



# 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: 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.

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.**

## 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 AI-driven software solutions for CROs.