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Navigating the Post-Capture Era of Clinical Trials

WHITE PAPER

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by AG Mednet

From Data Capture to Data Liberation

The evolution of data management in clinical trials has been profound. In a matter of decades, clinical research has shifted from paper-based systems to electronic data capture (EDC), representing a monumental leap forward. With this shift, clinical trials have benefited from a wealth of improvements, including accurate reporting, reduced double data entry, and faster data collection. Moving from handwritten forms to electronic submissions introduced efficiencies that were once thought impossible, allowing clinical trials to operate with far greater precision and speed.

However, while this shift marked a significant advancement, it also introduced a new challenge. The very systems that captured this critical data have, in many ways, held it captive. Once data is collected, it is often locked within the electronic systems designed to house it, with limited capacity for stakeholders to access, aggregate, or enhance it in real time across multiple systems. This limitation has created a bottleneck in the decision-making process for clinical trials, restricting the potential for data to truly drive outcomes.

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The Prison of Data Capture Systems

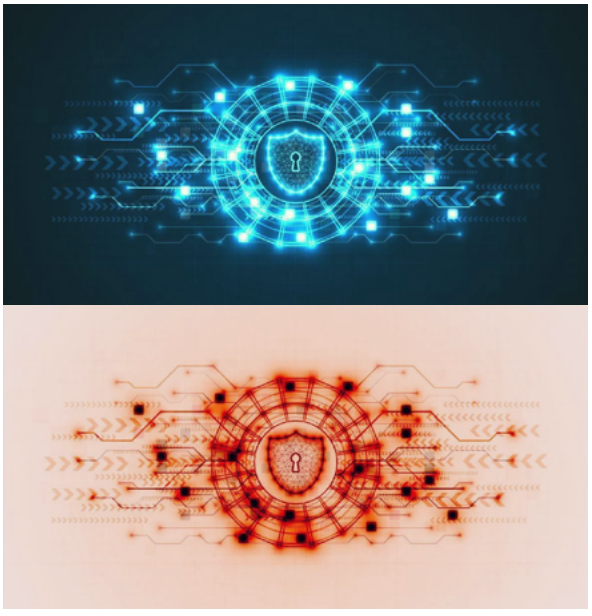
When we transitioned from paper to electronic forms, we gained the ability to capture and store data in structured formats that could be easily accessed within their own systems. However, this shift also meant that data became compartmentalized. Each system in the clinical trial ecosystem—whether it's an EDC system, Clinical Trial Management System (CTMS), eCOA, or ePRO—plays a specific role, but they each operate largely in isolation. While these systems do their jobs well, the data they capture often remains confined to those specific environments.

Even in cases where a single platform offers multiple modules (e.g., EDC, eCOA, ePRO) within one system, the workflows are still typically designed to focus on data capture rather than supporting the full life cycle of trial processes. These "all-in-one" systems may seem like an answer at first glance, but they remain capture-centric—focused on the input, storage, and reporting of data—rather than facilitating how that data is utilized, enriched, and moved through decision-making pathways.

Quantifying the Opportunity Cost of Captured Data

The cost of relying solely on capture-centric systems goes beyond operational inefficiency—it has direct financial implications. On average, a single day's delay in a clinical trial can cost anywhere from $40,000 to $500,000 , depending on the phase of the trial and the therapeutic area. Trials that rely on fragmented or siloed data systems are more prone to bottlenecks, delays, and errors in decision-making, which can easily compound over time.

By not liberating data through workflows that facilitate real-time collaboration and decision-making, organizations risk costly delays in key trial processes, such as adverse event adjudication, patient eligibility determination, and data analysis. In aggregate, these delays can stretch trials out by weeks or even months, inflating costs by millions of dollars. Furthermore, the longer a trial takes, the later a drug or treatment reaches the market, extending the time it takes for patients to access potentially life-saving therapies and for companies to generate revenue.



Unlocking and Navigating Data Capture Systems

Beyond the direct financial burden, there's also the potential for reduced trial quality and increased regulatory scrutiny. Without an organized, workflow-driven approach to aggregating and enhancing trial data, errors can occur that compromise the integrity of the trial. The cost of addressing these errors—whether through additional investigations, regulatory delays, or even trial restarts—further inflates the opportunity cost of not adopting a data-liberation approach.

The Post-Capture Era: Liberating Data Through Workflow Management

We are now entering the post-capture era of clinical trials, where the focus is no longer solely on gathering data but on liberating it. This next phase is defined by the ability to take the data captured in multiple systems—whether from one platform or several—and use it effectively. However, the solution goes beyond mere access—it's about organizing that access through structured workflows that ensure collaboration and process efficiency.

The future of clinical trials depends not only on integrating data from various systems but on channeling it through predefined workflows that are designed specifically for each trial. These workflows enable stakeholders to aggregate, enhance, and analyze the data, applying quality control and decision-making processes in a structured, step-by-step fashion. By defining these workflows upfront, each process in a clinical trial—whether it's adverse event adjudication, patient eligibility, or final analysis—can proceed with clear direction, ensuring that data flows smoothly from one stage to the next.

The Power of Workflow in Clinical Trials

Workflow management transforms captured data from something static into something actionable. It enables people—not just systems—to engage with the data at the right time, adding context, insights, and adjustments as needed. This means that data is not only aggregated from multiple sources but also enhanced and analyzed in ways that lead to real-world outcomes. By guiding the data through defined, trial-specific workflows, stakeholders are empowered to make informed decisions that directly influence the success of the trial.

This approach goes beyond the capture-centric workflows of traditional systems or all-in-one platforms. Instead of focusing merely on collecting data, these workflows are designed to channel the data toward decision-making, quality control, and collaboration. It's not just about data entry; it's about using that data to produce results in a structured, actionable way.

Conclusion

The clinical trial landscape is evolving. As we move beyond the era of data capture, we must focus on liberating the valuable information we've collected, ensuring it can be used effectively to drive decisions and shape outcomes. Workflow management, tailored to the specific needs of each trial, is the key to unlocking the full potential of data. By guiding the aggregation, quality control, augmentation, and analysis of trial data, we can ensure that the next phase of clinical trials is not only more efficient but also more successful—saving both time and money, and accelerating the path to market for critical therapies.

Tech and AI pioneer, Abraham Gutman, founded AG Mednet in 2005. Abraham is a leader at the forefront of transforming the way clinical trials are conducted. He is a technologist with 35 years of experience in the conception, implementation and sales of advanced software systems and platforms in fields including Telecommunications and Life Sciences. He holds a B.A. in Computer Science from Cornell, and an M.S. in Computer Science (AI) from Yale.
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