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Client Alert

FDA and Life Sciences

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FDA Announces Completion of AI-Assisted Scientific Review Pilot and Deployment of Agency-Wide AI-Assisted Review

On May 8, 2025, the Food and Drug Administration (FDA) announced the completion of its generative artificial intelligence (AI) pilot program for scientific reviewers.[1] FDA Commissioner Marty Makary was quoted in the announcement as saying that he was "blown away by the success" of the pilot. Commissioner Makary has directed that all FDA centers "begin deployment immediately, with the goal of full integration by the end of June."

THE ANNOUNCEMENT PROVIDED LITTLE DETAIL ABOUT THE AI-ASSISTED SCIENTIFIC REVIEW PILOT

The Deputy Director of CDER's Office of Drug Evaluation Sciences 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, FDA's announcement did not provide any 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 success criteria.

FULL DEPLOYMENT OF AI-ASSISTED SCIENTIFIC REVIEW

Commissioner Makary has directed all FDA centers to begin deployment of AI-assisted scientific review, with the goal of a complete roll-out by June 30, 2025. The announcement notes that FDA will continue to expand use cases and improve functionality after June 30th.

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 (CDER) for new drug application (NDA) review, in the Center for Biologics Evaluation and Research (CBER) for Biologics

License Application (BLA) review, and the Center for Devices and Radiological Health (CDRH) for device marketing submission review (e.g., 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 FDA's Office of Strategic Policy. Mantha also co-chaired CDER's AI Council, which was established in 2024 to oversee and coordinate CDER activities around AI use.[2]

OPEN QUESTIONS

The brief announcement from 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. For example:

- **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 FDA will continue to perform reviews in line with existing review timelines. Additionally, there has been concern in industry that layoffs at 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.
- **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, the Agency's use of AI could become a topic in future appeals, requests for supervisory review, or Formal Dispute Resolution Requests following unfavorable decisions on premarket applications. In other words, will AI be used as a decision support tool, or it will have what could be seen as undue influence over FDA's review? This question is the same one FDA asks regarding clinical decision support software. And importantly, these questions would likely be new questions that Courts would have to deal with should applicants seek judicial review.
- **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 FDA is using a "closed" system, protecting the information reviewed by the AI from public disclosure, the press release does not say.
- **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 in an application compares to other similar drugs, biologics, and devices. Such insight could make premarket reviews more consistent.
- **How will the AI review tools be designed to minimize bias?** As sponsors know, 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 FDA's AI review tools will adapt to 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.

FDA has stated that it will be releasing "additional details and updates on the initiative" in June. These updates could take the form of a guidance document or other public release (e.g., webinar). While it does not appear at this time

that FDA is seeking comment or feedback from industry stakeholders, it is possible that FDA could provide some answers to these open questions. We will continue to monitor this development and provide updates as appropriate.

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[1] FDA, News Release, FDA Announces Completion of First AI-Assisted Scientific Review Pilot and Aggressive Agency-Wide AI Rollout Timeline (May 8, 2025), https://www.fda.gov/news-events/press-announcements/fda-announces-completion-first-ai-assisted-scientific-review-pilot-and-aggressive-agency-wide-ai.
[2] *See* FDA, Artificial Intelligence for Drug Development (Feb. 20, 2025), https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/artificial-intelligence-drug-development.