Deloitte.

GENAI IN LIFE SCIENCES BLOG

Generative AI to accelerate clinical development

In today's challenging economic environment, leaders in life sciences are faced with the difficulty of executing flexible and adaptable trials that can serve the unique needs of different stakeholder groups in a cost-effective manner. This is not an easy task as clinical trials are inherently labor-intensive, complex, and regulated.

Novel digital technologies, automation tools, and patient experience solutions have been an effective lever to mitigate manual activities and, in turn, reduce overall cycle time and cost. However, these digitization tools have historically provided incremental, but not transformational, impact to clinical trials. Generative artificial intelligence (GenAI) may finally be the technology innovation that can be the transformative lever.

Notably, Generative AI has the potential to slow growing costs and transform the landscape of clinical development by accelerating tasks across the clinical life cycle, bringing a greater share of services back within the four walls of biopharma companies, improving experience for internal resources and patients alike, and ultimately contributing to more efficacious therapies.

Potential outcomes enabled by Generative AI

Study startup	Automate document generation activities to increase velocity. Working from previous examples of clinical trial protocols, site contracting agreements, clinical report forms, and other key pieces of paperwork required to jump-start clinical trials, biopharma organizations can quickly draft and refine the documentation required to establish new test sites. This can be a critical step in creating diversity within patient cohorts, allowing sites in underserved geographies to be easily established more quickly and for less effort.
Patient engagement and retention	Increase study retention by amplifying patient engagement. Attracting and retaining patients can be a major pain point for clinical trial sites. Generative AI can facilitate patient recruitment by activating personalization at scale, identifying the doctors and ZIP codes that could benefit most from a new therapy and creating customized outreach. The conversational nature of GenAI can function as the front line in answering patient questions, sharing relevant information, and triaging the concerns that will cause patients to leave clinical trials early. Attrition can cost as much as $20,000 per patient, providing organizations significant incentive to explore all avenues for retaining more clinical trial participants.
Regulatory submissions	Improve regulatory engagement with tailored submissions. To successfully deliver a submission to regulators like the EMA or the FDA, clinical teams must assemble immense dossiers that draw from all of their laboratory research and clinical development activities. Intelligent or semantic search capabilities enabled by Generative AI—wherein you search based on meaning rather than individual keywords—enables much faster identification of the relevant materials, and ongoing, automated GenAI-enabled document tagging can make critical documents even easier to locate.

Many of the life sciences leaders we talk to are excited by the potential of applying Generative AI to clinical trials but are understandably concerned about managing risks to quality and employee experience. To that end, we provide the following considerations:

1. **Recognize the difference between a task and a job.** As GenAI use cases grow, many are concerned there will be an equal and opposite reduction in human workers. While a valid concern, leaders must clearly differentiate between a task (i.e., an activity one performs as part of their work) and a job, which has a far greater scope. Clinical development is made up of a variety of tasks ripe for automation: repetitive, manual, and rule-based activities. The jobs attached to them, however, remain critical.
2. **Anticipate a shift toward more and more specialized knowledge.** As discrete tasks are increasingly shifted toward Generative AI, organizations will need to stand up the proper guardrails to ensure the integrity of the outputs. Generative AI will increasingly drive content creation (e.g., outreach to trial participants, plain language summaries of clinical data) and, as a result, humans will need to validate those outputs.
3. **Be cautious of historical data.** Clinical development has faced challenges related to creating diverse clinical trial cohorts. For that reason, leaders in R&D should be careful not to over-index on historical clinical data, or they risk amplifying biases inherent in existing datasets. Moreover, ensuring that trustworthy AI frameworks and governance approaches are in place will mitigate potential for bias and unintended outcomes.

Want to learn more?

If you are curious about embarking on this journey, please reach out to learn how Deloitte can help you enable these Generative AI capabilities.

For additional blogs on life sciences Generative AI, check out:
Can life sciences companies unlock the full value of GenAI?

The creative power of Generative AI to amplify marketing excellence

Authors

Andy Bolt
Principal
Deloitte Consulting LLP

Amy Chueng
Principal
Deloitte Consulting LLP

Aditya Kudumala
Principal
Deloitte Consulting LLP

Adam Israel
Senior Manager
Deloitte Consulting LLP