FDA Seeks Public Input on Evaluating AI-Enabled Medical Devices

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The FDA's Digital Health Center of Excellence is requesting public comment on methods for measuring and evaluating the performance of artificial intelligence-enabled medical devices. This initiative aims to improve regulatory clarity and foster innovation while ensuring safety and effectiveness. Stakeholders—including developers, clinicians, and researchers—are encouraged to share feedback on evaluation frameworks, performance metrics, and uncertainty quantification. Comments are due December 1.