Paper RM01

From Oversight to Insight – Rethinking Risk-Based Quality Management

Madhumita Ghosh, Capish, Raleigh, USA

Eva Kelty, Capish, Malmö, Sweden

ABSTRACT

Risk-Based Quality Management has become a cornerstone of modern clinical trial oversight, but its success depends on how easily teams can access and understand the signals that matter. When critical insights are buried in disconnected listings or locked in isolated systems, identifying emerging risks often relies on experience and manual effort rather than clarity and context.

An effective RBQM approach brings data together conceptually, not just operationally. By connecting deviations, safety events, and operational trends within a structure that mirrors how trials actually unfold, teams can explore quality signals dynamically. This enables a shift from chasing after inconsistencies to understanding how different factors relate – supporting earlier interventions and smarter prioritization.

In this session, we'll share how making data relationships visible and navigable empowers teams to monitor quality continuously, not just at pre-set checkpoints, and focus their attention where it can make the greatest impact.

INTRODUCTION

Risk-Based Quality Management (RBQM) is now firmly embedded in regulatory guidance and industry practice, with clear expectations to prioritize oversight based on risk to patient safety and data integrity. While most organizations have adopted RBQM frameworks, the ongoing challenge lies not in defining risk, but in recognizing meaningful signals early and interpreting them consistently across the trial lifecycle.

In practice, RBQM relies on the review of numerous indicators - protocol deviations, safety findings, operational performance metrics, and monitoring outcomes, originating from different functions and systems. Each of these data streams offers a partial perspective on trial quality and is often reviewed through separate listings, dashboards, or reports. As a result, teams may spend considerable effort reviewing individual data points without gaining a clear understanding of how they relate to one another.

This fragmentation can mask emerging risk. For example, a protocol amendment introducing additional visit procedures may lead to longer visit durations and scheduling challenges at certain sites. Operational metrics may show increasing visit delays, while monitoring data reflects a rise in documentation corrections or missed assessments. Individually, these signals may appear manageable. When viewed together, however, they can indicate a growing risk to data completeness and protocol compliance that warrants early intervention.

In such situations, identifying the underlying risk often depends on informal discussions or individual insight rather than a shared, structured view of the data. Teams may recognize each issue in isolation but struggle to assess whether they are interconnected or determine which sites or trial activities require focused attention. This can delay escalation and result in corrective actions that address symptoms rather than root causes.

As trial designs continue to evolve - incorporating decentralized elements, adaptive protocols, and increasingly complex visit schedules, the limitations of fragmented RBQM approaches become more pronounced. To fully realize the intent of RBQM, oversight must evolve from procedural review toward insight-driven risk management by reinforcing three foundational principles:

- **understanding quality signals in context rather than isolation**, enabling teams to recognize how operational changes, deviations, and safety findings interact
- **aligning RBQM review with how trials actually unfold,** focusing on trial activities and execution rather than functional data silos
- **enabling continuous, proactive awareness of emerging risk**, supporting earlier prioritization and more targeted intervention as data evolves

The sections that follow examine how applying these principles can help teams move beyond reactive oversight toward a more integrated and actionable understanding of trial risk.

UNDERSTANDING QUALITY SIGNALS IN CONTEXT

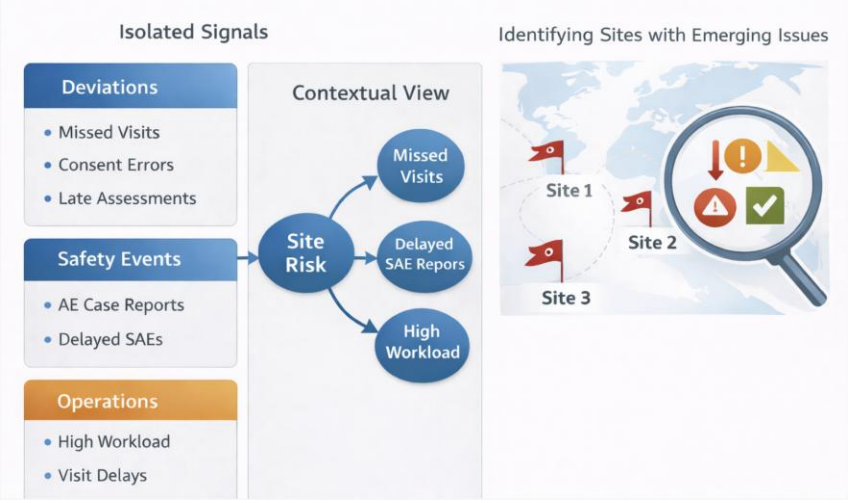
A core objective of Risk-Based Quality Management is the early identification of risks that may impact patient safety or data reliability. In practice, these risks are rarely present as isolated events. More often, they emerge through related signals that develop across trial activities, sites, and time. Interpreting these signals effectively requires an understanding of their context, how they connect, evolve, and influence one another.

When quality data is reviewed through separate listings or summaries, each signal is assessed independently. While this supports documentation and compliance, it can limit the ability to recognize emerging patterns. Individual findings may appear minor or expected when viewed alone, even as underlying risk increases through their combined effect.

For example, an increase in adverse events at a site may initially appear as routine variability. When examined in context, by considering event severity, timing relative to treatment exposure, related protocol deviations, and concurrent operational changes, teams can better determine whether the trend represents an emerging safety concern or a transient fluctuation. Similarly, missed or out-of-window assessments may appear isolated until viewed alongside increased visit complexity, staffing changes, or workload during the same trial phase, where they may indicate execution pressure that could compromise data completeness.

Comparable dynamics may be observed in safety oversight and protocol compliance. Reporting delays or deviations related to informed consent or eligibility criteria may seem inconsequential in isolation, but when they cluster around site initiation or follow process changes such as the introduction of remote or hybrid trial activities, they may signal gaps in training or operational readiness.

Viewing quality signals together, across sites, trial activities, and over time, helps teams spot meaningful patterns earlier and focus their attention before issues escalate.



ALIGNING RBQM WITH HOW TRIALS ACTUALLY UNFOLD

Moving Beyond Functional Silos

Clinical trials rarely move in straight lines. They advance through handoffs, between teams, vendors, and trial phases, where responsibility shifts and assumptions are tested. Yet RBQM oversight is often structured around stable functional roles rather than these moments of transition, creating blind spots in how risk is managed.

Consider a trial that transitions laboratory services or monitoring support mid-study. Contracts may be updated, responsibilities reassigned, and documentation reviewed to confirm readiness. From a functional perspective, each step may be completed as planned. From an execution perspective, however, inconsistencies can emerge as new teams interpret procedures differently or as historical context is lost during the handoff.

When RBQM reviews remain confined to functional checklists, these transition-related challenges may not be discussed until they surface as quality findings or operational delays. Aligning RBQM with how trials actually unfold means shifting attention to these moments of change, where execution risk is often highest, rather than reviewing functions in isolation.

Framing oversight around trial events such as vendor transitions, role changes, or operational handovers encourages teams to ask different questions: Are responsibilities clear? Has context been transferred effectively? Are processes working the same way in practice as they did before the change?

From Task Completion to Risk Understanding

RBQM activities are frequently designed to confirm that required steps have been completed - training delivered, documentation approved, and oversight plans updated. While necessary, this approach can create a false sense of confidence when completion is equated with readiness.

For example, following a change in monitoring approach, teams may confirm that new monitoring plans are in place and that monitors have been trained. However, early site interactions may reveal uncertainty about expectations or differences in how findings are documented and escalated. If RBQM discussions focus only on completed tasks, these execution issues may remain unaddressed until they escalate.

An execution-aligned RBQM approach encourages teams to revisit how changes are playing out during trial conduct. Oversight discussions can then focus on whether processes are being applied consistently, whether roles are clear, and whether adjustments are needed to maintain quality as the trial evolves.

By aligning RBQM review with real-world trial flow, oversight becomes more adaptive and forward-looking. Teams can respond to change as it happens, rather than waiting for issues to crystallize into formal findings.

CONTINUOUS AND PROACTIVE RISK AWARENESS

Beyond Periodic Review Cycles

Many RBQM approaches rely on scheduled reviews and predefined checkpoints. While these reviews provide structure, they can also limit visibility into changes that develop between review cycles, when early signs of risk often begin to surface.

In practice, sites may continue to meet key performance expectations while subtle shifts occur in how trial activities are executed, such as after staff turnover or changes in enrollment patterns. Individually, these changes may not raise concern. Over time, however, they can influence data consistency or signal emerging execution pressure if they remain unnoticed.

An exploratory approach to oversight helps address this gap. Rather than waiting for the next formal review, teams can follow a signal as it emerges, looking across related data, timelines, and trial activities to understand whether observed changes represent routine variability or something that warrants attention.

This does not require continuous manual review of all data. Instead, it emphasizes flexibility, the ability to ask questions, explore connections, and assess developing trends as trial conditions evolve. By complementing periodic reviews with exploratory analysis, RBQM supports ongoing awareness during the moments when meaningful change is most likely to occur.

Smarter Prioritization Through Connected Signals

Effective prioritization in RBQM depends on understanding how different quality indicators relate to one another, rather than assessing each finding in isolation. Individual issues may appear manageable on their own, but their significance often changes when viewed alongside related operational or process-level changes.

For example, recurrent protocol deviations may warrant increased attention when they coincide with rising operational workload or recent staffing shifts at a site. Similarly, emerging safety findings may take on added importance when they follow changes in trial processes or execution approach. In other situations, operational delays or disruptions may precede downstream quality issues, offering early indications that risk is increasing before formal findings are observed.

Recognizing these relationships allows teams to focus oversight where it is most needed. Instead of responding uniformly to all findings, RBQM efforts can be directed toward areas where multiple signals suggest increasing risk. This supports more targeted use of monitoring resources, earlier intervention, and more informed escalation decisions.

By prioritizing based on connected signals rather than isolated events, RBQM becomes a more proactive and efficient process. Teams are better equipped to anticipate where risk may develop next and to address underlying drivers before issues escalate, supporting more effective protection of patient safety and data integrity.

CONCLUSION

Risk-Based Quality Management delivers its greatest value when it moves beyond procedural oversight to insight-driven decision-making. Understanding quality signals in context, aligning oversight with how trials actually operate, and maintaining continuous awareness of emerging risk are critical to achieving this shift.

By reinforcing these principles, RBQM can support earlier identification of meaningful risk, clearer prioritization, and more timely action. When quality signals are interpreted as part of a connected story rather than isolated events, RBQM becomes a strategic tool for protecting patients and ensuring trial quality throughout the study lifecycle.

As clinical trials continue to increase in complexity, applying these principles consistently can help organizations strengthen RBQM practices in ways that are practical, scalable, and aligned with the realities of trial execution. This approach supports not only compliance with regulatory expectations, but also more effective oversight and sustained focus on patient safety and data integrity.

REFERENCES

1. ICH E6(R3). Guideline for Good Clinical Practice
2. PHUSE. RBQM and Data Integration White Papers
3. FDA. Guidance for Industry: Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring
4. TransCelerate BioPharma. Risk-Based Monitoring Methodology
5. The Potential Power of Data, E.Kelty, C.Dahlbo, ET22 PHUSE US Connect 2024

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the authors at:

Author Name:	Madhumita Ghosh
Company:	Capish
Address:	100 Montgomery Street, San Francisco, CA, USA
Work Phone:	+5712367039
Email:	madhumita.ghosh@capish.com
Website:	www.capish.com

Author Name:	Eva Kelty
Company:	Capish
Address:	Lokgatan 8, Malmö, Sweden
Work Phone:	+46 40 10 88 80
Email:	eva.kelty@capish.com
Website:	www.capish.com