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FDA Continues Focus on AI Fronts, Seeks Public Comment on Measuring and Evaluating AI-enabled Medical Device Performance in the Real-World

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On September 30, 2025, the Food and Drug Administration (FDA) published a Request for Public Comment to obtain feedback from interested parties on current approaches to measuring and evaluating the performance of AI-enabled medical devices. Specifically, FDA is seeking feedback on best practices, methodologies and approaches for measuring and evaluating real-world performance of AI-enabled medical devices from the public.

As FDA acknowledged in announcing the request for public comment, AI, including GenAI, presents opportunities to improve patient outcomes, advance public health and accelerate medical innovation. Many factors impact the performance of AI-enabled medical devices, including patient demographics, data inputs and changes in clinical practice. In announcing the request for public comment, the agency outlined how these dynamics can lead to data drift, which in turn can lead to performance degradation, among other issues. FDA further noted that many of these devices are evaluated primarily through retrospective testing or static benchmarks and these methods are not designed to predict behavior in real-world environments.

FDA is specifically interested in comments on (1) performance metrics and indicators; (2) real-world evaluation methods and infrastructure; (3) post-market data sources and quality management; (4) monitoring triggers and response protocols; (5) human-AI interaction and user experience; and (6) additional considerations and best practices. The agency hopes insights gathered from this request will build on discussions and insights shared during the

November 2024 meeting of the FDA Digital Health Advisory Committee. FDA has requested comments be submitted by December 1, 2025.

Categories

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