations will actually decrease the likelihood or impact of an error that matters and whether their QC checks will detect them in a timely manner. Engage the team in a discussion of thresholds for action if they skip over this.</p>
Workshop Facilitator	<p>Moderate breakout group report outs. Make sure that groups articulate their rationale for selecting CTQ elements and identify any CTQs that weren’t considered by the team.</p> <p>Challenge the teams where proposed mitigations are not focused on “errors that matter” or are reactive in nature (vs. proactive in preventing the problem). Identify and highlight proactive solutions that are both effective and efficient in either preventing an error that matters or in rapidly detecting it.</p>