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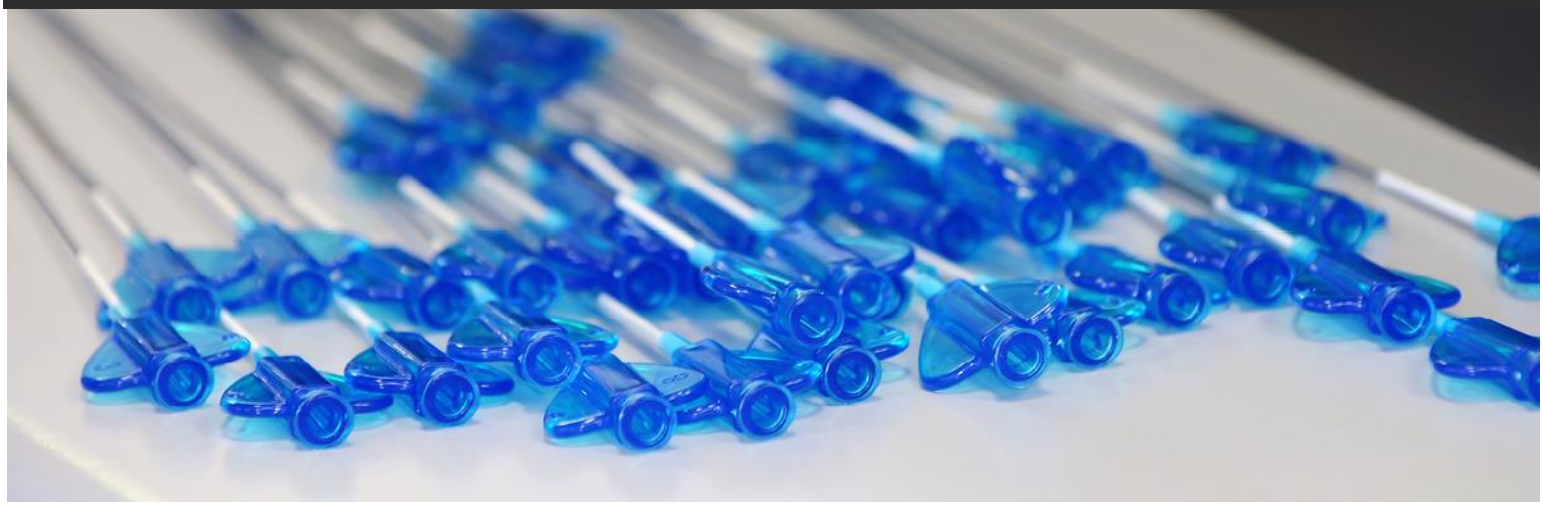

January 2025

FDA Releases Draft Guidance on AI-Enabled Medical Devices

Go-To Guide

- The FDA issued draft guidance on AI-enabled medical devices, emphasizing a total product life cycle approach from design to post-market monitoring.
- The guidance outlines recommended documentation for marketing submissions, including device descriptions, performance validation, and risk management plans.
- Transparency and bias mitigation are highlighted as crucial elements in fostering trust and ensuring equitable outcomes for AI-enabled devices.
- The FDA encourages manufacturers to provide clear, user-friendly labeling that explains AI functionality, limitations, and instructions for use.
- This guidance may be subject to review and revision in light of President Trump's recent AI-focused Executive Order.

On Jan. 7, 2025, the FDA issued its draft guidance, "Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations." In its latest draft guidance on medical devices, the FDA provides recommendations on the documentation and information that should be included in marketing submissions for devices that include AI-enabled device software functions.

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The guidance emphasizes the FDA's holistic total product life cycle (TPLC) approach, which requires manufacturers to consider the entire lifespan of an AI-enabled device—from initial concept and design to post-market performance monitoring. The guidance also underscores the importance of transparency and bias mitigation in AI-enabled devices to foster trust and equitable outcomes. By addressing the unique challenges AI poses, the guidance establishes standards for transparency, accountability, and flexibility in managing AI-enabled devices across their TPLC.

Total Product Life Cycle Approach

The guidance highlights the importance of managing AI-enabled devices using a TPLC approach. This method seeks to ensure continuous oversight, from design and development through post-market performance. The FDA's recommendations for manufacturers at each TPLC phase include:

- **Design and Development**: Integrate risk management and human factors engineering early in the design process to mitigate potential risks associated with AI functionalities.
- **Validation and Testing**: Utilize rigorous methodologies to validate AI performance, ensuring effectiveness across diverse patient populations and real-world settings.
- **Post-Market Monitoring**: Continuously monitor in real-time to identify and address performance deviations or safety concerns, supported by mechanisms for timely updates.

Marketing Submission Requirements

The FDA emphasizes the critical elements that sponsors should provide in premarket submissions for AI-enabled devices. These include:

- **Device Description**: Clear, comprehensive details about the device's inputs and outputs, an explanation of how AI is used to achieve the device's intended use, a description of the intended users, the level and type of training intended users have or will receive, the intended use environment, the intended workflow of the use of the device, and a description of installation and maintenance procedures, as well as any calibration or configuration procedures that must be regularly performed by users.
- **User Interface Information**: Information that demonstrates the device workflow and how that information is presented to users, which may be accomplished through graphical representations, written descriptions, example reports, and recorded videos.
- **Labeling**: Explanations, in an appropriate reading level, that the device includes AI, how AI is used to achieve the device's intended use, model inputs and outputs, any automated functions, model architecture, development and performance data and metrics, performance monitoring, any known limitations of the device, and instructions for use. Appendix E provides exemplar communication models for sponsors to consider when developing labeling.
- **Training and Testing Data**: Descriptions of data collection, data cleaning and processing, test data independence, reference standards, and representativeness.
- **Performance Validation**: Evidence to demonstrate accuracy, reliability, and repeatability in clinical and non-clinical settings, including testing for specific populations. Appendix C includes recommendations for clinical performance validation, while Appendix D describes human factors considerations.

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- **Change Management Plans**: Information regarding performance monitoring plans, including measures to capture device performance after deployment, including updates, mitigations, and corrective actions.
- **Risk Management**: A risk management file that includes a risk management plan and robust assessments to evaluate the risks of AI functions and their impact on patient safety, considering biases, software malfunctions, or data inaccuracies.
- **Cybersecurity and Data Integrity**: Information regarding the measures taken to protect against data breaches and ensure the integrity of AI models.
- **Public Submission Summary**: A summary with details about the AI-enabled device's characteristics for use in public facing documents. Appendix F provides examples for communicating the required information.

Appendix B includes recommendations for developing a transparent device centered on users. The draft guidance encourages sponsors to take a holistic, user-centered approach to transparency, beginning at the design phase of the TPLC to ensure important information is both accessible and functionally understandable. Because transparency is contextually dependent, appropriate information to include would vary across devices, and the draft provides examples for sponsors to consider.

Conclusion

By focusing on lifecycle management, transparency, bias mitigation, and flexibility, the FDA aims to balance innovation with public safety. Aligning with these recommendations may help manufacturers accelerate AI technology deployment in healthcare. The FDA actively seeks input from stakeholders, including manufacturers, healthcare professionals, and the public, to refine this draft guidance. Comments on the guidance are welcomed through April 7, 2025.

While currently uncertain, President Trump's rescission of President Biden's AI Executive Order No. 14110 and issuance of his own AI-focused Executive Order entitled "Removing Barriers to American Leadership in Artificial Intelligence" on Jan. 23, 2025, may lead to a widespread reevaluation of all AI policies and guidances agencies such as the FDA have submitted. Accordingly, relevant stakeholders should monitor the viability and advancement of this draft guidance.

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