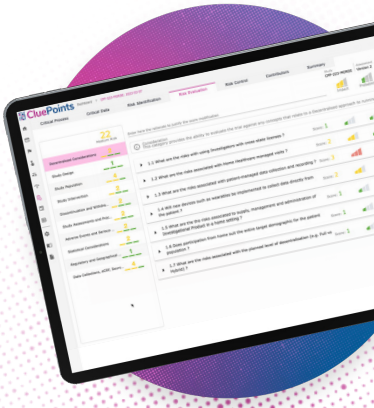
CluePoints

Risk-Based Quality Management (RBQM)

Our latest research with the Tufts Center for the Study of Drug Development (CSDD) shows that in 2023, the highest adoption of RBQM components was in the documentation stage (60%), followed by planning and design (56%). The execution stage had the lowest adoption at 52% but anticipates high growth through 2027, with specific components anticipated to increase by up to 133%.



Risk assessment and control planning, along with critical data identification, were the most leveraged components. By 2027, companies expect a **133% increase in duplicate patient detection and a 92% increase in targeted data management reviews,** reflecting the growing complexity of trial protocols.

CluePoints' Central Monitoring Platform has long addressed the demands of rising data volumes and trial complexity through advanced RBQM technology. By leveraging cutting-edge advancements in statistics and machine learning, we offer AI-powered solutions that transcend traditional data analysis. **RBQM illuminates outliers and data anomalies in real time, offering users a better way to identify, visualize, manage, and document trial risks.**

RBQM Across the Clinical Trial Lifecycle

CluePoints has worked with a multitude of Sponsors and CROs. Although assessing the risk landscape early in trial design is ideal, we've also successfully implemented RBQM at various stages of execution and during ongoing monitoring.

Trial Design

Implement RBQM proactively from trial design to ensure risk management practices are integrated at every stage, enhancing cost efficiency across clinical operations, data management, quality, and medical review.

Inspection Readiness

Preparing for inspections near the study's end facilitates a smooth transition to study lock, optimizing data integrity and cleanliness for submission. This is crucial, as over 25% of studies fail first-cycle regulatory reviews due to data quality issues.

Oversight

Monitoring CROs and study teams ensures efficient trial execution and protocol adherence, focusing on critical endpoints while maintaining data quality and integrity, especially for remote and decentralized methodologies.

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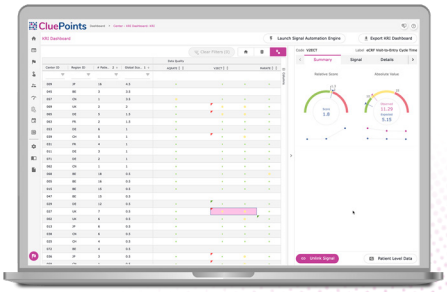
Our Proven Approach to RBQM



Detection

As RBQM pioneers and innovators, CluePoints takes a two-fold approach to clinical trial management. First, we lay a foundation, utilizing advanced analytics to scrutinize trial data for patterns and insights. This proactive approach is essential for managing clinical risks and optimizing trial processes.

Key Risk Indicators (KRIs)
Evaluate site performance and metrics to identify and address 'at-risk' locations promptly.

Patient Profiles
Identify unusual patient patterns, prioritize investigations, and focus on significant data anomalies.

Central Statistical Monitoring
Analyze all data to uncover atypical patterns that could indicate operational challenges.

Quality Tolerance Limits (QTLs)
Identify systematic issues, monitor key metrics, and document deviations to maintain accountability in trials.

Business Intelligence (BI)
Examine clinical and operational data from various perspectives using configurable formats and data widgets.

Duplicate Patients
Create a priority list of potential duplicates by configuring variables to indicate duplicates, enhancing review based on similarity scores.

Documentation

Secondly, we focus on the meticulous documentation and management of risks identified during the detection phase. This ensures that all actions taken are well-documented, fostering regulatory compliance and transparency across the organization.

Risk Assessment & Mitigation
Identify vulnerable areas, establish controls, and enhance detection capabilities to monitor evolving threats throughout the study.

Signal & Action Tracker
Assess and document issues, utilize automatic auditing, and leverage extensive data exporting capabilities.

CluePoints developed these features and functionalities, including Central Monitoring services, to ensure RBQM identifies and manages risks early, preserving clinical trial integrity. Our team configures and processes clinical and operational data, providing actionable insights to guide RBQM implementation, align strategies with FDA and ICH guidelines, and secure ongoing trial success through comprehensive SaaS support and expert data analysis.

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