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The Power of AI to Improve Clinical Trial Monitoring

AI can serve as a valuable tool to complement and enhance the clinician's role.

The Power of AI to Improve Clinical Trial Monitoring

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Artificial intelligence (AI) systems are increasingly shaping medical manufacturing, drug formulation development, and clinical trial execution. Its application to clinical monitoring remains nascent, but pharmaceutical sponsors, clinical research associates (CRAs), and investigators are finding new ways to leverage AI tools. By analyzing vast patient data sets, AI enhances predictive analytics, supports real-time patient alerts, and strengthens continuous monitoring—improving the overall efficiency and effectiveness of clinical trial oversight.

Currently, each of these AI applications is used in clinical settings, but building trust in these systems, ensuring the accuracy of the data they generate, and determining their return on investment (ROI) all remain a challenge. Narrowing AI's clinical monitoring use to fit-for-purpose tasks, increasing transparency in decision-making, and establishing clear ROI metrics—both during the trial and after it concludes—are key steps toward improving its effectiveness in clinical monitoring.

What Can AI Offer To Clinical Monitors?

To adequately serve clinical monitoring without introducing new challenges, AI tools must provide seamless, high-quality data integration and operate transparently—especially to mitigate bias. AI tools also must be designed and integrated to assuage regulatory and ethical concerns often associated with their use. To meet these goals, it is essential to train AI systems on diverse, high-quality data sets that reflect the broader patient population, avoiding oversimplification or bias.

Some larger sponsor companies have created proprietary AI systems, guided by trackers and templates, that can generate data from protected health information (PHI), laboratory data, and imaging results. For example, ChatGPT-like tools enable CRAs to input entire protocols and streamline day-to-day monitoring. Publicly accessible AI tools cannot be used in clinical trials due to the significant risk of compromising PHI or other personally identifiable information, which could violate ethical standards and regulatory requirements such as HIPAA.

Other companies, including those in manufacturing and biotech, are utilizing AI infrastructure to address complex challenges in the development of effective treatments and diagnostics, with the goal of streamlining the clinical trial process. For example, Owkin, a biotech company, "use[s] AI to identify new drug candidates, de-risk and accelerate clinical trials, and build diagnostic solutions that improve patient outcomes."[1] In the manufacturing faucet, Nanox.AI "solutions analyze routine medical CT scans for any clinical indication to help identify patients with asymptomatic or undetected findings correlated with chronic conditions in cardiac, liver and bone, promoting preventive care management."[2]

How Can AI Tools Best Benefit Clinical Monitoring?

The implementation of AI tools varies significantly by organizational need. Before adoption, leadership must define ROI and identify the most impactful applications, such as patient recruitment and retention. Or AI may be deemed a boon to data management (i.e., collating EHR systems with lab results or imaging); CRAs are tasked with "cleaning" clinical data to ensure monitoring has been optimally conducted and recorded, so streamlining that task may be a worthwhile investment.

Ultimately, tangible results must align with cost effectiveness for AI implementation in clinical monitoring to be feasible. For example, the application of AI tools should measurably reduce monitoring costs (e.g., as a result of fewer site visits or less manual data cleaning), as well as contribute to improvement in patient recruitment and retention rates. CRAs or clinicians being able to perform more effectively or efficiently can drive down trial costs, but company leadership must determine up front how much they are willing to invest in that long-term goal.

AI's value is clearer in well-established applications, like back-end data processing, versus monitoring tools — for example, predictive tools like an algorithm can flag potential heart failure, AI analysis can prompt earlier intervention that helps a critical care patient experience fewer complications throughout their therapy, or wearable devices can detect irregular vital signs in an at-risk patient.

Larger organizations generally are better equipped to invest the money, time, and effort to create and implement proprietary AI tools, but it is a misconception that the cost of entry is prohibitive for smaller organizations. All companies, but particularly smaller ones, can still benefit by focusing first on targeted tasks, such as patient recruitment, where the technology can assist in identifying patients who meet the criteria for clinical trials. AI may also be able to predict which recruitment channels (e.g., social media) might be most effective. Additionally, AI can support risk-based monitoring after any type of data cut, helping to detect anomalies indicative of protocol violations, safety issues, or data integrity problems.

Regardless of a company's size or the extent of its goals for AI usage during its clinical trial, continuous updates are essential to maintain AI accuracy. System training must reflect evolving standards of care or industry trends. Otherwise, the tool may draw from inaccurate data.

Additionally, robust SOPs must guide AI usage to prevent PHI or other patient-identifying breaches, ensure HIPAA compliance, and align with ICH Good Clinical Practice (GCP) guidelines. Security measures, including secure Wi-Fi connections at monitoring sites, are also critical to safeguarding patient data.

How To Minimize Rollout Complications

Rolling out AI tools within a clinical trial can be tricky, but healthcare institutions and sponsors can take several measures to streamline workflow without causing unnecessary interruptions or delays. As noted above, AI's scope should align with ROI potential and risk mitigation.

A phased rollout can help as well. A phased rollout—starting with select CRAs, line managers, or data managers—allows organizations to assess effectiveness and address issues before wider adoption. Prioritization is study dependent, including which AI tools are used, how they are implemented, when, and to what extent.

Examples of this limited use might include applying AI to investigate whether any new site staff have been added to the delegation of authority (DOA) log or if any tasks remain unassigned. Investigators can compare the current DOA log to a previous version, using AI to check whether any sub-investigators or principal investigators (PIs) have been omitted. This application would be particularly helpful to CRAs working within a large organization.

Another potential limited-scope clinical monitoring application could be the analysis of concomitant medications (AKA "conmeds"). Manually determining which medications are trending across a particular study is time-consuming, particularly in a study where numerous diverse conmeds may be present, such as an oncology study.

Please Show Your Work

Despite AI's potential, maintaining trust and patient safety is paramount. The "black-box" nature of AI decisions — which refers to the lack of transparency in how AI models make their predictions or decisions — must be overcome. In healthcare, this ambiguity can have serious implications, as it makes it difficult to trust AI's recommendations, particularly when those recommendations impact patient care.

In many AI systems, particularly those processing vast amounts of data using complex algorithms like deep learning, the decision-making process is not easily understood or interpretable by humans. As a result, it can be difficult to explain how the AI arrived at a particular decision, which raises concerns around accountability, trust, and potential biases in sensitive areas like healthcare.

To address this, companies need AI models that offer explainability, tailored to organizational, therapeutic, and site-specific needs. Transparency mechanisms should be developed with input from physicians and sponsors to ensure AI's outputs align with clinical expectations. Finally, it is critical to always have human interaction or confirmation in place to ensure that any data entry mistakes by personnel or system errors are identified immediately. One potential issue is "sticky fingers," which is an industry term referring to an individual mistakenly entering inaccurate data into some part of the system. The AI can be trained to seek out and flag certain keywords in documentation, but a PI, CRA, or clinician should be responsible for double-checking the machine's work.

Do It Right, And Then Do It Better Next Time

AI-assisted clinical trial monitoring can provide a significant ROI, but organizations must focus on maximizing impact while minimizing cost and risk. Key considerations include:

- Budget allocation: Does the organization have capital funds available to support several applications, or is a singular focal point likely to be most effective?
- Desired outcomes: What perceived benefits does the organization seek?
- System reliability: Is there evidence of the system's effectiveness?
- Integration: How will AI be seamlessly incorporated into workflows?
- Performance measurement: What metrics will gauge AI's success?
- Maintenance: How will the system be updated, using what data, when/how regularly, and by whom?

For the CRAs who conduct clinical trial monitoring and would be the AI system's principal users, both on-site impact and ROI can be gauged by several metrics. For example, optimizing the frequency of monitoring could be a way to determine AI's effectiveness in a monitoring role, provided the system helps to eliminate unnecessary visits or checks, thereby reducing CRA burdens and the trial's overall cost. Costs associated with travel to and from sites, for both CRAs and patients, could provide another window into monitoring the effectiveness of AI's support.

ROI determinations tend to be study specific, then further refined at the site level. With AI support, a baseline of expected performance should first be established at the study level, then adjusted for each site's unique factors, such as personnel, patient pool, and complementary resources.

AI in clinical trials must evolve alongside standards. Algorithm, personnel training, and post-trial AI performance reviews must be regular and consistent to ensure data security, patient safety, and smooth usability. As with most clinical trial-related elements, both the training and system updates must be clearly documented. Notably, no standard exists to guide this review, so it would need to be developed by each organization individually.

The unique skillset of clinicians — their expertise, personalized care, ability to address patients' emotional concerns, and capacity to patiently explain complex medical conditions — could never be replaced by AI. However AI can serve as a valuable tool to complement and enhance the clinician's role, through its capabilities in predictive analytics, real-time alert systems, and continuous monitoring, AI does offer valuable tools clinicians can use for early detection of health issues and enables a more proactive approach to patient care. To learn more, contact the authors or visit https://inseptiongroup.com.

References

1. *https://www.owkin.com/*

2. *https://www.nanox.vision/ai/*

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