Paper ML29

AI-powered trial performance co-pilot to accelerate clinical trials

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ABSTRACT

Clinical trials generate vast amounts of complex data, presenting challenges for clinical study teams in efficiently analyzing and extracting meaningful insights. AI-powered Trial Performance Copilot offers an effective solution to this issue. It can rapidly analyze vast quantities of structured and unstructured data, serving as a powerful study team companion, which can generate insights and suggest effective interventions to improve clinical trial outcomes. It supports operational decision-making during clinical development by providing a single source of insights to speed up clinical trials. It empowers study teams in three important ways: conversational AI capabilities to provide tailored, context-aware, real-time actionable insights; smart alerts that enable proactive, early interventions; and automatic drafting of communications to enhance coordination and collaboration with cross-functional team members. This presentation discusses how this co-pilot helps study teams make faster go/no-go decisions and accelerate the delivery of life-saving treatments to patients.

INTRODUCTION

Despite dedicated efforts within the biopharmaceutical industry to streamline clinical development, clinical trials continue to be complex, costly, and time-consuming. These challenges are amplified by a competitive and crowded trial landscape. However, accelerating clinical development is essential—not just for patients, but also for the organizations involved. Leading biopharmaceutical companies are tackling this challenge by implementing artificial intelligence (AI) and machine learning (ML) to expedite trials through scientific and operational improvements. These technologies can help identify optimal trial sites, enhance enrollment, and predict real-time enrollment performance, allowing for earlier, more proactive interventions. On average, applying AI/ML techniques across various assets and therapeutic areas can shorten development timelines, enabling the faster delivery of innovative therapies to patients and communities. With the rise of Generative AI (Gen AI), clinical development organizations are building on these advancements to further streamline trial processes, improve stakeholder engagement, and support decision-making with deeper insights. Even greater cost efficiencies and speed gains can be realized by combining traditional AI/ML methods with Gen AI techniques and new operational approaches. Particularly promising is Gen AI's potential to achieve optimal performance in various operational aspects of clinical development. For example, Gen AI-powered digital processes—such as automatically drafting trial documents—can reduce process costs by up to 50 percent. Gen AI enhances interactions with health authorities, driven by improved data quality and signal management. Additionally, Gen AI has enabled trial acceleration through optimized site selection and rapid, collaborative decision-making across trial operations. In this paper, we will examine how an AI-powered clinical trial performance copilot enhances the speed, efficiency, and success rates of clinical trials by improving decision-making and collaboration among study teams.

CLINICAL TRIAL PERFORMANCE COPILOT TO IMPROVE TRIAL SPEED, EFFICIENCY AND SUCCESS RATE

To manage the vast amount of data generated during clinical trials, leading organizations often implement a "clinical control tower"—a centralized dashboard that integrates real-time insights on trial performance. This includes tracking milestones, site activation and enrollment, sponsor-CRO interactions, clinical drug supply, costs, and resource allocation. However, monitoring this data can be a daunting task for clinical trial managers. They need to track thousands of data points daily and are frequently overwhelmed by urgent alerts, which makes effective prioritization nearly impossible. Furthermore, control towers typically capture only about 70 to 80 percent of the critical insights that trial managers require for active oversight. A generative AI trial performance "copilot" can provide relief by identifying and prioritizing critical issues, executing specific tasks (such as drafting targeted emails to sites based on historical performance and principal investigator preferences), and enabling deeper custom analytics that traditional control towers cannot perform. Over time, this copilot learns which interventions are successful in various contexts, ultimately becoming a more effective guide that enhances a trial manager's productivity.

AI-powered trial performance copilot requires clinical data and operation data in one single, unified data platform (UDP). UDP supports the seamless collection of data from various sources, ensuring real-time data capture that enhances accuracy and timeliness. To ensure consistency and interoperability, the platform employs standardized data formats and terminologies, such as CDISC standards, facilitating the integration of diverse data sets and improving data analysis quality. It integrates clinical trial data with operational data, such as patient recruitment metrics, site performance, and resource utilization. The copilot identifies patterns, trends, and correlations, supporting evidence-based decision-making. Ensuring the security and privacy of sensitive clinical data is critical, with the platform adhering to regulatory requirements like HIPAA and GDPR through robust encryption and access control measures.

KEY CONSIDERATIONS FOR MODEL SELECTION

When selecting a model for building a copilot, several key considerations are essential to ensure effectiveness and reliability. The model should be grounded in a strong foundation of medical knowledge and have the capability to be fine-tuned with domain-specific data, enhancing its understanding of clinical trial contexts. Compliance with healthcare regulations, such as HIPAA and GDPR, is crucial, along with robust data encryption to protect sensitive information. The model must demonstrate excellent language understanding and response quality, accurately interpreting complex medical texts. Seamless integration with existing clinical trial management systems and the ability to scale to handle large volumes of data are vital for operational efficiency. An intuitive user interface and built-in feedback mechanisms can enhance user experience and facilitate continuous improvement. Addressing potential biases in training data and ensuring the ethical use of AI are necessary to align with ethical guidelines. Additionally, organizations should evaluate cost-effectiveness and resource requirements, including computational resources and licensing fees, to ensure sustainable deployment. By considering these factors, organizations can select a model that enhances clinical trial performance while adhering to ethical, legal, and operational standards, leading to a reliable and efficient AI-powered copilot.

ADOPTING AI SYSTEMS SUCCESSFULLY IN ORGANIZATIONS

To scale the impact of AI, it's essential to go beyond just the technology itself. It requires dedication and commitment from all levels of the organization. Senior leaders must invest in a long-term vision and model the necessary changes, while the frontline leads adapt to new expectations and workflows. Here are key strategies organizations can use:

- **Define Clear Objectives**
  - Clearly outline the goals you aim to achieve with AI. Having specific objectives helps in selecting the right AI technologies and measuring success
- **Assess Readiness and Infrastructure**
  - Evaluate your current technological infrastructure to ensure it can support AI systems. This includes having adequate data storage, processing capabilities, and network infrastructure
  - Consider the quality and availability of data, as AI systems rely heavily on large datasets for training and operation
- **Build a Skilled Team**
  - Invest in training and hiring skilled professionals who understand AI technologies and the clinical domain
  - Encourage cross-functional teams where AI experts collaborate with domain experts to ensure AI solutions are practical and aligned with business needs
- **Choose the Right AI Tools and Platforms**
  - Select AI tools and platforms that align with your organization's objectives and technical capabilities.
  - Consider scalability and flexibility of the AI solutions to adapt to future needs
- **Pilot Projects and Iterative Development**
  - Start with pilot projects to test AI applications on a smaller scale. This allows for learning and adjustments before a full-scale rollout
  - Use an iterative approach to development, where feedback is continuously incorporated to refine AI models and processes
- **Ensure Ethical Use and Compliance**
  - Establish guidelines for ethical AI use to prevent biases and ensure fairness in AI-driven decisions
  - Stay informed about regulatory requirements related to data privacy and AI deployment to ensure compliance
- **Foster a Culture of Innovation**
  - Encourage a culture that embraces change and innovation. This involves educating employees about the benefits and potentials of AI, reducing resistance to new technologies
  - Promote collaboration and openness to experimenting with new ideas and approaches
- **Monitor and Evaluate Performance**
  - Continuously monitor the performance of AI systems to ensure they meet the desired objectives and provide value
  - Use metrics and KPIs to evaluate the effectiveness and impact of AI solutions, making adjustments as necessary

By following these strategies, organizations can successfully integrate AI systems, unlocking new opportunities for growth and efficiency while navigating the challenges that come with technological transformation.

RESPONSIBLE USE OF AI

AI has the potential to transform clinical trials, improve efficiencies, and enhance decision-making processes. However, with great power comes great responsibility. The responsible use of AI is crucial to ensure that its benefits are maximized while minimizing potential risks and ethical concerns. Key principles of Responsible AI Use are:

- Transparency: AI systems should be transparent in their operations. Users and stakeholders should have access to information about how AI models make decisions, including the data sources and algorithms used. This transparency helps build trust and facilitates accountability.

- Fairness: AI should be designed and deployed to avoid bias and discrimination. Ensuring fairness involves using diverse datasets, regularly auditing AI systems for bias, and implementing corrective measures when biases are detected.

- Privacy and Security: Protecting user data is paramount. AI systems must comply with data protection regulations and implement robust security measures to safeguard sensitive information. Users should be informed about how their data is collected, stored, and used.

- Accountability: Organizations deploying AI systems should be accountable for their outcomes. This includes having clear governance structures, assigning responsibility for AI decisions, and being prepared to address any negative consequences that arise.

- Human-Centric Design: AI should be designed to augment human capabilities, not replace them. It is essential to maintain human oversight and control over AI processes, ensuring that AI serves human interests and values.

- Sustainability: The environmental impact of AI technologies should be considered. Efforts should be made to minimize energy consumption and resource use in AI development and deployment.

CONCLUSION

Gen AI is poised to transform clinical trials by making such processes as documentation generation, protocol design, and performance monitoring more time and cost efficient. However, success requires organizational change. Leaders will need to model new behaviors, foster innovation, redesign processes, and develop talent to fully capture AI's potential to enable faster delivery of treatments to patients.

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