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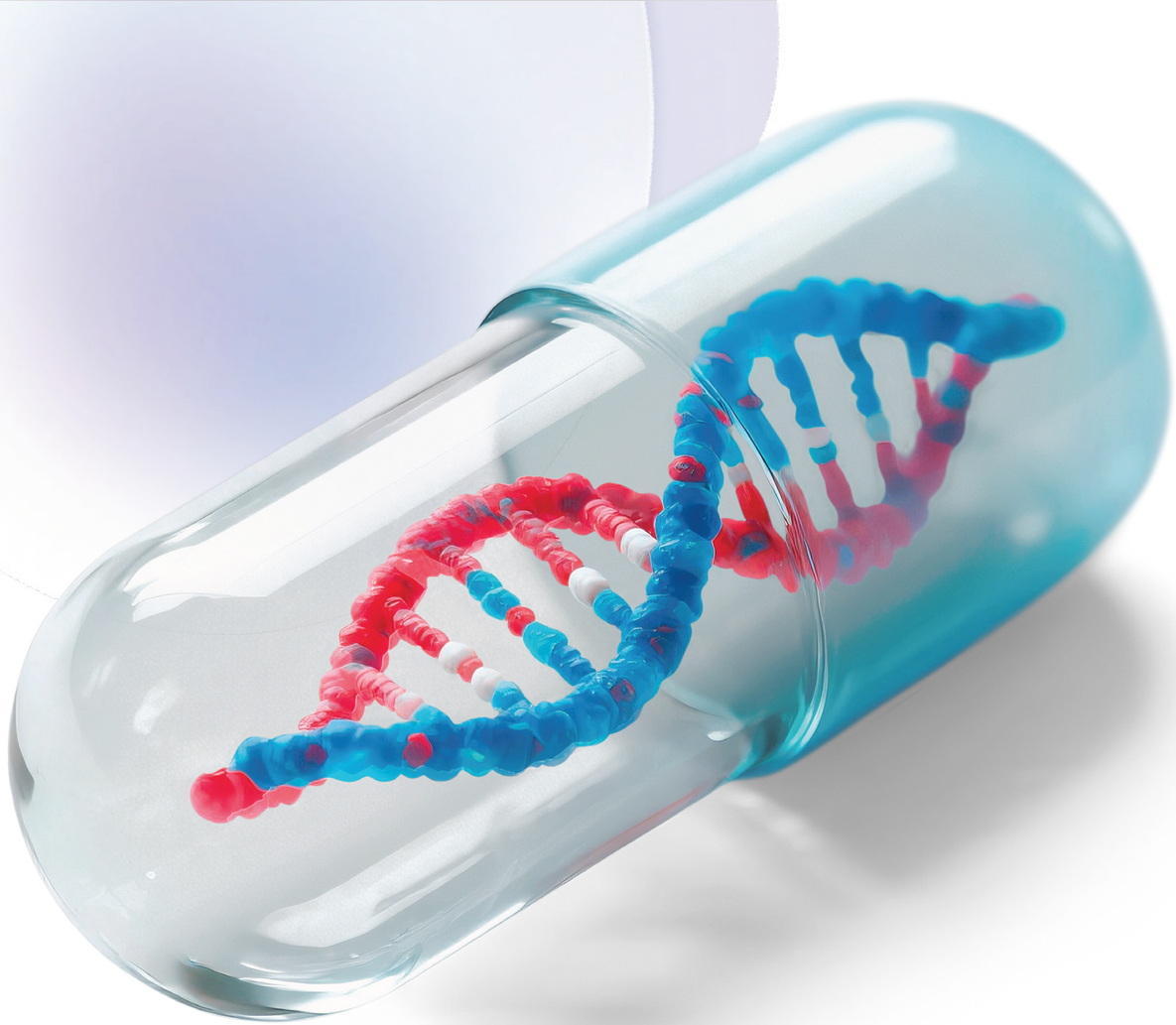
Real-Time Clinical Data Insights Delivered by Automation and AI



WHITE PAPER

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As clinical trials generate ever-larger and more complex datasets, drug sponsors must adopt automated data handling and artificial intelligence solutions to gain real-time insights while meeting tightening regulatory demands. Recent updates to global good clinical practice (GCP) standards, notably ICH E6(R3), require continuous, traceable data oversight and sponsor accountability. Novel solutions, such as Signals Clinical™ from Revvity Signals, can unify disparate data, enable AI-driven monitoring, and ensure complianceready audit trails to accelerate drug development.

Regulatory Environment and Impact on Clinical Trials

Over the past three decades, clinical trials have become increasingly global. Now, it is common for studies to be conducted in multiple countries to recruit the targeted patient enrollment. Today's regulatory guidelines increasingly reflect this evolution, but this was not always the case. In the early 1990s, pharmaceutical sponsors faced a hodgepodge of regulations related to drug approvals in the United States, Europe, and Japan. In 1996, however, the ICH E6 guideline on Good Clinical Practice was finalized, with the goal of bringing order to this fragmentation. The guideline significantly harmonized requirements across multiple regulatory bodies, allowing pharmaceutical sponsors to operate trials more efficiently, with clear guidelines for the design and conduct of trials, as well as monitoring and data standards.

For nearly 20 years, ICH E6 provided the foundational regulatory framework for clinical trials worldwide. However, as technologies began to play an increasing role in clinical studies, the guideline began to lose relevance. In the 1990s and early 2000s, most trials were still site-centric. Data volumes, by today's standards, were small, and many processes related to data collection and trial monitoring were paper-based and managed manually. But by the beginning of the last decade, as trials became multisite, global projects with increasingly large datasets, it became clear that new regulatory guidelines were needed. The result was the first major modernization of GCP standards in 2016, with ICH E6(R2). This revision was not a wholesale change; rather it was adopted as an addendum to the original ICH E6 document, seeking to maintain the original framework of the guideline while modernizing expectations around trial oversight.

Important changes in this revision included a shift to risk-based monitoring of trials to ensure patient safety and data integrity; updated guidance on trial quality that focused on proactive risk management; clearer language on expectations for sponsor oversight of clinical research organizations (CROs) and technology vendors; and recognition of the shift toward centralized trial monitoring and electronic data capture (EDC) methods that leverage emerging technologies.

E6(R2) was an important recognition of the evolution from the paper- and PDF-based era to electronic data collection and management. However, because E6(R2) still leaned on the original guidance, many drug sponsors struggled to understand how compliance would be assessed within the emerging digital clinical trial ecosystem.

ICH E6(R3)—Built for Modern Clinical Trials

This time, however, the industry would not need to wait another two decades for an update: In 2024, ICH E6(R3) was finalized. Unlike E6(R2), this is not an incremental revision. Rather, it represents a significant rethinking that recognizes the value of data capture technologies in managing the volume and velocity of clinical trials data as well as the increasing role artificial intelligence can play to inform the quality and safety of modern trials.

ICH E6(R3) clarifies that sponsors must be able to show how decisions are made, reviewed, and documented across the full trial lifecycle. This expectation aligns with existing FDA requirements under 21 CFR Part 312 (sponsor responsibilities) and Part 11 (electronic records). This modernization in ICH E6(R3) explicitly spells out that trial oversight of data must be continuous and traceable.

Importantly, despite the reliance in trials on CROs and other technology partners, Annex 1 of ICH E6(R3) is an inflection point: It makes sponsors explicitly accountable by requiring independent, real-time review of trial data and decisions. Oversight can no longer be delegated to CROs with only periodic checks. Sponsors must now independently review data and decisions throughout a trial's lifecycle. Every material decision made within the context of a study must be supported by an ALCOA+ (attributable, legible, contemporaneous, original, and accurate)-compliant audit trail that documents who reviewed the data, when the review occurred, and the reasoning behind specific actions. The old model of manual reviews, static listings, and spreadsheet-driven workflows cannot meet this standard.

Annex 2 builds on Annex 1 by emphasizing centralized monitoring and multisource governance. Sponsors are expected to unify data from EDC systems, external vendors, digital health technologies, and other datasets into a coherent oversight model. Review is expected to be continuous and analytics-driven, replacing the old model of episodic review. Annex 3 extends these principles to new decentralized, hybrid, and data-rich trial designs. These expectations are now the new normal for clinical trials.

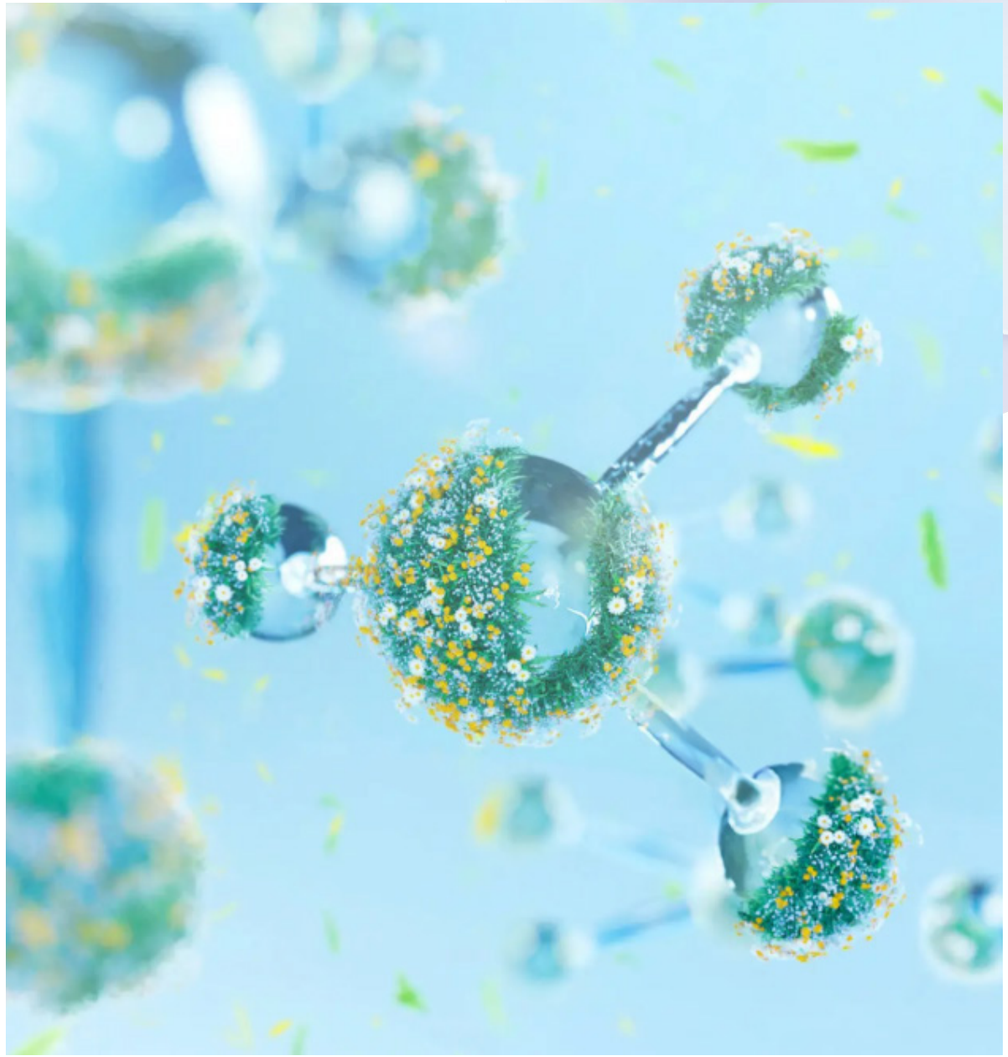
Complying with Updated Regulations

To comply with the requirements of ICH E6(R3), sponsors need solutions that can efficiently automate data collection while providing an airtight audit trail. Signals Clinical from Revvity Signals supports this regulatory shift by providing analysis-ready data and integrated review workflows to provide continuous oversight without adding work or headcount. By bringing clinical, operational, and external data together in a single environment, the solution allows sponsors to review data in real time, rather than waiting for answers from programmed queries. This capability shortens review cycles, reduces queues, and allows any issues to be identified earlier, when they are easier to address.

Signals Clinical supports audit readiness by embedding traceability directly into how clinical data reviews are performed. The platform captures review actions, decisions, and supporting context within the workflow, helping teams maintain data integrity consistent with ALCOA+ principles. These capabilities align with ICH E6(R3) expectations for data governance, metadata, and audit trails, and support FDA expectations for secure, traceable electronic records and audit trails under 21 CFR Part 11, as well as sponsor oversight responsibilities described in 21 CFR Part 312.

A Clinical Trials Roadmap

In many ways, ICH E6(R3) does more than establish the regulatory framework for modern clinical trials. It provides a roadmap for pharmaceutical sponsors looking to take advantage of advances in data capture and management, while leveraging data insights derived from large



language models (LLMs) and other forms of AI. Together these technologies can provide active monitoring and risk-based quality management by flagging important tasks, allowing sponsors to focus their attention on high-priority action items.

In the past, clinical trials could easily get bogged down by the time- and laborintensive processes of accessing, unifying, and mapping data from various sources. Given the volume and complexity of data in modern clinical trials, leveraging technology that can collect data from multiple sources, accurately map it, and make it available in real-time is now essential for success.

Automated Data Collection and Mapping

It is vitally important to understand, however, that the primary role of any technology designed to improve the efficiency of clinical trials management is to facilitate the work of the entire ecosystem of people tasked with ensuring a trial's success. Signals Clinical's rolebased access ensures that all members of the team, whether data managers, medical monitors, or trial-site managers, have all the appropriate and relevant data needed to perform their jobs efficiently and collaborate seamlessly.

A core capability for any clinical trial management system is its ability to automate the mapping of data from disparate EDC systems and other data sources to provide it in a standard format for downstream analysis by the trials team. While the automation of ingesting and mapping the data eliminates the hands-on work of the past, it retains a human-in-the loop who can either approve suggested mapping or manually adjust it, as needed, before releasing it to the solution. It's a best-of-both-worlds scenario: Timeconsuming manual mapping is now automated and completed in a fraction of the time, while human experts working in the trial leverage their knowledge and skills to ensure that the mapping is accurate and provides the vital data needed to propel a clinical study.

In addition, developing a consistent and repeatable method for ingesting and unifying disparate datasets can provide value beyond its worth; this is true even in a single trial, but the benefits are amplified when applied to multiple studies. Manual mapping is prone to errors as well as inconsistent structure and formatting from one study to the next. By establishing a proven format for data mapping, data from past studies can be reused to inform new clinical trials and begin to eliminate the age-old lament of pharmaceutical company executives that data of value to the enterprise was locked away in separate silos.

Now, with consistent, automated mapping, sponsors can extract full value from their in-house data stores.

Adding Value to Data via AI

The standardization of data is even more important in the age of artificial intelligence (AI) and its ability to nimbly query clinical trial data in near real time. If manual data mapping has been a bottleneck to fast and efficient trials in the past, querying data within a trial to unlock insights about how a drug is performing has often been a brick wall. Trial managers looking to answer a particular question needed to ask an internal programmer to write taskspecific code to extract information from the collected data, a process that could take weeks. If the answer to the original question suggested another question, the process would start all over again, slowing the trial to a crawl.

In today's clinical trials, however, large language models (LLMs) allow data managers and medical monitors to query the latest data to search for drug efficacy, how well a specific trial site is performing, or to uncover data on adverse events via a simple prompt such as "show me all serious adverse events missing a start or end date." Importantly, iterative queries of the data can be conducted on the fly, freeing data managers from writing

code for each query to instead focus on data interpretation and development of actionable information to speed the trial.

But as with data mapping, the use of AI and LLMs to develop data insights in Signals Clinical is governed by a human. All queries are transparent and identify the data used, allowing users to drill down, to the line level if needed, to better understand what the data is telling them. Everything needs to be verified, and if a person reviewing data finds an error such as a misspelling, an ambiguous term, or a mapping that might be slightly out of line, the reviewer can correct it immediately. While the speed of automating data mapping and allowing LLMs to query the data are vital to powering efficient clinical trials, enabling human reviewers to continuously examine that data at hand ensures that speed never comes at the expense of accuracy.

In this way, the automated data mapping, and data queries via LLMs enabled by Signals Clinical are not about replacing expertise, but rather about amplifying it. AI handles the repetitive, mechanical steps of locating and assembling data, while humans validate, interpret, and make decisions based on it. The result is a faster, more consistent, and more trustworthy data review process that produces compliance-ready records as required by regulatory bodies.

Security and Data Privacy

In clinical research, data privacy and regulatory compliance are not optional. Signals Clinical was built with enterprise-grade security and compliance as a baseline. From a compliance standpoint, the solution aligns with SOC 2, ISO 27001 standards, and FDA 21 CFR Part 11 requirements. These frameworks govern how systems are built, how data is handled, and how access is controlled. They also provide roadmaps for audit trails, electronic records, and electronic signatures to govern how AI is leveraged in a study's workflow.

Data segregation is also crucial. In Signals Clinical, data is isolated by customer and by study, ensuring that AI models only operate on the data they are explicitly authorized to access. Unlike general-purpose chatbots that may rely on broad training data or probabilistic guesses, the LLM capabilities in Signals Clinical are constrained to the user's specific clinical dataset as defined by their persona, or role within the study. These constraints reduce the risk of unintended data leakage.

Empowering and Unifying the Clinical Trial Team

A clinical trial only performs well if clinical trials teams have control of the data, tools to query the data to monitor progress, and the ability to seamlessly communicate with each other in real time. Organizations can meet these needs by deploying a modern clinical data management solution, like Signals Clinical, that unifies disparate data and harnesses AI capabilities.

ICH E6(R3), which aligns with FDA requirements under 21 CFR Part 312 and Part 11, embraces the use of AI while clarifying the responsibility of drug sponsors to ensure data integrity and the highest levels of data security. Within this framework, Signals Clinical accelerates data management via advanced AI and analytic tools while facilitating regulatory compliance by building traceability into data review and ensuring a human-in-the-loop.

At the same time, the solution enables seamless collaboration across the globe. Whether clinical teams are in Europe, Asia, or the United States, they can work together as if they are all in the same room, ensuring swift decision making and more efficient management for clinical studies.

Learn more

To learn how Signals Clinical can help power your clinical studies and provide traceable, compliance-ready data aligned with current regulatory frameworks, visit our website.

https://revvitysignals.com/products/clinical-development/signals-clinical

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