Dan Noyes
Patient Leader & Responsible AI Health Strategist

Oct 2, 2025

To the FDA Digital Health Center of Excellence,

As both a patient living with a chronic neurological condition and a healthcare AI strategist, I strongly support the FDA's initiative to establish clear methods for evaluating AI-enabled medical devices in real-world use.

From the patient perspective, approval is not the finish line — it is the starting line. Patients need confidence that these devices will continue to perform safely and fairly after deployment. Without transparent monitoring, silent failures such as model drift or bias could erode trust and jeopardize outcomes.

From the system perspective, hospitals and clinicians need practical, consistent guardrails that fit within clinical workflows. Continuous monitoring must be not only technically rigorous but also operationally feasible — providing clear alerts when models degrade, requiring transparent disclosure of model updates, and ensuring interpretability for frontline clinicians.

I urge the FDA to prioritize three principles in its framework:

1. Lifecycle transparency — patients and clinicians should be notified when models are updated or materially change.

2. Equity and inclusivity — monitoring systems must test across diverse populations to ensure that performance is not unevenly distributed.

3. Patient-centered disclosure — patients deserve accessible explanations of how AI tools are influencing their care decisions.

The FDA's leadership in this area can help balance innovation with accountability. As someone who bridges lived experience and system strategy, I view continuous monitoring not as regulatory burden but as essential infrastructure for trust.

Thank you for the opportunity to comment, and for ensuring that patient voices remain central to the future of digital health.

Respectfully,

Dan Noyes
Certified Patient Leader
Healthcare AI Consultant & Advisor
(585) 230-9565
dan@dannoyes.com