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5 Open Questions About FDA's AI-Assisted Review Plans

By **Lisa Dwyer, Jeffrey Shapiro and McKenzie Cato** (June 12, 2025, 6:20 PM EDT)


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On May 8, the U.S. Food and Drug Administration announced the completion of a generative artificial intelligence pilot program for scientific reviewers.

FDA Commissioner Marty Makary was quoted in the announcement as saying that he was blown away by the success of the pilot. Makary has directed that all FDA centers "begin deployment immediately, with the goal of full integration by the end of June."

On June 2, the FDA made a separate more detailed announcement — that the agencywide AI tool, known as Elsa, was already being deployed by the agency to "accelerate clinical protocol reviews, shorten the time needed for scientific evaluations, and identify high-priority inspection targets."

Apparently, Elsa can also "summarize adverse events to support safety profile assessments, perform faster label comparisons, and generate code to help develop databases for nonclinical applications."

Little Detail About the AI-Assisted Scientific Review Pilot

Quoted in the May 8 announcement, the deputy director of the Center for Drug Evaluation and Research's Office of Drug Evaluation Sciences, Jinzhong Liu, called FDA's generative AI technology a game-changer, as it allowed him to perform scientific review tasks in minutes that used to take three days.

However, the FDA's announcement did not provide details about the completed AI-assisted scientific review pilot, including when it was initiated, whether it was conducted in all FDA centers or only one, how many products were reviewed during the pilot program, or criteria for success.

Full Deployment of AI-Assisted Scientific Review

Makary has directed all FDA centers to begin deployment of AI-assisted scientific review of premarket filings, with the goal of a complete rollout by June 30.

The announcement notes that the FDA will continue to expand use cases and improve functionality after

June 30. Given the direction to begin deployment in "all FDA centers," it appears that AI-assisted scientific review will be used in the Center for Drug Evaluation and Research for new drug application review, in the Center for Biologics Evaluation and Research for biologics license application review, and the Center for Devices and Radiological Health for device marketing submission review, e.g., Section 510(k)s, de novo requests and premarket approval applications.

The full deployment of AI-assisted review is being coordinated by a newly appointed chief AI officer, Jeremy Walsh, and Sridhar Mantha, who is the former director of the FDA's Office of Strategic Policy. Mantha also co-chaired CDER's AI council, which was established in 2024.

Open Questions

The brief May 8 announcement from the FDA leaves a number of open questions for FDA-regulated product sponsors on how AI will be used by FDA centers in scientific review of premarket applications. The June 2 announcement offered more detail, but questions remain.

1. Will AI-assisted review actually lead to more efficient reviews?

While the stated goal of AI-assisted review is more efficient review of premarket applications, FDA premarket review is conducted in accordance with user-fee driven review goals. It remains to be seen whether sponsors will see tangible improvements in review timelines, or whether the FDA will continue to perform reviews in line with existing review timelines.

Additionally, there has been concern that layoffs at the FDA could lead to review delays. There is a possibility that AI-assisted scientific review could provide a counter-balance that keeps premarket reviews on time.

2. Will sponsors know that AI was used in review of their premarket applications?

If sponsors are aware that AI was used in scientific review of their applications, a review team's use of AI could become a topic in future administrative supervisory appeals or formal dispute resolution requests following unfavorable decisions on premarket applications.

In other words, will AI be used as a decision support tool, or will it have what could be seen as undue influence over the FDA's review? This question is the same one the FDA asks industry regarding clinical decision support software.

3. Will there be protection of trade secret and confidential commercial information?

Generative AI necessarily relies upon an existing universe of data and information. In the context of AI-assisted scientific review, it is possible that other sponsors' FDA review documents will be used by the AI, as part of its knowledge base, in the review of future applications.

If so, it is unclear to what extent trade secret and confidential commercial information from one application could be used to evaluate data in an application from a different sponsor.

Although we expect that the FDA is using a closed system, protecting the information reviewed by the AI from both public disclosure and improper use across applications, the press release does not say

anything about these important issues.

4. Will AI-assisted scientific review allow for a more holistic review of premarket applications?

One challenge that sponsors sometimes face in FDA review of a premarket application is detailed critiques on the minutiae of data from preclinical and clinical trials. AI-assisted review has the potential to give FDA reviewers the benefit of a broader perspective on how the data fits in with the broad sweep of published scientific literature and the FDA's prior published decisions. Such insight could lead to more informed premarket reviews and greater consistency.

5. How will the AI review tools be designed to minimize bias?

As sponsors know, the FDA's approach to a category of drugs, biologics or devices can evolve over time and adapt to advances in technology. It is unclear how the FDA's AI review tools will adapt to the FDA's evolving approaches to a particular product category and whether it is designed to forget or exclude prior applications that could inappropriately bias review of a future application.

There is a degree of judgment required to know what is still state of the art and what has become obsolete, particularly in medical device technology. Will AI improve or hinder this judgment?

Conclusion

Although FDA was short on detail regarding the parameters of the AI pilot, the fact that they have been piloting AI tools is not surprising. There was an early sign in February last year, when the FDA's device center flagged an alarming trend of bad data in device applications related to testing data generated by third parties, particularly laboratories in China and India.

All FDA stakeholders are now on notice that they should be proactively deploying AI tools to vet their applications for data anomalies, among other things. Developing AI tools for regulatory purposes is now essential, not only to avoid regulatory vulnerability, but also to meaningfully reduce costs.

Looking ahead, the FDA has stated that it will be releasing additional details and updates on the agency's deployment of AI for the scientific review of applications. These updates could take the form of a guidance document or other public release, e.g., a webinar.

While it does not appear at this time that the FDA is seeking comment or feedback from industry stakeholders, we urge the FDA to provide answers to critical open questions.

Makary has promised radical transparency. Such transparency regarding the FDA's use of AI would be very much appreciated by the stakeholders who are investing millions of dollars in cutting-edge medical technology, which needs the FDA's approval to reach the market.

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