

Proactively recognizing and managing trial risks with Xcellerate® Central Monitoring



A KEY QUESTION



How can clinical study teams use an AI-powered centralized monitoring solution to help detect risk earlier and maintain timelines?

KEYWORDS

Adverse Event Reporting, Safety Assessment, Risk-Based Monitoring, Patient Recruitment, Quality Management

Clinical studies face several types of risks—spanning protocol adherence to data entry—that can extend study duration, delay database lock and postpone the availability of study results.

Learn how Fortrea has helped sponsors proactively manage risk with Xcellerate® Central Monitoring (XCM), keeping key timelines on track across the clinical trial lifecycle.

Enabling earlier detection of adverse event underreporting

Understanding the challenge: In a Phase IIa oncology clinical trial, Fortrea was conducting periodic reviews of key risk indicators as part of its central monitoring deliverables, but risk was unlikely to be identified manually at the site level.

Analyzing cross-site data to identify, track and mitigate emerging risks: With XCM's analytics and visualizations, Fortrea observed lower-than-average reporting of adverse events (AEs) and serious adverse events (SAEs) at one site.

The result: Working with the clinical research associate (CRA) and principal investigator (PI), the central monitor supported site staff to identify six AEs and one SAE at the next on-site visit. As part of this mitigation process, the CRA collaborated with site staff and the PI to reinforce critical safety assessment processes and data entry for AE/SAE reporting.

Identifying risks earlier with Xcellerate® Central Monitoring (XCM)

Fragmented systems and manual processes often hinder timely interventions when managing study risk. As part of the Fortrea Intelligent Technology™ (FIT) suite, XCM helps teams improve data integrity and compliance by providing AI-driven risk detection and near-real-time insights on inconsistencies or gaps.

By reducing manual effort associated with traditional central monitoring, XCM can help drive efficiency gains as teams improve data integrity and compliance.

Meeting challenging enrollment targets with risk-based monitoring

Understanding the challenge: A sponsor asked Fortrea to conduct two Phase III studies, which needed to recruit 1,400+ patients across 13 countries and 150+ sites in eight months.

Proactively managing monitoring visits with XCM:

Facing this aggressive timeline, Fortrea used XCM to monitor multiple aspects of the study, such as the amount of data, interval of site contact/visits and quality concerns. With this level of monitoring oversight, Fortrea enabled early identification and resolution of site issues and helped promote adherence to the protocol.

The result: Fortrea completed target enrollment two and a half months ahead of schedule in one study and one month ahead in the other, and also exceeded the originally planned enrollment per the sponsor's request.

Improving data quality by identifying site risks

Understanding the challenge: Fortrea was supporting a Phase III oncology study, which had a primary endpoint that required an invasive disease-free survival (IDFS) procedure. Drawing on lessons learned from running similar trials, Fortrea wanted to detect compliance issues as early as possible.

Identifying non-compliant sites and applying meaningful mitigation:

Using XCM, Fortrea developed a study-specific risk indicator to identify sites that hadn't completed the IDFS procedure per the schedule. Alongside these efforts, the team also performed active mitigation by offering a site staff retraining webinar, sending newsletters to reemphasize the critical processes and refreshing site-level documentation.

The result: By performing risk-based quality management through XCM and implementing quality-by-design strategies, Fortrea achieved a 144% improvement in compliance for critical processes/data collection.

Learn how Xcellerate® Central Monitoring helps improve data quality and reduce the risk of errors at every stage of the clinical trial lifecycle.

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