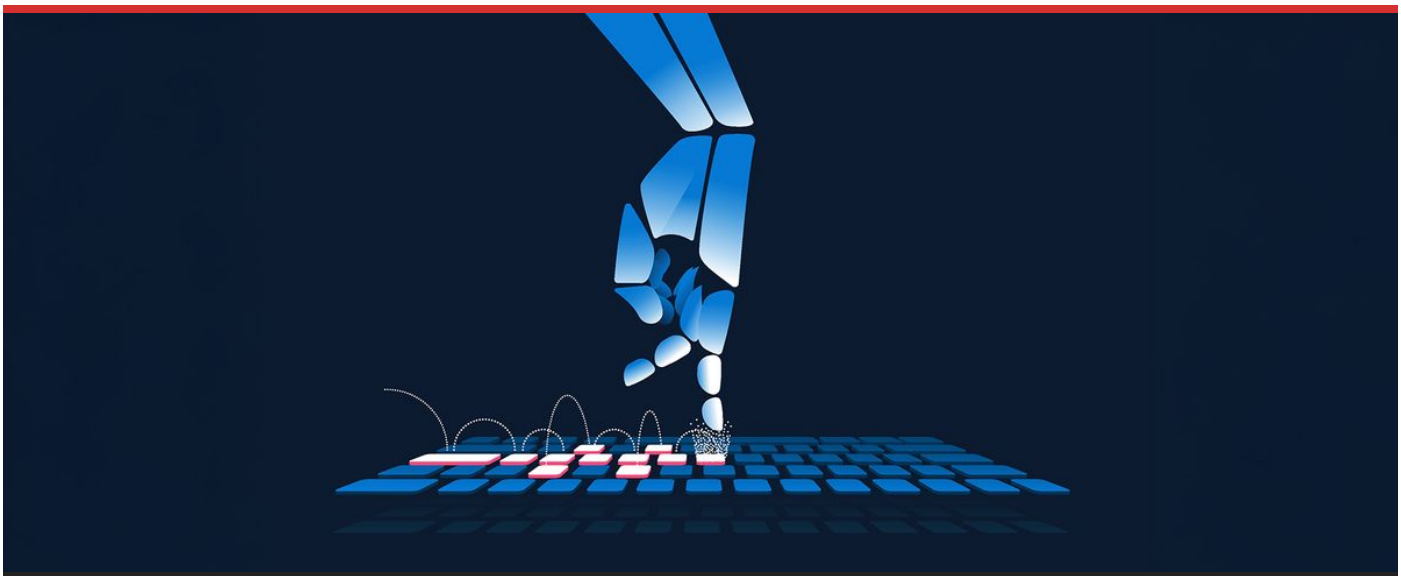
TheScientist
EXPLORING LIFE, INSPIRING INNOVATION

READ THIS ARTICLE ONLINE



AI could help drug developers fast-track through regulatory bottlenecks, getting drugs into clinical trials faster.

IND Applications Are Tedious. Can AI Help?

Drug developers can now leverage large language models to draft regulatory documents, which they hope will shorten the time to market.

Kamal Nahas, PhD

Mar 25, 2025 (UTC)

In August 2024, Bin Xia Yang, a portfolio director at the pharmaceutical company Axcynsis Therapeutics, geared up to move the company's new tumor-fighting antibody-drug conjugate into clinical trials. However, one crucial step remained before human trials could begin.

The Food and Drug Administration (FDA) requires drug developers to provide evidence that their drug is relatively risk-free before administering it to people. The form in question is called an investigational new drug (IND) application and a drug's sponsor (typically the manufacturer or a marketer) must fill out hundreds to thousands of pages of material for the FDA to inspect. The paperwork includes details about several aspects of the drug: data from animal experiments or from

foreign human trials providing safety and efficacy, an outline for how they plan to run clinical trials, and details of how the manufacturer will produce the drug (if eventually licensed). “The information is quite a lot. We have a lot of study reports,” said Yang.

Though IND applications are a rigorous necessity, they often put a strain on drug developers. Pharmaceutical companies must file a patent early in a drug’s development—that is, before drafting an IND proposal. Spending months poring over regulatory forms delays how soon a drug can get to market. Even though Yang began drafting an IND form in August last year, it was only finished and approved in January 2025. Even after submission, these applications continue to waylay workers: IND applications are “living” documents, which sponsors must regularly update every time a change is made to the clinical trial design or the manufacturing protocol. Moreover, in the 30-day evaluation period post submission, the FDA can request additional information or revisions, if they find the need, further delaying the pipeline.

Drug developers have a strong incentive to expedite IND form submissions while maintaining accuracy and thoroughness. With artificial intelligence (AI) programs on the rise in biology, developers are eager to try AI-based solutions to accelerate this step. “If AI can really help us quickly summarize all the information and how it aligns with the regulatory requirements for the FDA, that will greatly help us save a lot of time with document preparation,” said Yang, who said she did not use AI assistance for the company’s recent IND application.

Drug developers have already begun harnessing AI tools to take some of the grunt work out of IND applications, potentially using large language models (LLMs) like ChatGPT to aid with drafting text. In fact, the Center for Drug Evaluation and Research, a division of the FDA, found that over 500 submissions of IND reports and other regulatory forms between 2016 and 2023 contained elements of AI. For example, when it comes to detailing how to manufacture the drug, sponsors used AI to find optimal strategies for scaling up production.

While tools like ChatGPT could help sponsors work through their applications, the

technology company Weave Bio decided to create AutoIND, the first AI tool designed to generate rough IND drafts within a single day. According to Brandon Rice, chief product officer at Weave Bio, IND applications can take up to six months to complete, but quick-drafting with AutoIND may cut down the time spent by at least half.

AutoIND is a web application that sponsors can use to upload all their source documents as PDFs, whether they are formalized reports or electronic laboratory notes. “Basically, anything you can make into a PDF, we can take as input,” Rice said. He suggested that users can swiftly generate drafts for each IND form, of which there are about 30 to 40 per application. “It’s literally clicking one button per document, so it’s straightforward.”

AI tools might prove alluring to startups that have never filed IND proposals before. Nathan McMahon, clinical project manager at Trace Biosciences, a company that makes fluorescent compounds to illuminate nerves during surgery, said he had no experience with IND application filings: “We’re a small startup, but we’re learning as we go. We were trying to find any way to go faster and leaner.” Rather than paying consultants to help them draft the IND documents, they gave AutoIND a whirl. “I generated 50 pages of content in an hour,” McMahon said. It only took him two months on and off to refine an application for a fluorescent nerve probe, and the team plans to submit the IND forms soon.

AutoIND uses a constantly-adapting selection of OpenAI LLMs to extract key information from text and tables (but not figures) in source documents to fill out the forms. However, LLMs have a reputation for making errors, such as fabricating citations for scientific papers that don’t exist. These so-called “hallucinations” arise when LLMs muddle information they source from their own databases. To avoid this issue, Weave restricted their LLMs to information from the uploaded documents. When McMahon generated drafts with AutoIND, he spent only one hour tweaking each document to address loose ends before sending the forms to consultants for review. “They were blinded too. I didn’t tell them how I made the content,” McMahon said. “The consultants came back and had stylistic changes, but the content itself was accurate,” he added. Nonetheless, sponsors must verify all the data are correct,

just as they would if humans drafted the forms, Rice said. This makes the refinement stage the most time-consuming part of the application. “It’s going to save a lot of time building the bases, but it will not take away the real oversight and the in-depth review that the team members will need to do,” said Maria de Assis, vice president of clinical operations at Axcynsis Therapeutics.

As AutoIND is still in development, there is room for improvement. For instance, McMahon found that the AI model struggled the most with the section on manufacturing: “There is so much documentation involved, so getting the model to sift through all of that and pull out the crucial pieces can be difficult,” McMahon explained. de Assis noted that it would be beneficial if AI tools could help with analyzing preclinical data or proposing clinical trial designs that conform to FDA guidelines, as this information is needed for the IND applications, but the work takes up considerable time. “We did [the IND paperwork] over a month and a half, but getting the results and leading up to it I believe is a minimum of six months,” she said.

Some drug developers are concerned about handing over their data to AI. Yang said, “A lot of information in the IND is confidential. How do you set up a firewall and make sure there is no information leaking?” She noted that even AI developers who make tools for filing IND paperwork shouldn’t have access to confidential material as there is a risk it could leak to competitor drug companies. Rice said, “We do all the industry best practices to make sure that their data is safe, encrypted, and protected from access by others.” He added that Weave Bio has a zero data retention agreement with OpenAI. “They have agreed that they will not use any of the data that we send to them to do any learning, and in fact, they won’t even keep it on their servers,” Rice said.

Though Rice believes that tools like AutoIND are relatively error-free and secure, the FDA wants to ensure sponsors use AI responsibly. (FDA officials were unavailable for comment due to a White House-instructed pause on external communications.) In January 2025, they published a draft guidance for the use of AI at all stages of the drug product life cycle, including IND applications. They did not outline legally enforceable responsibilities; however, the guidance provides recommendations for

how sponsors should test the credibility of the AI models they use. For example, it suggests that sponsors should quantify “model risk,” which is the probability that their model will produce inaccurate output, resulting in a poor decision and an adverse outcome for trial participants.

Future AI programs could come equipped with additional features that simplify IND paperwork filing. For example, they could improve communication by summarizing data in more succinct and clear ways, such as with graphs or diagrams, McMahon proposed. While there are a whole host of features that developers could append to the bots, Rice has set his priorities: “We want to make automatic updating of the content very streamlined,” so sponsors don’t have the living documents hanging over their heads.

AI’s helping hand could allow drug developers to progress swiftly through the pharmaceutical pipeline. “Instead of me having to sit there and type the whole thing, and learn how to write it, I can spend more time thinking about our clinical trial strategy moving forward,” McMahon said. AI will likely have a growing presence in the drug industry, and with more such tools, developers could get new therapies from the lab bench to bedside at a record pace.