

How Effective Risk-Based Quality Management Transforms CRO Operations

Risk-Based Quality Management (RBQM) is an ICH and FDA-advocated approach to managing risk for the entire clinical trial lifecycle—a set of software and services with the potential to dramatically change the way CROs control compliance.

Adopting a risk-based approach to study execution lets CROs finally focus on what matters most.



Vocabulary Check

Why has the life sciences industry shifted away from risk-based monitoring? It's all about being proactive, from study design to planning and execution.

Let's look at the top terms to know.

RBM was first recommended by the FDA in 2013. With the final draft version of ICH E6 (R3) in 2023, RBQM has gained traction as a holistic, end-to-end clinical trial methodology.

RBM: Risk-Based Monitoring

RBM, linked to Quality by Design (QbD), is the use of software, data, and analytics to monitor risk primarily in high-risk areas, supporting critical thinking and strategic trial decision-making.

RBQM: Risk-Based Quality Management

RBQM applies the principles of RBM to all areas of quality management. CROs now embrace RBQM to address the growing crisis in research complexity, duration, and cost.

RBDM: Risk-Based Data Management

RBDM focuses on modern, adaptive, and intelligent analytics that pinpoint real-time outliers, such as training deficiencies or fraud, and enable prompt corrective action.

CSM: Central Statistical Monitoring

CSM drives RBQM with a unique set of algorithms that interrogate clinical and operational data in real time to illuminate anomalies and discrepancies that typically go undetected.

Smarter Ways to Run Trials at Every Size

All sizes of CROs can use RBQM to identify, visualize, manage, and document trial risks that could compromise patient safety and delay the approval of investigational products.



Large CRO

Efficiency & Cost Reduction Compliance at Scale Centralized Oversight



Small-Mid CRO

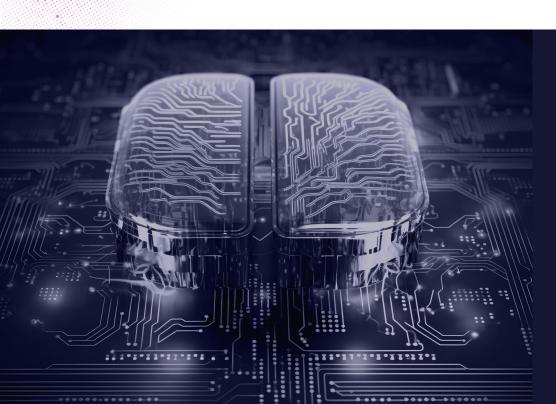
Resource Optimization Credibility & Competitiveness Flexibility & Scalability



Commercial CRO

Client Satisfaction Legal & Liability Risk Mitigation Market Differentiation

APPROXIMATELY HALF OF CLINICAL TRIALS USE RBQM COMPONENTS. LACK OF INTERNAL AWARENESS IS THE **TOP CHALLENGE TO ADOPTION.**



Ready for RBQM?

Elevate your competitive advantage with CluePoints, the leader in statistical and Al-driven software solutions for CROs.

