

FDA issues draft lifecycle guidance for AI-enabled medical devices

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Today, the U.S. Food and Drug Administration issued draft guidance that includes recommendations to support development and marketing of safe and effective AI-enabled devices throughout the device's Total Product Life Cycle . The guidance, if finalized, would be the first guidance to provide comprehensive recommendations for AI-enabled devices throughout the total product lifecycle, providing developers an accessible set of considerations that tie together design, development, maintenance and documentation recommendations to help ensure safety and effectiveness of AI-enabled devices. This guidance complements the recently issued final guidance on predetermined change control plans for AI-enabled devices, which provides recommendations on how to proactively plan for device updates once the product is on the market. "The FDA has authorized more than 1,000 AI-enabled devices through established premarket pathways. As we continue to see exciting developments in this field, it's important to recognize that there are specific considerations unique to AI-enabled devices," said Troy Tazbaz, director of the Digital Health Center of Excellence within the FDA's Center for Devices and Radiological Health. "Today's draft guidance brings together relevant information for developers, shares learnings from authorized AI-enabled devices and provides a first point-of-reference for specific recommendations that apply to these devices, from the earliest stages of development through the device's entire life cycle." The draft guidance includes recommendations for how and when, in marketing submissions, sponsors should describe the postmarket performance monitoring and management of their AI-enabled devices. The proposed recommendations reflect a comprehensive approach to the management of risk throughout the device total product life cycle. The FDA encourages sponsors to engage with the agency early and often, and to use this guidance, once finalized, to guide their activities throughout the life cycle of the device, including during planning, development, testing and ongoing monitoring. Importantly, this draft guidance also includes the FDA's current thinking on strategies to address transparency and bias throughout the life cycle of AI-enabled devices. The draft guidance describes specific recommendations intended to help a sponsor demonstrate they have addressed risks associated with bias and provides suggestions for the thoughtful design and evaluation of AI-enabled devices. Notably, this announcement is specific to AI-enabled devices. Today, the FDA also published draft guidance with recommendations regarding the use of AI to support development of drug and biological products. The publication of these guidances, among other actions, continues to demonstrate the agency's efforts to provide transparency and to help ensure product safety and effectiveness while supporting innovation in this rapidly growing field. The FDA is requesting public comment on this draft guidance by April 7, 2025. In addition to general comments, the FDA is specifically requesting public comment on the draft guidance's alignment with the AI lifecycle; the adequacy of the recommendations to address concerns that may be raised by emerging technology such as generative AI; the approach to performance monitoring (including use of a performance monitoring plan as a means of risk mitigation for AI-enabled devices); the type of information about AI-enabled devices that should be conveyed to users and the most appropriate approach to deliver that information. The FDA will also hold a webinar on February 18, 2025, to discuss the draft guidance.

Related Information

Related Information

Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations – Draft Guidance for Industry and FDA Staff
FDA - Artificial Intelligence and Machine Learning in Software as a Medical Device
FDA's list of Artificial Intelligence and Machine Learning-Enabled Medical Devices
FDA Blogs: The Promise Artificial Intelligence Holds for Improving Health Care and A Lifecycle Management Approach toward Delivering Safe, Effective AI-enabled Health Care

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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.