How RBQM Fits into An AI World

Sophie Henderson, Senior Strategic Consultant at CluePoints, discusses how risk-based quality management (RBQM) can harness the power of artificial intelligence and advanced analytics to transform clinical trial execution and oversight.

Risk-based quality management (RBQM) is now widely recognised as crucial to improving data quality and clinical trial efficiency. Regulatory backing and increasing complexity are driving adoption and the RBQM market is expected to maintain a CAGR of 12% through 2033, reaching approximately $7 billion.[1] The percentage of clinical trials implementing RBQM elements by 2027 is expected to increase to 82% in planning and design, 81% in execution and monitoring and 79% in documentation and resolution.[2]

With the industry accepting the benefits of RBQM, now is the time to more effectively leverage the real-time data collected to support risk-based decision making and regulatory confidence. This requires us to harness artificial intelligence (AI)-powered technology and advanced analytics.

A Unified AI-powered Ecosystem

Creating a unified AI-powered ecosystem can redefine how clinical trial teams detect, act on and learn from data. This new era of RBQM incorporates central statistical monitoring (CSM) and harnesses new AI powered tools.

CSM applies statistical algorithms to identify outliers and discrepancies in clinical trial data. The investigation and documentation of identified issues can be simplified in AI-powered RBQM tools which provide root cause identification insights. These techniques support a more proactive data-driven form of RBQM. By integrating AI, sponsors gain deeper insight into deviations, site variability and emerging risks. Ultimately, this accelerates timelines and reduces oversight burden.

At the same time, integrating new tools with existing RBQM technology can extend the reach of AI-powered insights beyond central monitoring. For example, adaptive site monitoring tools can equip teams to decrease site visits, guide critical thinking for site monitoring and decrease manual data processing. Another area ripe for AI transformation is medical coding. For example, a deep learning-based medical coding model can guide researchers to the correct term in seconds, drastically reducing coding errors, creating resource efficiency gains and saving time across the study life cycle.

To maximise the impact of these advanced technologies and new tools, they should be combined with human intelligence. This includes effective change management and strategic problem solving that goes beyond the software itself, helping sponsors appropriately prioritise initial investments with a clear line of sight to value attainment.

Regulatory Backing

Centralised approaches, enabled by new technologies which leverage the power of statistical analytics, have received backing from regulators. ICH E6(R3)[3] expands on the concept of centralised monitoring and its ability to identify systemic or site-specific issues. This in turn has had an impact on industry approaches. Survey data presented at eClinical Forum found more than 44% of respondents were either piloting new processes or were already fully ICH E6(R3) compliant.[4]

FDA guidance states statistical and analytical methods which allow centralised monitoring of critical data may be "particularly advantageous"[5] The FDA also uses a central monitoring platform (CMP) to support its own regulatory oversight.[6]

As global regulators raise the bar, AI-powered technology and advanced analytics can empower sponsors and CROs to embed risk-based strategies into operations, ensuring readiness for what comes next.

Intelligent Risk Detection

Intelligent risk detection offers real-time oversight and actionable insights to empower clinical trial teams to navigate complexity successfully and make smarter decisions, faster. This includes the ability to resolve data issues and anomalies in critical areas like query detection and medical safety review.

Intelligent query detection (IQD) can automate data discrepancy detection using high-precision, specialised large language models (LLMs). By streamlining manual query detection throughout a clinical trial, IQD enhances efficiency, accuracy and consistency in query identification and resolution. This can reduce the manual workload for data managers, improving their oversight and allowing them to gain a more powerful voice in driving data quality and trial success.

Medical and safety reviewers have historically had to rely on manual processes to analyse patient data and safety outcomes from EHRs, lab results and other sources during clinical trials – methods prone to error and inefficiency. By contrast, an accurate, AI-powered process can rapidly identify common outliers, enhance query management with clear status updates and seamlessly integrate data review and query generation with automatic communication of queries to the source system via API.

Conclusion

Every trial is a race against time. By harnessing AI-powered technology and advanced analytics we can accelerate risk detection and course correction, helping teams succeed faster, fail smarter and focus resources where it matters most.

As ICH E6(R3) pushes a unified risk-based model, new technologies can simplify RBQM adoption, helping sponsors, CROs and regulators move from outdated methods to data-driven oversight. With sponsors also continuing to examine streamlining the integrated data review process, new technologies can streamline and simplify oversight and reconciliation across teams.

Extending outside of RBQM alone, new AI-driven technologies go beyond risk detection, operationalising analytics, empowering teams to make proactive decisions and helping to resolve issues before they escalate.

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