# FDA teases faster approval times with new agency-wide AI tool

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## SUMMARY

The US Food and Drug Administration (FDA) launched Elsa, a generative artificial intelligence (AI) tool designed to assist FDA employees with tasks such as reading, writing, and summarizing. The press release on the tool's launch states that FDA is already using the tool to accelerate clinical protocol reviews, speed up scientific evaluations, support safety profile assessments, and identify high-priority inspection targets. FDA's May 8, 2025, announcement that it would be ramping up use of AI across all centers teased faster regulatory approvals as a result, along with a quote from FDA Commissioner Dr. Martin A. Makary stating FDA's widespread adoption of AI "hold[s] tremendous promise in accelerating the review time for new therapies."

## IN DEPTH

The launch of Elsa comes less than a month after FDA Commissioner Makary directed all FDA centers to begin deploying AI, with a stated target of full integration of AI across the agency by June 30, 2025. The use of AI allows scientific-review tasks that typically take days to complete to be performed within minutes. FDA states it is already using Elsa to summarize adverse events as part of safety profile assessments, identify high-priority inspection targets, perform label comparison, speed up clinical protocol reviews, and accelerate scientific evaluations. Elsa can also generate code that can be used to help develop databases for nonclinical applications. FDA intends to evaluate further use cases for Elsa and other AI tools moving forward, with data processing and generative AI functions as an early focus.

FDA appears confident that generative AI could allow its scientists and other experts to reduce the time spent on repetitive tasks that slow down the review process. FDA Commissioner Makary indicated that AI tools could help reduce "the amount of non-productive busywork that has historically consumed much of the review process." Like FDA's bid to phase out animal testing, which we previously covered, this initiative is the latest in a series of efforts at FDA that the agency claims have the potential to reduce approval times for new therapies.

Elsa is the latest example of the agency's willingness to engage with AI's impact on the industry. We previously addressed two draft guidance documents released by FDA in January 2025 that address AI-enabled device software

functions and the use of AI to support regulatory submissions related to drugs and biologics. These guidance documents are the latest in a series of workshops, discussion papers, and guidance on the use of AI from FDA. FDA's focus on the technology does not appear to be waning, with FDA Commissioner Makary recently commenting that the agency will have to think creatively about how it regulates new AI technologies. Elsa demonstrates that FDA is taking this concept a step further and adopting AI within its own processes.

Elsa is powered by large language models (LLMs) and built within a high-security GovCloud environment that FDA says allows agency staff to securely access internal documents while ensuring the data remains within the agency. According to FDA, Elsa's models were not trained on data submitted by regulated industries.

McDermot will continue to monitor FDA's AI rollout and how it may impact the agency's review times for new therapies and ongoing oversight activities for existing therapies. If you have any questions about FDA's recent actions or about the FDA review process, please contact a member of McDermott's Food, Drug & Medical Device Regulatory Group.

## GET IN TOUCH


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