CASE STUDY

Simplifying and accelerating risk identification and assessment with Xcellerate® Risk-Based Quality Management

A KEY QUESTION

How can innovative technology improve the consistency and quality of clinical trial risk identification?

KEYWORDS Clinical Trial Risk, Risk-Based Quality Management (RBQM), Data Integrity

A large biopharmaceutical sponsor was seeking new ways to streamline processes and increase productivity by adopting digital automation tools. Based on their long-standing history collaborating with Fortrea, they asked the team to demonstrate how solutions in the Fortrea Intelligent Technology™ (FIT) suite could reduce effort and reduce costs across their portfolios.

This case study shares Fortrea's evaluation of how they could help the sponsor proactively manage trial risks and prioritize high-risk areas to reduce effort and costs across its portfolio.

Proactively managing trial risks with FIT's Xcellerate® RBQM

Clinical trial risk identification is often a manual process that requires teams to interpret protocols, search templates and reconcile lessons learned across functions.

The sponsor recognized that these inefficiencies could delay startup, create variability in how risks are captured and leave critical mitigations underspecified until later, when remediation costs were higher.

The sponsor asked Fortrea to evaluate the potential benefit of Xcellerate® RBQM, an AI-enabled solution designed to simplify and accelerate risk identification and assessment.

Enabling smarter risk management

As part of FIT, Xcellerate® RBQM uses natural language processing (NLP) and machine learning (ML) to analyze key study documents, such as protocol and related documentation and compares it to Fortrea's risk knowledge base to surface historically relevant patterns.

With this automated risk identification, Xcellerate® RBQM surfaces relevant risks and rationale-based risk suggestions. Teams can then choose suggested risks to adopt, which flow into the study's RBQM workflow for tracking, assignment and management.

Fortrea

Analysis: Calculating the effort and time of managing risk at study startup

	Baseline (without RBQM)	With RBQM
Number of protocol amendments per study[1]	3.3 amendments (with 76% of studies having one substantial amendment)	2.3 amendments (average reduction of one protocol amendment observed per study)
Relevant risks undetected	~40 potentially undetected risks	Avoided five major or critical Quality Events (QEs) and Corrective and Preventive Actions (CAPAs)
Effort required per major and critical deviation	220+ hours for the sponsor study team; 1,100+ hours for the Fortrea study team	Potentially saving ~1,320 hours per major and critical deviation

Fortrea analyzed how Xcellerate® RBQM supplements current risk identification methodology to reduce the time and effort required to reach a credible, consistent baseline risk set. With earlier, more structured risk conversations, the sponsor could potentially:

- Improve quality metrics and reduce protocol amendments
- Save $141K - $535K of direct costs per amendment[1] *
- Avoid protocol deviations and CAPA management
- Avoid a recruitment pause (~85 days) and the inconvenience of re-consenting patients[1]
- Proactively focus on patient safety and data integrity through earlier identification of risks

By demonstrating how Xcellerate® RBQM can result in faster startup and more efficient trial initiation across a portfolio, the sponsor requested an immediate rollout of Xcellerate® RBQM as part of Fortrea's Intelligent Technology™ ecosystem.

Fortrea Intelligent Technology™ helps deliver trials faster, with greater predictability, agility and quality.

LEARN MORE at fortrea.com

References

1. Getz K, Smith Z, Botto E, Murphy E, Dauchy A. New benchmarks on protocol amendment practices, trends and their impact on clinical trial performance. *Ther Innov Regul Sci.* 2024 May 58(3):539-548.

* The sponsor's cost savings were derived from the costs associated with the sponsor's rate card.

Fortrea