December 1, 2025

U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Measuring and Evaluating Artificial Intelligence–Enabled Medical Device Performance in the Real World
(Docket No. FDA-2025-N-4203)

The American Medical Informatics Association (AMIA) appreciates the opportunity to provide comments on the U.S. Food and Drug Administration's (FDA) request for public input regarding approaches to measuring and evaluating artificial intelligence (AI)–enabled medical device performance in real-world clinical settings. The American Medical Informatics Association is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, and public health experts who bring meaning to data, manage information, and generate new knowledge across the health and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

AMIA brings unique expertise regarding AI implementation in healthcare settings. AMIA's perspective is grounded in its Public Policy Principles, which emphasize safe, effective, ethical, and evidence-based AI adoption in healthcare[1]. The FDA's request for comment recognizes the dynamic nature of real-world healthcare environments and the need for ongoing assessment of AI-enabled device performance after deployment, which is consistent with established informatics and responsible AI frameworks.

Alignment with Informatics Governance and Responsible AI Principles
AMIA supports the FDA's attention to real-world performance assessment, given that AI-enabled medical devices may behave differently across populations, settings, workflows, and infrastructural contexts. The AMIA Public Policy Principles stress the importance of prudent AI introduction, governance, and maintenance, emphasizing data quality, safety, and meaningful clinical benefit. Similarly, CHAI's Responsible AI Guide identifies lifecycle governance, encompassing safety, effectiveness, fairness, transparency, and documentation, as foundational to trustworthy AI.[2] The FDA's recognition that factors such as shifting patient demographics, contextual variability, and data drift can influence device

[1] American Medical Informatics Association (AMIA). *AMIA Public Policy Principles 2024.* Available at: https://brand.amia.org/m/11e36a0494d4bc9a/original/AMIA-Public-Policy-Principles-2024-Final.pdf

[2] Coalition for Health AI (CHAI). *Responsible AI Guide.* Available at: https://www.chai.org/assurance-standards-guide

performance highlights the limitations of static pre-market evaluation and reinforces the importance of sustained post-market oversight.

Recommended Metrics and Framework for Real-World Performance Evaluation
A comprehensive real-world evaluation framework requires standardized, multidimensional metrics that extend beyond model accuracy alone. These include clinical outcome impact, safety indicators, stability of performance across data distributions and subpopulations, human–AI interaction measures, usability, reliability, and workflow integration outcomes. This approach aligns with CHAI's recommendations emphasizing usefulness, usability, safety, fairness, and operational clarity. In addition, AMIA's informatics-driven quality measurement principles underscore the importance of shared data standards and clear definitions to enable reproducible assessment across sites. Continuous monitoring for performance drift, such as changes in data distributions, clinical practice patterns, or patient characteristics, should be standard practice. The FDA's call for input acknowledges that drift poses a risk to patient safety and device effectiveness, thereby supporting structured surveillance frameworks.

Lifecycle Management, Governance, and Post-Market Oversight
AMIA supports a lifecycle governance model in which AI-enabled devices undergo continuous monitoring, documentation, and version control after market authorization. AMIA's principles affirm the need for infrastructure that enables ongoing safety assessment, maintenance, and iterative improvement of digital health technologies. CHAI's Responsible AI Guide similarly emphasizes robust governance, including audit trails, model update documentation, and periodic reevaluation to ensure continued alignment with clinical intent and risk thresholds. For adaptive or updateable algorithms, post-market processes analogous to pharmacovigilance may be necessary. Such mechanisms should include triggers for revalidation or corrective action when performance degradation or unintended impacts are detected. Institutional governance committees comprising informaticians, clinicians, and technical experts play a critical role in oversight and accountability.

Transparency, Documentation, and Stakeholder Communication
Transparent documentation and communication regarding AI-enabled devices are essential for clinical integrity and user trust. AMIA emphasizes the importance of clarity around intended use, model design, training data characteristics, limitations, and governance procedures. CHAI likewise identifies transparency, explainability, and documentation as key dimensions of responsible AI. Transparency should extend to device updates, including changes that occur during retraining, shifts in model performance, and corrective actions taken in response to drift or safety concerns. Such communication enables informed clinical decision-making and supports safe and effective integration of AI into clinical workflows.

Equity, Bias Assessment, and Health Disparities
AMIA underscores that equity and bias assessment must be integral components of real-world performance evaluation. The AMIA Public Policy Principles emphasize that AI systems should advance equitable care and avoid perpetuating existing disparities. CHAI

likewise identifies fairness and bias mitigation as essential elements of responsible AI throughout the lifecycle. Real-world evaluation processes should require robust subgroup analyses, such as by age, gender, race and ethnicity, socioeconomic variables, or SDoH, to identify differential performance or disparate impact. When disparities are detected, remediation strategies such as recalibration, targeted retraining, or revised usage guidance may be appropriate. Integrating equity evaluation into post-market monitoring helps ensure that AI-enabled devices support fair and inclusive healthcare delivery.

Research, Data Sharing, and Aggregate Reporting

AMIA supports cross-institutional data sharing and aggregated performance reporting to facilitate scientific learning, transparency, and comparative evaluation. AMIA's principles emphasize the need for interoperable data standards, data quality infrastructure, and shared resources to support learning health systems. CHAI's guidance also highlights the importance of ongoing monitoring, published documentation, and systematic reporting. Aggregated real-world evidence, including performance trends, bias analyses, drift observations, and outcomes associated with device updates, can support evidence-based regulation and continuous improvement in the use of AI-enabled medical devices.

Conclusion

AMIA appreciates the FDA's leadership in advancing the evaluation of AI-enabled medical devices and supports the agency's commitment to developing frameworks that ensure real-world safety, effectiveness, transparency, and equity. The convergence of FDA's priorities with AMIA's principles and CHAI's Responsible AI Guide provides a strong foundation for lifecycle-oriented, metrics-driven, equitable, and transparent oversight. AMIA welcomes continued collaboration with the FDA and the broader digital health community as regulatory and methodological frameworks for AI-enabled medical devices evolve.

For questions or additional information, please contact Tayler Williams, AMIA's Senior Manager of Public Policy, at twilliams@amia.org.

References

1. U.S. Food and Drug Administration. *Request for Public Comment: Measuring and Evaluating Artificial Intelligence–Enabled Medical Device Performance in the Real World.* Available at: https://www.fda.gov/medical-devices/digital-health-center-excellence/request-public-comment-measuring-and-evaluating-artificial-intelligence-enabled-medical-device
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