FACT SHEET

Risk-Based Quality Management

Effectively plan and monitor clinical trials with IQVIA Technologies' configurable, SaaS-based solution that helps you mitigate risk and identify the "next best action." RBQM is part of IQVIA Technologies' Digital Trial Management Suite. Intuitive, Intelligent, and Interoperable, end to end trial quality, improving subject safety, data quality and operational efficiency, reducing trial risk and cost, and speeding time to market.

Challenges

As the complexity and size of clinical trials and regulatory requirements continue to increase, the standard approach to monitoring is no longer practical or acceptable. Traditional Monitoring is often not possible in today's pandemic world, and is time and labor intensive, representing as much as 50% of overall trial costs. Siloed and unstructured data from disparate sources make it difficult to identify trends, risks, and outliers early on, leading to concerns with subject safety and integration challenges for data management. This can result in increased costs, poor data quality, and a lack of actionable data that can further delay trials.

With subject safety at the forefront, and the connection of siloed, disparate systems hampering actionable insights, the industry is at an inflection point of change.

Have confidence in your RBQM solution

RBQM is part of IQVIA Technologies Orchestrated Clinical Trials, the end-to-end site and subject-centric Health Cloud platform that provides an unparalleled data infrastructure,ecosystem agnostic seamless connectivity and intuitive design to drive smarter, faster trials.

IQVIA Technologies RBQM solution automates planning and monitoring using IQVIA's vast and deep-rooted risk-based experience to reduce risk, while improving study quality, data flow, and subject safety. Utilizing Therapeutic and Indication aligned repositories of Trial and Protocol risks increases productivity and reduces inadvertent omissions in risk identification. Employing AI and ML, RBQM is engineered for flexible business models and has built-in predictive intelligence to proactively assess and prevent risks. Holistic reviews at trial, site, subject, regional and other levels conducted through Integrated Monitoring identify robust real-time trends and issues through automated alerts and data analytics allowing immediate remediation and prevention of further trial-related risks.

With intuitive automation and intelligent recommendations, the system provides transparency and insights so sponsors can improve data quality and integrity. Our intelligent application also automates content management and intelligent alert management.

REDUCES RISK AND COST

- **Intelligent** AI/ML-enhanced application for more robust and accurate data analysis
- **Intuitive and flexible** operational workflows for rapid, informed decisions
- **Interoperable** with IQVIA Technologies or 3rd party applications

IMPROVES STUDY QUALITY

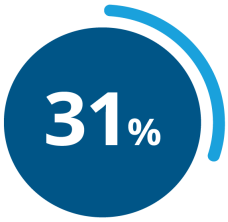
- Lowers error rate, reduces aged queries and missing pages with near real-time data entry and site communication
- Drives timely actions with advanced, real-time predictive and prescriptive analytics and interoperability with external systems
- Improves trial quality by leveraging current and historical data, identifying risk triggers and suggesting "next best action"

ENHANCES SUBJECT SAFETY

- Identify and resolve issues immediately at the trial, site, subject, country and other levels with predictive and advanced analytics
- Place focus on higher risk sites, data, events, and subjects with timely site communication and compliance
- Perform subject-level data reviews to identify trends and ensure medical accuracy and congruency

RBQM AND DTMS-ENABLED OUTCOMES

days faster to database lock vs. non-RBQM studies



less SDV backlog for RBQM studies vs. non-RBQM studies

reduction in subject visit data entry lag

Cost savings
Up to **25% cost savings** when compared to traditional monitoring

Improved subject safety
67% of queries resulted in data base updates, with **74% of these related to subject safety**

Discover how IQVIA Technologies Risk-Based Quality Management helps planners and monitors reduce costs, improve workflows, and increase accuracy for safer and more efficient trials.

IQVIA TECHNOLOGIES

LEARN MORE
iqvia.com/DTMS