

FDA issues first draft guidance on AI used in drug and biologic submissions

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Today, the U.S. Food and Drug Administration issued draft guidance to provide recommendations on the use of artificial intelligence (AI) intended to support a regulatory decision about a drug or biological product's safety, effectiveness or quality. This is the first guidance the agency has issued on the use of AI for the development of drug and biological products. "The FDA is committed to supporting innovative approaches for the development of medical products by providing an agile, risk-based framework that promotes innovation and ensures the agency's robust scientific and regulatory standards are met," said FDA Commissioner Robert M. Califf, M.D. "With the appropriate safeguards in place, artificial intelligence has transformative potential to advance clinical research and accelerate medical product development to improve patient care." The FDA has substantial experience in reviewing regulatory submissions with AI components. Since 2016, the use of AI in drug development and in regulatory submissions has exponentially increased. AI can be used in various ways to produce data or information regarding the safety, effectiveness, or quality of a drug or biological product. For example, AI approaches can be used to predict patient outcomes, improve understanding of predictors of disease progression and process and analyze large datasets (e.g., real-world data sources or data from digital health technologies). A key aspect to the appropriate application of AI modeling in drug development and regulatory evaluation is ensuring model credibility—trust in the performance of an AI model for a particular context of use. Context of use is defined as how an AI model is used to address a certain question of interest. Given the range of potential applications of AI modeling, defining the model's context of use is critical. For this reason, this guidance provides a risk-based framework for sponsors to assess and establish the credibility of an AI model for a particular context of use and determine the credibility activities needed to demonstrate that an AI model's output is credible. This approach is consistent with how FDA staff have been reviewing applications for drug and biological products with AI components. The FDA encourages sponsors to have early engagement with the agency about AI credibility assessment or the use of AI in human and animal drug development. The FDA's human and animal medical product centers, along with the agency's Office of Inspections and Investigations, Oncology Center of Excellence and Office of Combination Products worked collaboratively on this draft guidance to ensure consistency across the agency. The agency recognizes that AI management requires a risk-based regulatory framework built on robust principles, standards and best practices. In developing these recommendations, the FDA incorporated feedback from a number of interested parties including sponsors, manufacturers, technology developers and suppliers, and academics. Specifically, this draft guidance was informed by feedback from an FDA-sponsored expert workshop convened by the Duke Margolis Institute for Health Policy in Dec. 2022, more than 800 comments received from external parties on two discussion papers published in May 2023 on AI use in drug development and in manufacturing, and the FDA's experience with more than 500 drug and biological product submissions with AI components since 2016. The FDA is seeking public comment on the draft guidance, *Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products*, within 90 days. In particular, the FDA is asking for feedback on how well this draft guidance aligns with industry experience and whether the options available for sponsors and other interested parties to engage with the FDA on the use of AI are sufficient. The agency will review and consider comments received before finalizing this guidance. Notably, this announcement is specific to the use of AI to support the development of drug and biological products. Today, the FDA also published draft guidance providing recommendations specific to AI-enabled medical devices. The publication of these guidances, among other actions, demonstrates the agency's ongoing efforts to provide transparency and to help ensure product safety and effectiveness while supporting innovation in this rapidly growing field. The FDA's medical product centers have a shared commitment to promote the responsible and ethical use of AI for medical products. As the field of AI evolves, the agency will continue to develop policies that support innovation and uphold the agency's rigorous standards for safety and

effectiveness.

Related Information

Related Information

Draft Guidance: Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products Artificial Intelligence and Medical Products Artificial Intelligence and Machine Learning (AI/ML) for Drug Development Artificial Intelligence & Medical Products: How CBER, CDER, CDRH, and OCP are Working Together

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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.