# FDA issues draft guidance for AI-enabled medical devices



The FDA has released draft guidance aimed at the design, development, and marketing submissions for AI-enabled medical devices, marking a significant intervention in the intersection of artificial intelligence and healthcare technology. This draft guidance outlines a framework intended to support the total product lifecycle while ensuring that manufacturers adhere to a risk-based approach.

The draft recommends that sponsors engage with the FDA early in the product development process to enhance the likelihood of successful marketing submissions. This process encompasses various stages of the product lifecycle, including development, validation, final device description, and postmarket management. Key emphasis is placed on areas such as risk assessment, data management, and comprehensive model descriptions.

In the development stage, emphasis is placed on risk assessment, effective data management, and an accurate depiction of model development. The validation stage focuses on the integrity of data management and the overall validation process. As products progress to the final device description stage, the guidance outlines the necessity for thorough descriptions of the device, model, user interface, labelling, and a clear public submission summary. Monitoring device performance and addressing cybersecurity issues are pivotal in the postmarket management phase.

Crucially, the FDA's draft guidance highlights the importance of transparency in the marketing of AI-enabled devices. By ensuring that “important information is accessible and functionally comprehensible,” the FDA aims to enhance consumer understanding of the technology at play. In this regard, manufacturers are encouraged to include detailed information on AI functionalities, model inputs and outputs, performance validation data, and known limitations of their devices.

Moreover, the draft guidance addresses the issue of bias, defined as the systematic tendency to yield incorrect results. To mitigate bias, companies must strive for representativeness in data collection across diverse demographic groups during the device’s lifecycle—from development and testing through to market introduction and ongoing evaluation.

The FDA also encourages manufacturers to be vigilant about data drift, which may affect device performance due to changing inputs from development to actual use. For this purpose, the FDA suggests that sponsors may employ a predetermined change control plan (PCCP), enabling them to seek premarket authorisation for modifications to device software without necessitating fresh marketing submissions or additional FDA authorisation.

It is important to note that this draft guidance does not stand alone; the FDA envisions it as a component of an expanded framework that includes existing guidance related to AI-enabled devices and various technologies.

The agency is seeking public comments on the draft guidance by April 7, 2024, to refine the final version based on stakeholder feedback. This initiative highlights the FDA's commitment to fostering innovation while maintaining robust standards for performance and safety in AI medical technologies. Companies interested in commenting or requiring assistance with the FDA’s submission processes can access support via the agency’s Q-submission program.

Source: [Noah Wire Services](https://www.noahwire.com)

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