White Paper

Artificial Intelligence and New Technology Adoption in Risk-Based Quality Management

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IQVIA TECHNOLOGIES

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Introduction

Risk-Based Quality Management (RBQM) has been evolving into a mainstream choice for the critical monitoring aspect of clinical trials.

This paper is the **second in a series of two papers** written by the same authors taking you through:

1) Right sized Risk-Based Quality Management Solution (RBQM) for your trials

Implementing RBQM from an operational standpoint – your journey through the early stages of RBQM, critical decisions to be made in identifying the right approach for your particular needs, de-risking your protocol, centralized monitoring, and more.

2) Artificial Intelligence (AI) and new technology adoption in Risk-Based Quality Management (RBQM)

Implementing RBQM from a technological standpoint – and on to implementation challenges and lessons learned, including data integration, and automation of processes using artificial intelligence and machine learning (AI/ML) with advanced and predictive analytics.

Leverage experts and technology for superior RBQM delivery

The alignment of RBQM experts and technology can improve data and study quality as a whole. Dedicated platforms from companies such as IQVIA cover the entire RBQM process, effectively making them a single solution for a company's RBQM needs. With built-in technological sophistication leveraging AI/ML and advanced analytics, these platforms drastically reduce human error and data integrity issues, and automated processes trigger faster corrective actions. It is important to understand more on how each component functions.

Data integration

Much has already been spoken of the importance of data integration in RBQM. It cannot, however, be overestimated how fundamental data mastering is when adopting a risk-based approach.

A common challenge in the realm of clinical trials is data that is spread across siloed systems with zero to minimal interoperability. Disconnected systems prevent centralized access to data and restrict efficiency in decision making and pose difficulty in scaling with progressing business needs.

Trial data captured separately in a disjointed manner prevents a cohesive view of subject data. To fully review the critical data at a subject level, monitoring teams must have access to a single data profile of the subject, sourced from a number of systems.

Orchestrated systems such as IQVIA's Clinical Data Analytics Suite (CDAS) provide an ideal solution for integrating disparate data (structured and unstructured) in near real-time, from various sources such as EDC, CTMS, clinical data repositories, eCOA, labs and others, while connections to additional proprietary systems can be built.

Automated workflows like those built into IQVIA's RBQM provide an optimal approach to real time risk management. They provide for greater transparency around the trial data, better KRI and trigger management and more efficient and compliant data flows that avoid manual errors and latency while maintaining strict data privacy controls. All this means less business risk, at a reduced cost.

RBM then leverages this data to run automated business logic, highlighting critical risks for the monitoring team to act upon. IQVIA's advanced analytics and reporting tools run on the orchestrated data and assist the monitoring team in taking optimal corrective and preventive actions.

This is vital for several metrics, such as protocol deviations. Having an orchestrated system ensures there is one common data warehouse for all deviations flowing in from various sources, allowing monitors and study teams to receive a holistic impression of the situation regarding site-level protocol deviation numbers or trends, allowing them to take the best possible actions.

IQVIA's Clinical Data Analytics Suite (CDAS)

Streamline the collection, standardization and analysis of clinical data from any source

Harness clinical research data

Streamline data collection from any source into a single ecosystem, and rapidly curate data for stakeholder use

Machine-augmented insights

Generate smarter insights by applying sophisticated ML analysis to subject data, risk management and more

Transform clinical outcomes

Embed data-driven intelligence in business workflows that automate manual tasks and empower stakeholders

CDAS enables customers to find greater insights into both the volume as well as variety of data across their organization. The design of CDAS allows its users to rapidly ingest their newly integrated data to glean insights from a wealth of sources simply and easily. This in turn enables better decision making and reduces ownership costs of R&D-focused operational and strategic business processes.

In short, this means that sponsors gain several valuable benefits from CDAS:

- **Faster database lock** with real-time and proactive data management
- **Shorter timeline** to deploy standard KPIs and KRIs for clinical trial oversight, and shortened development timelines and costs
- **Productivity improvements** due to intelligently automating data mapping processes
- **Less effort needed** in harmonizing data when introducing new sponsor-specific systems for data exchange

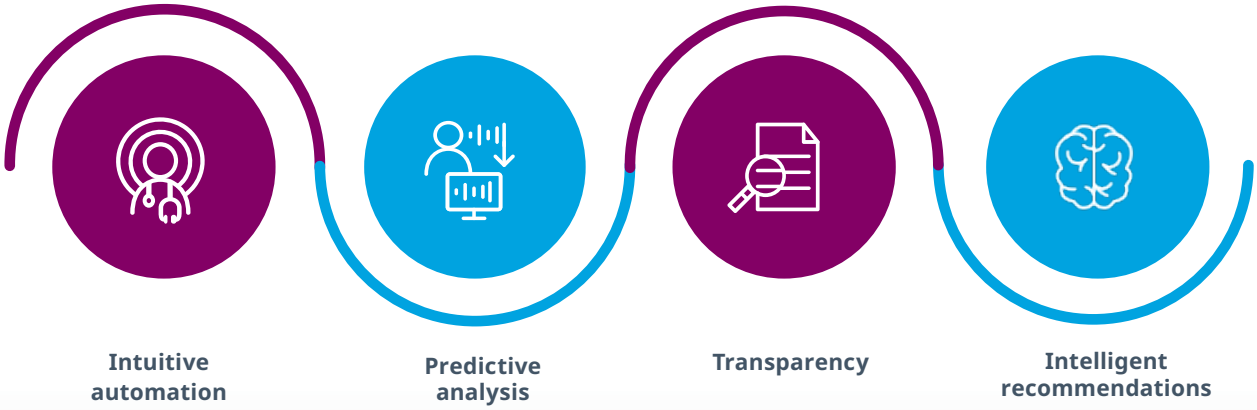
Automation

Building automation into clinical process workflows leads to quicker turnaround times. Automation aids in minimizing handoffs and streamlining workflows.

There are several potential areas of RBQM, which could be automated to enhance efficiencies and reduce timelines, including:

- **Creation of automated risk plans** by templatizing the process at a therapeutic area indication level, ensuring swifter study risk plan creation and approvals
- **Automated filing of approved risk plans** in eTMF, ascertaining regulatory compliance
- **Automated alerts** based on configurable thresholds and business logic, which helps central monitors focus their attention on truly critical risks
- **Automated action item creation** and assignment to specific role/persona based on risk type and severity

IQVIA's RBQM automation workflow



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Putting AI and ML to work for predictive analytics

The overall success of a RBQM application depends on its ability to highlight critical areas that require immediate attention. The effective techniques of AI and ML are a pharma company's best chance of rapidly achieving this goal, employing advanced algorithms and statistical models for faster and more informed decision making. AI/ML algorithms can be leveraged for risk mitigation of various kinds, such as:

- **Monitoring high-risk subjects** through detection of subject outliers
- **Identification of duplicate subjects** or fabricated subjects entered at the site using fraud detection algorithms
- **Study document quality tracking** and management in eTMF
- **Holistic site risk assessment** using composite risk indicators for identification and monitoring of high-risk sites

The true power of AI lies in its ability to proactively assess and highlight clinical risks as well as operational risks. AI/ML can help identify problems based on the large volumes of data gathered from previous studies. Deep learning algorithms can recognize patterns and associations within the data that are far beyond human capabilities to analyze and identify.

Predictive analytics leveraged in modern RBQM technology such as IQVIA's RBQM solution can help identify sites that are more likely to have recruitment and performance issues or highlight subjects that are at a higher risk of potential adverse events.

By facilitating advanced monitoring controls for high-risk subjects, and leveraging monitor data from various studies where similar issues have occurred, modern RBQM tools could suggest the necessary actions, which when taken by central monitors would lead to swift mitigation of projected risks. A robust set of dashboards and reports facilitate quick understanding of the identified risks and provide visibility into potential trends. Empowered by such insights, trial monitors can respond proactively to reduced risks and avert the problems that they would have otherwise had to correct reactively, after the problem occurred.

Improving central monitoring with AI and ML

Machine learning has shown remarkable outcomes in the world of central monitoring, especially in aspects of subject safety. When looking to improve the utility of central monitoring with ML, it is important to understand the data types that must be fed back into the algorithm to enhance its performance. Among these, the priority would be clinical data such as lab test results and vital signs assessments, that can help identify subject outliers, or site enrollment data, for decision making with regard to a company's overall strategy when targeting low-enrolling or high-enrolling sites, depending on where its focus is.

For ML to be truly effective, large volumes of coherent data are quintessential. The problem here lies in the sheer volume of data needed for training an ML model. Despite the increasing volume of data entering the sector, currently it can still be difficult for companies to take in the amount necessary to improve and train ML algorithms. Given this shortage of data, focusing on clinical data is key when discussing ML, as is looking to use ML capability to determine what can be done further with the information ML can provide.

CROs such as IQVIA can help with these data issues. IQVIA's fully integrated RBQM solution works with your data to vastly increase intake and fine tune ML algorithms. Their unique centralized monitoring solution, along with data orchestration, can help integrate and validate data efficiently. IQVIA also has an expert team who can assist with risk assessments, data surveillance, leveraging their predictive and advanced analytics reports, and dynamic monitoring of KRIs and triggers, both centralized and on site.

Among other benefits, working with a company like IQVIA can:

- **Integrate data from different streams**—for example, lab data, ECG, and biomarker data—to better identify potential site performance and patient safety issues
- **Highlight early subject** data issues
- **Provide optimal support** for any amount of scalability
- **Enhance site services** and CRA efficiency

An effective RBQM solution provides configurable monitoring constructs with the latitude to target all monitoring and oversight efforts toward the volume and value of the data.

With data-driven triggers and intelligent case management, IQVIA's RBQM solution elevates site level issues to a study or country level, drawing on the integrated CD/Ps, QTLs and KRIs to ensure the scale of issues are handled effectively. Each issue receives the necessary amount and level of scrutiny, resulting in the most optimal corrective and preventive actions that ensure the identified issue is mitigated and a similar issue does not repeat. The primary value drivers in terms of time savings are prevention of repeated issues leading to a reduced time to clean, lock and submit the data.

Conclusion

The new technologies entering the RBQM and risk management field have the potential to change and improve almost every aspect of RBQM.

Whether a company takes on the task of implementing their own RBQM strategies or works with a company like IQVIA to shoulder the task for them, there is a considerable benefit to be gained from initiating the change.

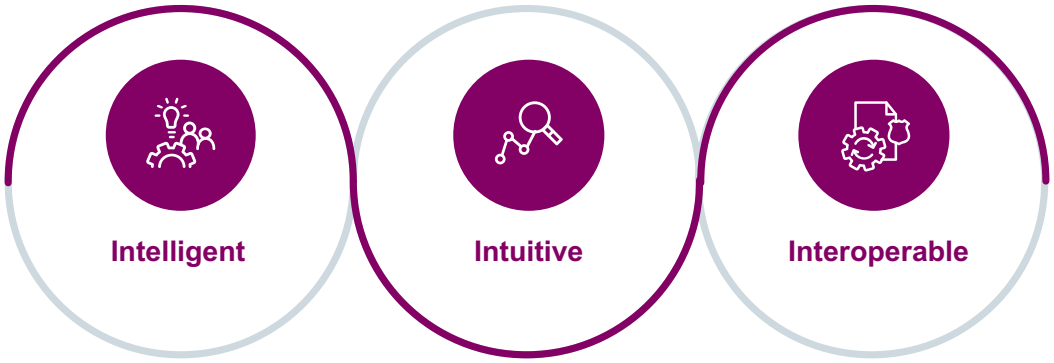
Even beyond new technologies, huge improvements can be made. Integrating centralized monitoring processes into the workflow means increased subject safety, increased data quality, more efficient on-site monitoring and easier prioritization of critical processes and inherent risks.

With newer technologies, RBQM's vast benefits are irrefutable. With tools such as IQVIA's, implementation of RBQM processes can transform businesses from a reactive, siloed, and inaccurate process to:

- **one that can predict risks** before they occur
- **reduce costs** many times over
- **fundamentally improve patient lives** every day

The technology is already here and waiting to transform risk management.

IQVIA's fully integrated RBQM solution



About IQVIA RBQM

As part of the Digital Trial Management Suite within IQVIA Technologies Orchestrated Clinical Trials (OCT) platform, RBQM helps manage patient risks efficiently. Our data driven algorithms and advanced analytics run on orchestrated data from various sources to enable faster, more informed decisions thereby enhancing patient safety. IQVIA Technologies RBQM is engineered for flexible business models and empowers Sponsors and CROs to risk-proof their clinical trials.

About IQVIA Technologies

IQVIA Technologies develops purpose-built solutions to enable life science organizations to orchestrate better outcomes across the entire product lifecycle. For more information about Orchestrated Clinical Trials, visit **www.iqvia.com/OCT**

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