# FDA issues draft guidance for AI in healthcare regulation



The Food and Drug Administration (FDA) has announced a significant development in the regulation of artificial intelligence (AI) in healthcare, seeking to provide key guidance for developers of AI-enabled medical devices. On Monday, the agency revealed that it is issuing draft guidance intended to assist these developers throughout the life cycle of their products. Troy Tazbaz, director of the FDA’s digital health centre of excellence, stated that if finalised, this would represent the first comprehensive set of recommendations from the agency pertaining to AI-enabled devices from inception to market and beyond.

The draft guidance arrives at a time when the pace of AI development in healthcare is outstripping the current regulatory frameworks. According to Tazbaz, the FDA has authorised over 1,000 AI-enabled medical devices through various pre-market pathways. The agency has brought together insights from these previously authorised devices to inform its guidance, which aims to offer a clear and accessible framework for maintaining and documenting AI-enabled medical technology. The guidance will address critical considerations such as transparency and the mitigation of bias throughout the total product life cycle. The FDA has invited public commentary on the draft until April 7.

Meanwhile, the FDA is also making strides in the drug development sector by issuing its inaugural draft guidance on the application of AI in this field. The surge in machine learning innovations over nearly a decade has led to a marked increase in drug regulatory submissions incorporating AI, with over 500 submissions since 2016, predominantly in oncology, neurology, and gastroenterology. Tala Fakhouri, who co-leads the FDA’s Centre for Drug Evaluation and Research’s AI Council, highlighted the exponential growth of such submissions, indicating a significant shift in regulatory bodies' engagement with AI technologies used in drug development.

This guidance follows a reflection paper from the European Medicines Agency, which addressed the use of AI in the drug product lifecycle and was finalised in September 2024. Xiaoyan Wang, senior vice president of life sciences solutions at clinical data company IMO Health, pointed out that "regulatory clarity is one of the top three barriers of adopting AI in this space". The FDA's draft guidance seeks to provide that much-needed clarity for industry stakeholders, facilitating the continued advancement of AI in drug development while ensuring compliance with regulatory standards.

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

## Bibliography

1. <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device> - This link corroborates the FDA's efforts in regulating AI and machine learning in medical devices, including the issuance of draft guidance for lifecycle management and marketing submission recommendations.
2. <https://www.fda.gov/news-events/press-announcements/fda-proposes-framework-advance-credibility-ai-models-used-drug-and-biological-product-submissions> - This link supports the FDA's inaugural draft guidance on the use of AI in drug and biological product development, highlighting the risk-based framework and the need for credibility assessment of AI models.
3. <https://www.fda.gov/news-events/press-announcements/fda-proposes-framework-advance-credibility-ai-models-used-drug-and-biological-product-submissions> - This link provides details on the FDA's commitment to supporting innovative approaches in medical product development using AI, emphasizing the importance of regulatory clarity and robust scientific standards.
4. <https://www.exponent.com/article/preparing-fdas-new-guidance-aiml-medical-devices> - This link explains how the draft guidance helps device manufacturers work with the FDA to specify and seek marketing authorization for AI/ML-driven modifications to medical devices through a predetermined change control plan.
5. <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device> - This link discusses the FDA's traditional paradigm of medical device regulation and how it is evolving to accommodate adaptive AI and machine learning technologies, including premarket reviews for modifications.
6. <https://www.fda.gov/news-events/press-announcements/fda-proposes-framework-advance-credibility-ai-models-used-drug-and-biological-product-submissions> - This link highlights the collaborative effort across various FDA centers and offices to ensure consistency in the regulatory framework for AI in drug and biological product development.
7. <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device> - This link mentions the FDA's draft guidance on AI-enabled device software functions, which includes lifecycle considerations and specific recommendations for marketing submissions, addressing transparency and bias mitigation.
8. <https://www.exponent.com/article/preparing-fdas-new-guidance-aiml-medical-devices> - This link explains how the draft guidance allows for future intended AI/ML-driven modifications to be documented in a predetermined change control plan, facilitating safe and effective product updates without additional marketing applications.
9. <https://www.fda.gov/news-events/press-announcements/fda-proposes-framework-advance-credibility-ai-models-used-drug-and-biological-product-submissions> - This link notes the FDA's encouragement for early engagement with the agency regarding AI credibility assessment and its use in human and animal drug development.
10. <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device> - This link discusses the FDA's efforts to provide transparency and ensure product safety and effectiveness while supporting innovation in AI-enabled medical devices.
11. <https://www.exponent.com/article/preparing-fdas-new-guidance-aiml-medical-devices> - This link outlines the importance of the draft guidance in providing a clear and accessible framework for maintaining and documenting AI-enabled medical technology throughout its lifecycle.
12. <https://www.modernhealthcare.com/digital-health/fda-guidance-ai-medical-devices-regulation> - Please view link - unable to able to access data
13. <https://news.google.com/rss/articles/CBMiogFBVV95cUxORzdQbHBpUUtJMHc0RXE5MFMyMFh3alFuWjRKRWM0ZnpJYnhKQUcwdEpTOE41REdhNm9yQ2w3cHZjSzVtWS1TTEtJcDZBVF9mSVc1OWwtbW1vTXJqVTZXbmJIWEpDaERGU0NnRWpFN2lNWnByWXFnNWxvcnY1UUF5cm5qZy1qbFVZNUtwa0F0bWlERWV1QXZSRFdRX2NqVzlUbWc?oc=5&hl=en-US&gl=US&ceid=US:en> - Please view link - unable to able to access data