

Monitoring AI Tools in Healthcare for Developers and Implementers

January 2026

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Executive Summary

Healthcare organizations are increasingly integrating artificial intelligence tools into clinical workflows; yet, there is a gap in guidance for what should happen after these tools go live. To fill the gap, this project recommends that developers and implementers of AI-enabled clinical decision support (AI-CDS) tools adopt a new framework to monitor the tools' performance after they are deployed. The new framework, TRACE, would track AI-CDS tools' performance across the criteria of Technical Integrity, Real-World Use, Alignment and Accuracy, Clinical Fairness, and Escalation and Safety Response. The project argues that incorporating TRACE would help organizations detect issues early, plan processes for responding to risks, and promote responsible adoption of AI in healthcare.

Problem

AI-CDS tools suggest diagnoses and recommend next steps for patients. However, the vast majority of these tools cleared by the U.S. Food and Drug Administration do not have postmarket surveillance plans. Therefore, without clinicians knowing, tools may fall out of sync with clinical guidelines or cause uneven results across patient populations. Further, studies have shown that unmonitored AI-CDS tools can lead to clinicians both distrusting the tools and over-relying on the tools' outputs. While safety frameworks exist for other stages of AI development, there are few guidelines for addressing these post-deployment performance risks.

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“Rather than requiring developers and health systems to design monitoring protocols from scratch, TRACE offers a clear, implementation-ready framework that can be integrated into existing quality improvement processes.”

Solution

This project proposes that AI-CDS developers and implementers prioritize post-deployment monitoring by adopting the TRACE framework early on in the process. The TRACE guidelines aim to help organizations monitor if a tool is functioning consistently and how clinicians actually use the tool. Rather than requiring organizations to design in-house monitoring protocols from scratch, the framework offers a flexible standard that can be easily adapted to fit each stakeholder’s existing processes. It can be incorporated into or used alongside existing standards developing by the Coalition for Health AI (CHAI) and the National Institute of Standards and Technology (NIST). The project predicts that the organizations’ combined efforts to use TRACE would support better understanding of tool performance in real-world use and increase confidence and adoption of AI-CDS tools across healthcare organizations.

If you’d like to learn more, see the full project at aspenpolicyacademy.org/project/ai-cds-monitoring-2025.



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