FDA rolls out 'Elsa', a generative AI assistant for all agency staff

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The U.S. Food and Drug Administration (FDA) today launched Elsa, a generative Artificial Intelligence (AI) tool designed to help employees—from scientific reviewers to investigators—work more efficiently. This innovative tool modernizes agency functions and leverages AI capabilities to better serve the American people. “Following a very successful pilot program with FDA’s scientific reviewers, I set an aggressive timeline to scale AI agency-wide by June 30,” said FDA Commissioner Marty Makary, M.D., M.P.H. “Today’s rollout of Elsa is ahead of schedule and under budget, thanks to the collaboration of our in-house experts across the centers.” Built within a high-security GovCloud environment, Elsa offers a secure platform for FDA employees to access internal documents while ensuring all information remains within the agency. The models do not train on data submitted by regulated industry, safeguarding the sensitive research and data handled by FDA staff. “Today marks the dawn of the AI era at the FDA with the release of Elsa, AI is no longer a distant promise but a dynamic force enhancing and optimizing the performance and potential of every employee,” said FDA Chief AI Officer Jeremy Walsh. “As we learn how employees are using the tool, our development team will be able to add capabilities and grow with the needs of employees and the agency.” The agency is already using Elsa to accelerate clinical protocol reviews, shorten the time needed for scientific evaluations, and identify high-priority inspection targets. Elsa is a large language model–powered AI tool designed to assist with reading, writing, and summarizing. It can summarize adverse events to support safety profile assessments, perform faster label comparisons, and generate code to help develop databases for nonclinical applications. These are just a few examples of how Elsa will be used across the enterprise to improve operational efficiency. The introduction of Elsa is the initial step in the FDA’s overall AI journey. As the tool matures, the agency has plans to integrate more AI in different processes, such as data processing and generative-AI functions to further support the FDA’s mission. Prioritizing efficiency and responsibility, the FDA launched Elsa ahead of schedule using an all-center approach. Leaders and technologists across the agency collaborated, demonstrating the FDA’s ability to transform its operations through AI.

Media: HHS Request for Comment 202-690-6343

Consumer: 888-INFO-FDA

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Boilerplate

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, radiation-emitting electronic products, and for regulating tobacco products.