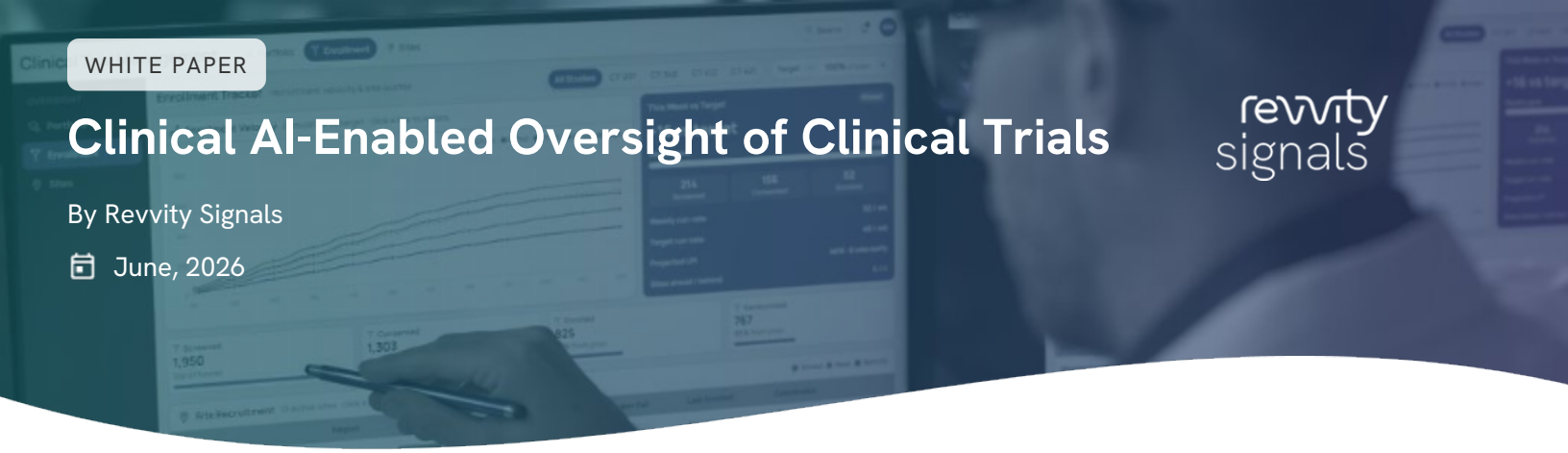

WHITE PAPER

Clinical AI-Enabled Oversight of Clinical Trials

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June, 2026

Introduction

Clinical trials today generate data from more sources, across more stakeholders than ever before. At the same time, regulatory expectations for data integrity, traceability, and documented decision-making have increased. Yet many organizations still rely on fragmented workflows, manual listings, and delayed review processes. More integrated, data-driven approaches to clinical oversight can support more timely, reliable, and inspection-ready decision-making.

New Challenges of Trial Oversight

Many of the challenges of clinical trial oversight today stem from the increasing sophistication of studies. Today's multi-arm, multi-vendor, global studies routinely involve multiple data streams, such as electronic data capture (EDC), imaging, multi-omics studies, lab results, electronic clinical outcome assessments (eCOA), and clinical trial operational systems. Adding to the complexity, these data streams involve multiple stakeholders, including teams at dispersed clinical trial sites, clinical research organizations (CROs), and other global partners. And with accelerated timelines, trial teams are racing against the clock.

While managing the growing volume and intricacy of clinical trial data is challenging enough, regulatory expectations have also become more rigorous. The ICH Guideline for Good Clinical Practice, E6(R3), which reached Step 4 on January 6, 2025, emphasizes fit-for-purpose systems and processes, data integrity, traceability, and documented oversight to support evaluation of trial conduct and decision-making. These expectations reflect a broader shift toward risk-based, proportionate oversight, where organizations must demonstrate not only that oversight occurred, but also how and why decisions were made.

Unfortunately, many organizations continue to rely on old, fragmented methods of handling clinical trial data. In these structures, review processes are fragmented—across medical, data management, and operational teams, each working with different tools and different objectives, delaying insights and making it difficult to coordinate responses to emerging risks. And because these review activities are disconnected from a trial's central workflow, where decisions are being made that influence the study, it is nearly impossible to reconstruct the decision-making process later—such as during an inspection.

This situation exposes drug sponsors to both operational and regulatory risk.

The Danger of Trial Complexity Outpacing Oversight

Real-world cases have shown how increasing trial complexity and fragmented oversight can undermine study execution.

In a multi-arm Phase IIb/III trial conducted across multiple CROs and vendors, vital aspects of protocol logic were implemented outside the drug sponsor's controlled systems. Relying on outside partners and CROs to help conduct trials is common. The fatal flaw, in this case, was the lack of a single system to capture all decisions, resulting in programming errors in randomization and dosing sequences. These errors went undetected until confounding signals began to emerge. By the time the problems were identified, it was too late; the errors had already impacted the integrity of the study data. The sponsor's reactive efforts to audit the data midstream did little more than produce uncertainty around data confidence and decision making.

As a result, this late-stage clinical trial failed to meet its endpoint, and market confidence in the company was materially impacted. If trial data management had been centralized, with timely oversight by the drug sponsor, anomalies in the execution of these basic components of the trial could have been identified and resolved much earlier, before they adversely affected study outcomes.

Timely Access to Clinical Data, Faster Collaboration, and Automated Recordkeeping

Managing modern clinical trials effectively, in alignment with more stringent regulatory guidelines, requires a fundamental shift in how oversight is managed. At the core of this transformation is the need to provide all stakeholders with timely access to clinical data and tools to analyze the data quickly.

A unified technology solution for clinical data review and oversight supports workflows across different roles and empowers trial managers to interact with data in real-time. For example, visual analytics can help a medical monitor review live safety data and immediately flag potential issues to other members of the team. These issues are then visible to data managers, who can review the underlying data to submit or manage an EDC query, all without leaving the unified system.

As team members perform their individual tasks, every step and decision is automatically documented, creating a complete and traceable record of actions taken and the final resolution. This automation eliminates the need for manual data exports and reconciliation, ensuring that review activities remain within the centralized review environment. As a result, organizations can achieve faster issue resolution while maintaining the level of documentation required for regulatory compliance.

The Role of AI in Clinical Oversight

Within the context of a unified clinical data review and oversight environment, AI capabilities provide additional power to help strengthen clinical oversight. Importantly, the role of AI is not to replace human decision-making, but to augment it.

Improving Analytical Efficiency

An example of the benefit of leveraging AI is the shift in how custom listings are generated. Traditionally, custom listings require extensive programming and quality control, often taking weeks or months to produce. With AI-powered self-service analytics and role-based access, users can generate listings instantly using natural language queries. With this capability, trial managers can engage in an iterative process, querying the available data fully and getting answers in moments, rather than months.

Flagging Errors, Omissions, and Anomalies

Another valuable assist provided by AI in clinical trial management is its ability to detect hidden signals and insights from the vast data troves that human eyes might otherwise miss. AI can proactively identify risks and issues that need immediate attention before they escalate.

For example, AI can more easily detect data errors and anomalies. When a trial manager examines data in a spreadsheet, columns of data can easily blur together. But AI reviews every piece of granular data and can spot errors easily—such as a patient listed as an implausible value, inconsistent data sequence, or other outlier—as part of its regular review. This ability to quickly identify data outliers allows trial managers to react appropriately.

In addition to flagging errors, AI can also identify gaps in documentation, such as missing informed consent records, which is a critical issue both from a regulatory and ethical standpoint. By identifying such omissions early, organizations can address them proactively, reducing both operational and regulatory risk.

Differences Between Generic AI and AI Built for Clinical Workflows

For any application, especially one as data-rich and complex as a clinical trial, AI applications need to be purpose-built. Public chatbots and other large language models (LLMs) trained on broad data sets lack the domain specificity needed to enable efficient and traceable research workflows.

AI systems designed specifically for clinical workflows operate within a controlled environment, using a curated and validated data set. These systems are built to efficiently unify and analyze clinical trial data and are grounded in the daily data streams generated in clinical research. When a user asks a question, the purpose-built AI does not invent an answer or approximate. Instead, it works exclusively with the available study data, generating a precise query that returns a verifiable answer derived directly from the underlying clinical research data.

This controlled performance is vital for meeting regulatory requirements. ICH E6(R3) states that systems and processes used in clinical trials should be fit for purpose and that records should preserve integrity and traceability. Purpose-built clinical AI systems are designed to meet these requirements to produce the data and documentation needed by both sponsors and regulators.

The Value Proposition of an AI-Enabled System

The adoption of AI-enabled oversight, within a centralized clinical data management solution, brings operational, risk-management, and compliance benefits. This type of system reduces the risk of errors and improves the integrity of trial data. It also enables faster and more confident decision-making by providing timely access to high-quality data and insights.

AI-enabled systems also streamline workflows and enhance collaboration across clinical trial teams, facilitating data sharing while ensuring role-based access. By integrating data and processes into a single environment, drug sponsors can improve coordination of activities to build more efficient studies that cost less to run, while allowing companies to bring drugs to market faster.

Conclusion

Clinical trial oversight is undergoing a profound transformation. As trials become more complex and regulatory expectations continue to evolve, traditional approaches based on fragmented workflows and manual processes are no longer sufficient.

Fortunately, these challenges can be addressed by implementing a centralized clinical data management system enhanced with governed AI capabilities, such as Signals Clinical from Revvity Signals. By centralizing data management, facilitating role-based collaboration, accelerating analytics, and leveraging AI to augment human capabilities, an AI-enabled unified data management solution reduces risk and enables more timely, integrated, and reliable decision-making.

Importantly, these capabilities, including automated recordkeeping, help sponsors meet current regulatory expectations, as outlined in ICH E6(R3), for risk-based oversight, sponsor

accountability, complete documentation, and the ability to reconstruct decisions made during a clinical trial.

With a unified system like Signals Clinical, sponsors improve operational performance while ensuring the real-time, proportionate, and continuously documented oversight of clinical trials needed to support regulatory expectations and inspection readiness.

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