# FDA issues first draft guidance on artificial intelligence in drug development



The United States Food and Drug Administration (FDA) has taken a significant step forward in the realm of pharmaceutical innovation by issuing its first draft guidance on artificial intelligence (AI) in drug and biological product development. This announcement, made on January 7, 2025, is poised to enhance the credibility of AI models used in regulatory submissions relating to the safety, effectiveness, or quality of medicines.

The draft guidance aims to provide a framework that assists sponsors—those who develop and submit drugs for regulatory approval—in assessing and establishing the credibility of AI models. The FDA noted that defining the model’s context of use is essential, given the diverse applications of AI technologies. For instance, AI can be employed to process and analyse large datasets, including real-world data and information derived from digital health technologies.

FDA Commissioner Dr Robert Califf underscored the potential of AI, stating, “With the appropriate safeguards in place, artificial intelligence has transformative potential to advance clinical research and accelerate medical product development to improve patient care.” He highlighted the FDA’s commitment to supporting innovative approaches within the medical product development field, emphasising the need for an agile, risk-based framework that adheres to the agency’s robust scientific and regulatory standards.

As part of its initiative, the FDA has also announced plans to seek public comment on its draft guidelines. The agency expressed particular interest in gaining insights on how effectively the draft aligns with industry experiences and whether the options for sponsors and other interested parties to engage with the FDA concerning AI usage in drug development are adequate.

This development marks a notable progression in the use of AI in the pharmaceutical sector, as previous discussions on the topic laid the groundwork for this comprehensive guidance. The new framework is anticipated to provide clarity and promote innovation, ultimately contributing to improved patient outcomes through enhanced regulatory practices in drug development. The FDA's ongoing dialogue with stakeholders reflects its intention to ensure that the integration of AI into pharmaceuticals occurs within a context of safety, effectiveness, and quality assurance.

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

## Bibliography

1. <https://www.biospace.com/fda/fdas-new-ai-guidance-highlights-risks-of-technology-urges-early-sponsor-engagement> - Corroborates the FDA's issuance of its first draft guidance on AI in drug development, the importance of defining the model’s context of use, and the need for early engagement with the regulator.
2. <https://citoday.com/news/fda-issues-draft-guidance-for-development-of-ai-enabled-medical-devices?c4src=home> - Supports the FDA's draft guidance for AI-enabled medical devices and the request for public comments on the alignment with the AI lifecycle and other specific considerations.
3. <https://www.europeanpharmaceuticalreview.com/news/242364/fda-issues-first-recommendations-on-ai-for-drug-development/> - Confirms the FDA's first recommendations on AI for drug development, emphasizing the framework for assessing and establishing the credibility of AI models.
4. <https://www.biospace.com/fda/fdas-new-ai-guidance-highlights-risks-of-technology-urges-early-sponsor-engagement> - Details the FDA's risk-based credibility assessment framework and the importance of providing detailed information on AI model development and maintenance.
5. <https://citoday.com/news/fda-issues-draft-guidance-for-development-of-ai-enabled-medical-devices?c4src=home> - Mentions the FDA's plans for a webinar to discuss the draft guidance and the request for public comments by April 7, 2025.
6. <https://www.europeanpharmaceuticalreview.com/news/242364/fda-issues-first-recommendations-on-ai-for-drug-development/> - Highlights the use of AI to process and analyze large datasets, including real-world data and information from digital health technologies.
7. <https://www.biospace.com/fda/fdas-new-ai-guidance-highlights-risks-of-technology-urges-early-sponsor-engagement> - Discusses the FDA's commitment to supporting innovative approaches and the need for an agile, risk-based framework in AI integration.
8. <https://citoday.com/news/fda-issues-draft-guidance-for-development-of-ai-enabled-medical-devices?c4src=home> - Provides context on the FDA's authorization of over 1,000 AI-enabled devices and the comprehensive recommendations for AI-enabled devices throughout their lifecycle.
9. <https://www.europeanpharmaceuticalreview.com/news/242364/fda-issues-first-recommendations-on-ai-for-drug-development/> - Reiterates the significance of defining the model’s context of use given the diverse applications of AI technologies in drug development.
10. <https://www.biospace.com/fda/fdas-new-ai-guidance-highlights-risks-of-technology-urges-early-sponsor-engagement> - Mentions the FDA's previous discussion paper on AI in pharmaceutical drug development that laid the groundwork for this comprehensive guidance.
11. <https://citoday.com/news/fda-issues-draft-guidance-for-development-of-ai-enabled-medical-devices?c4src=home> - Supports the ongoing dialogue between the FDA and stakeholders to ensure the safe and effective integration of AI in pharmaceuticals.
12. <https://www.europeanpharmaceuticalreview.com/news/242364/fda-issues-first-recommendations-on-ai-for-drug-development/> - Please view link - unable to able to access data