CASE STUDY

Simplifying and accelerating risk identification and assessment with Xcellerate® Central Monitoring

A KEY QUESTION

How can a real-time, AI-powered central monitoring solution improve data integrity, streamline decision-making and proactively manage trial quality?

KEYWORDS Clinical Trial Central Monitoring, Medical Review, Safety Data Review, Proactive Risk Management, Data Quality Assessment

Clinical trial oversight requires detecting data anomalies and safety risks early, yet study teams often face reactive processes and manual reviews when working across fragmented systems with limited visibility.

This case study shares three examples of how medical review teams have used Xcellerate® Central Monitoring (XCM) to identify discrepancies, highlight missing/inconsistent data and make timely interventions that help reduce risk and increase compliance.

Evaluating trends in treatment response

Understanding the challenge: Fortrea was supporting a respiratory study that used blood eosinophils as a biomarker to evaluate treatment response, but manually reviewing data from 3,600+ subjects would be time-consuming.

Efficiently delivering data-driven insights: Fortrea used XCM to evaluate blood eosinophil counts across multiple visits for thousands of subjects. Through this targeted review, XCM revealed that average eosinophil levels decreased slightly overall and dropped significantly at specific visits across all subgroups.

These insights generated by XCM would have been difficult to achieve in a tight timeframe with traditional monitoring. Based on these findings, Fortrea could confirm treatment effects on eosinophils and help the sponsor guide data-driven decisions during study evaluation.

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Improving data integrity through medical review

As part of the Fortrea Intelligent Technology™ (FIT) suite, XCM supports medical and safety data review. By accessing near-real-time insights and trends through XCM, medical monitors can:

- Conduct cohort-based analyses
- Perform subject- and site-level drill-downs
- Detect early safety signals using configurable, validated visualizations

Identified medical findings and anomalies are escalated into shared Xcellerate® workflows for risk and issue management, creating traceable documentation and coordinating actions to enable proactive safety oversight and confident, data-driven decision-making.

Reviewing subject safety and treatment efficacy

Understanding the challenge: Fortrea recognized that inconsistent adherence to protocol-defined management in an oncology clinical trial could compromise both subject safety and study drug exposure.

Assessing the use of prohibited medicines and study drug modifications: Using XCM, Fortrea medical data reviewers cross-checked 1,400+ subjects across 250+ sites and matched drug timelines.

XCM highlighted subjects who used prohibited drugs without dose changes, which triggered queries, highlighted protocol deviations and resulted in screen failures. As part of this comprehensive assessment, data for 99 subjects were amended.

Identifying and correcting missing data

Understanding the challenge: In a non-small cell lung cancer (NSCLC) study, a pulmonary function test (PFT) was used to inform dose modification in response to an Adverse Event of Special Interest (AESI). If data from this test were missing, Fortrea and the sponsor would be unable to assess patient safety and perform real-time risk assessment.

Detecting gaps in safety-critical data: Fortrea used XCM to determine that 126 visits did not report PFT data. Queries were sent to the sites regarding the missing data, along with follow-ups to resolve the issues. Sites were also retrained on the importance of accurate and timely EDC data entry. As a result, Fortrea helped increase data completeness to support accurate safety assessments.

Learn how Xcellerate® Central Monitoring transforms operational oversight into proactive quality management.

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