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# Tracking AI-Enabled Healthcare Tools' Safety

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## Executive Summary

Clinicians are increasingly integrating artificial intelligence tools into their 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 and the Coalition for Health AI (CHAI) 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 stakeholders incorporating TRACE would help organizations detect issues, plan processes for responding to risks, and promote reliable health AI standards.

## 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' diagnostic results. While safety frameworks exist for other stages of AI development, there are few guidelines for addressing these post-deployment performance risks.

**To learn more about this project, visit aspenpolicyacademy.org. Please note that the author's opinions published here are their own. This publication does not reflect the views of the Aspen Policy Academy or the Aspen Institute.**

*"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 CHAI, AI-CDS tool developers, and AI-CDS tool users prioritize post-deployment monitoring by adopting the TRACE framework early on in the approval 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, the framework offers a standard that can be adapted to fit each stakeholder's existing processes and CHAI's certification criteria. The project predicts that the organizations' combined efforts to use TRACE would not only support continued safety but accelerate shared learning across the AI-CDS industry.

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

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