CASE STUDY

Fortrea Intelligent Technology: Advancing central monitoring and medical review with Xcellerate® Central Monitoring

A KEY QUESTION

How does Fortrea Intelligent Technology help detect risks early, improve data quality and help prevent protocol deviations across clinical trials?

KEYWORDS Data Quality, Data Management, Compliance, Safety, Central Monitoring, Medical Review

Case studies

Clinical trial oversight requires early detection of data anomalies and safety risks to enable timely interventions and improve data integrity. However, clinical trial monitors often encounter fragmented systems and manual reviews, which can increase operational complexity and introduce compliance risks.

To demonstrate how central monitors can manage trial quality and make informed decisions, these case studies share the role of Fortrea Intelligent Technology (FIT).

Improving data quality in a Phase III breast cancer study

Understanding the challenge: Fortrea was providing central monitoring for a Phase III Disease-Free Survival (IDFS)/Recurrence Assessment procedure.

Based on their experience with similar studies, Fortrea sought to avoid the risk of low compliance, which had typically been observed during database lock (DBL) efforts in similar trials.

Proactively mitigating risk: Using Fortrea Intelligent Technology, Fortrea central monitors developed a study-specific risk indicator to identify sites that did not complete the procedure per the protocol schedule. They also drove process change from the source by delivering retraining webinars to site staff, creating newsletters to re-emphasize the procedure and refreshing site documentation.

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Improving compliance: As a result of these efforts, Fortrea achieved a 144% improvement in compliance for critical processes and data collection, demonstrating the potential effectiveness of integrated quality-by-design and risk-based monitoring with Fortrea Intelligent Technology.

Reviewing and correcting adverse event reporting

Understanding the challenge: Adverse events (AEs), serious adverse events (SAEs) and adverse events of special interest (AESI) are critical elements of clinical trial safety monitoring, enabling the early identification of potential safety signals to support patient safety, effectively manage risks and help sponsors characterize the safety profile of a study drug.

Fortrea's Medical Monitors and Centralized Medical Data Review (CMR) team have provided meticulous oversight of participant data in several studies.

In an oncology trial, Fortrea's Centralized Medical Data Review (CMR) team examined 290 adverse events (AEs) across 28 participants. The team found 24 issues affecting 11 individuals and initiated queries in the Electronic Data Capture (EDC) system, collaborating closely with the principal investigator and Clinical Operations. As a result of these efforts, 8% of the previously reported AEs were confirmed as AESIs.

Identifying potential underreporting of AE/SAEs: In a Phase IIa oncology clinical trial, the Fortrea team used Fortrea Intelligent Technology to compare the number of adverse event reports at each site. Sites with lower-than-average AE/SAE reporting were identified and triggered further analysis by the central monitor, who worked with CRAs to share safetydata reporting requirements and engage principal investigators (PIs) on process improvement. In addition, targeted source data review (SDR) was scheduled for the next onsite visits to identify potential underreported AEs. As a result of the proactive steps, six AEs and one SAE were identified, reported and tracked by site staff.

Recognizing the benefits: In this case, the medical monitor, Centralized Medical Data Review and central monitors played a key role in ensuring that the study's AEs and AESIs were accurately reported in accordance with study protocols.

The supporting role of Fortrea Intelligent Technology

With FIT, AEs/AESI can be filtered out by the serious/non-serious events, relations to trial products, severity and action taken with the study drug.

Medical reviewers can use summary tables to view a dataset's status in the study and support quantitative analysis.

FIT also allows users to select subjects for each type of adverse event to further analyze the data at the subject level, as needed, to review labs/vitals and the patient profile.

With sharing and reporting capabilities, FIT creates an audit trail and can escalate issues to a tracking system. Together, these FIT tools help enable thorough query follow-up and support high-quality clinical trial data.

Identifying and avoiding protocol deviations

Understanding the challenge: Following a clinical trial protocol is crucial for supporting data integrity, patient safety and regulatory compliance. However, human error or operational issues may result in protocol deviation/violation and affect the resulting data analysis.

Understanding the importance of early detection of protocol deviations, Fortrea has employed Fortrea Intelligent Technology.

Identifying prohibited medications: In an Acute Myeloid Leukemia study, the use of a prohibited medicine by a substantial number of trial patients could impact the study outcome. Fortrea reviewed 747 concomitant medications to identify potential prohibited medications. They found 14 issues, three of which were confirmed as major protocol deviations. In follow-up with sites, they then confirmed that the patients were no longer receiving these medications.

Avoiding protocol deviations: After migrating a case report form (CFR), the study treatment dosage was mistakenly updated, which would lead to safety issues and major protocol deviations. The Centralized Medical Data Review identified this issue and raised queries to CRAs and clinical trial operation teams. As a result, all doses were updated, and more than 350 queries related to protocol deviations were avoided.

Recognizing the benefits: A strong collaboration between the lead physicians and Centralized Medical Data Review, CRAs and clinical trial operations helped support protocol alignment across the study.

With the support of Fortrea Intelligent Technology tools, clinical trial management and medical monitoring teams can detect critical issues such as protocol deviations and safety signals early, which can reduce the burden on sites and help focus resources where needed to support integrity and compliance.

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