DCRI **THINK TANKS**

FROM INSIGHT TO ACTION

Embracing Generative AI in Clinical Research and Beyond: Opportunities, Challenges and Solutions

BACKGROUND AND CONTEXT

The DCRI Think Tank is an interactive meeting that engages the diverse perspectives of key stakeholders to address crucial issues in clinical research, policy, and practice to improve health.

On January 24-25, 2024, a DCRI think tank session on "Embracing Generative Artificial Intelligence (AI) in Clinical Research and Beyond" brought together leadership from academia, industry, government, agency, and payer groups to explore the current and potential future application of AI/Large Language Models (LLMs) in clinical research, considerations for review and validation of their outputs, privacy and security concerns, regulatory considerations and needs, and ethical concerns. This meeting brief provides an overview of the key themes and actionable items from the session.

KEY TAKEAWAYS AND THEMES

Generative AI can and should help conduct clinical research
Current generative AI capabilities have the potential to dramatically improve the clinical research process. These benefits range from incremental process improvements to transformative applications that promise to redefine the landscape of clinical research, with the goals of accelerating clinical research, increasing accessibility to large and diverse participant groups, and improving the probability of success. Expected use cases include generating drafts of tools and documents required for clinical research; directly engaging participants and communities throughout the research process, from recruitment through to result dissemination; and providing new avenues for data collection, analysis, and synthesis. Generative AI could propel clinical research into a new era of efficiency, precision, and discovery, and accelerate our progress towards learning health systems where evidence generation is embedded within practice. However, achieving this promise is not straightforward. Setting a trustworthy foundation requires careful navigation of technical, ethical, and regulatory considerations, as well as ongoing oversight, to ensure that these advancements are realized safely and effectively. Critical to this endeavor is for stakeholders to evaluate the consequences of deploying generative AI, both positive and negative, and to share lessons learned. Failure to do so has the potential for exacerbating potential harms of AI without ever achieving the full benefits.

The critical role of evaluating the effectiveness and impact of AI use cases
Generative AI is being rapidly adopted, thanks in part to its remarkably user-friendly interface and minimal technical barriers to entry. This pace of unfettered adoption underscores the urgency for organized, informed, and strategic integration of AI-informed tools into clinical research. Indeed, the speed of implementation must be carefully balanced with the need for rigor, safety, and caution. Use of generative AI will soon become commonplace in clinical care and research and by research participants. Before these technologies become fully embedded, there is a critical need for systematically learning about the full spectrum of benefits and potential harms that generative AI may have within the clinical research domain. Careful evaluation using rigorous research methods is essential to ensure successful and seamless adoption of AI into clinical research in ways that maximize the benefits and minimize the harms. Of greatest importance is broadly sharing the evaluations of AI. Without sharing experiences in this rapidly evolving domain, we run the risk of creating random practice and not best practice. Leveraging change management strategies and lessons learned from other technological advances may help accelerate the process from research to implementation. Cross-pollination of knowledge will support rapid implementation of evolutionary enhancements in clinical research practices, and pave the way for revolutionary applications of AI in clinical research. A well-charted course that harmonizes rapid integration with meticulous evaluation is essential to safeguarding the integrity and future progress of clinical research.

Trust and transparency must serve as the guiding principles for fostering integrity in innovation

Establishing and nurturing a foundation of trust among all stakeholders—researchers, participants, sponsors, regulators, and clinicians—is crucial to the deployment of AI technologies. Trust is cultivated through open and ongoing dialogue about the capabilities and limitations of AI models, creating an environment where performance is continuously evaluated and optimized. Transparent and real-time feedback loops on model performance will be necessary as there are drifts in populations or medical practice. It will also be essential to adaptively recalibrate AI models as their predictions start influencing the data used for continuous evaluation, maintaining their accuracy and relevance. Further, the ethical integration of generative AI will require proactive efforts to mitigate biases or unintended consequences and reinforce equity; while AI has the potential to expand access to and increase engagement in clinical research, careful consideration of source data and AI use in practice is critical so as not to perpetuate bias. Bias in the clinical research process will systematically bake inequities into healthcare for generations to come. The symbiotic goals of expanding research inclusivity while upholding the highest ethical standards are the cornerstones of trustworthy AI practices in clinical research, guiding AI innovators toward responsible and equitable tools.

Safeguarding the future requires guardrails and universal ethical standards

Robust guardrails and industry-wide standards are essential for establishing an effective and ethical environment for AI in clinical research. Data management challenges include ensuring availability, quality, privacy, and security. It is vital that data are also discoverable and reusable, upholding the rigor and reproducibility of the research data ecosystem. Guardrails must establish a culture of algorithmic vigilance in which AI systems are continuously monitored and refined, maintaining their effectiveness, reliability, and ethical compliance over time. Furthermore, these guardrails must encompass ethical standards, integrating principles like fairness, accountability, and inclusivity into every facet of AI application. Ethical considerations should be deeply embedded in the infrastructure, guiding every decision and development. Sharing knowledge and best practices about the ethical deployment of clinical research studies augmented with AI will be integral, requiring tools to ensure AI products conform to stringent standards of integrity and ethical use. This integrated ecosystem is not just an aspiration but a foundational component of the future of clinical research, ensuring that advancements in generative AI are pursued with the highest standards of integrity and responsibility.

ACTIONABLE ITEMS

Map the clinical research process in detail

Detailing each step in the clinical research process will allow for clearer outlining of current challenges and the opportunities for AI-informed solutions. This will enable identification of areas amenable to incremental advances where immediate action is possible to use AI tools and study their impact, as well as identification of more transformative advances, which could fundamentally alter the research process. For example, AI can quickly and cost-effectively translate informed consent documents (incremental), while its use through chatbots or avatars could engage participants in a personalized and engaged consent process (transformative). Transforming the consent process requires not just a technological change but complex inter-disciplinary coordination between regulators, policy makers, ethicists, and clinical researchers. This is the first time in almost a century that we have an opportunity to overturn a consent process that does not always serve the best interests of the participant and frequently fails to meet the goals of truly informed and voluntary consent. Transformational changes, while complex and multi-disciplinary, will enhance clinical research for all.

Share successes and failures

Rapid but effective integration of AI into clinical research will require knowledge sharing and collaboration across the clinical research landscape. Work is ongoing, and much more is needed, to study and disseminate the outcomes from adopting AI-based inventions, including those that are already being used. The field should aim for the development of open-access platforms that promote sharing of algorithms, training datasets, models, and best practices and foster collaboration and innovation. In addition, stakeholders should take advantage of lessons learned outside of clinical research. Fields such as e-commerce and the gaming industries already have extensive knowledge of participant engagement, visual learning, and human-computer interactions, which can be leveraged to enhance the impact of generative AI in clinical research. The goal of transparently learning as we go will nurture a culture of innovation and adaptability, preparing the foundation for AI to not just enhance, but transform clinical research.

Prioritize collaborative efforts and community engagement

Rapid and effective implementation of AI in clinical research requires a collaborative community that includes patients as well as AI developers, payers, policy makers, regulators, funders, drug and device developers, clinical providers, and researchers. Early and meaningful interactions among these stakeholders are crucial to create a cooperative ecosystem that promotes innovation and ensures compliance, building trust and transparency as the field advances. Collaborative efforts are essential to ensure consistency in technological advancements and rapid progress towards industry-wide standards, and to foster a harmonious and efficient clinical research environment. With a unified approach, every participant becomes an integral co-architect of the future, shaping a conducive landscape for generative AI to be responsibly and effectively integrated and adopted into clinical research.

For more information, please visit https://dcri.org/think-tanks/.