TRANSPARENCY OF ARTIFICIAL INTELLIGENCE / MACHINE LEARNING (AI/ML)-ENABLED MEDICAL DEVICES: FDA VIRTUAL PUBLIC WORKSHOP

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www.fda.gov/digitalhealth
Advances in AI/ML

Transforming Health Systems and Daily Lives

Some of the greatest benefits are AI/ML’s ability to learn from real-world use and experience, and its capability to improve its performance.
Unique Considerations

We recognize the need for careful oversight to **ensure the benefits** of these advanced technologies **outweigh the risks** to patients.
Proposing a Regulatory Framework

Published in 2019
Discussion Paper and Request for Feedback

- Received stakeholder feedback through:
  - > 1,000 comments on public docket
  - > 30 publications in peer-reviewed journals
  - Pre-submission meetings on AI/ML devices
  - Patient Engagement Advisory Committee Meeting
Partnering to Foster Responsible Innovation

Launched in 2020
FDA’s Digital Health Center of Excellence

• Part of the planned evolution of the digital health program
• Aligning strategy with implementation
• Driving synergy for digital health efforts
• Preparing FDA for the digital health future
Next Steps: Tailoring a Regulatory Framework

Published in 2021
Action Plan for AI/ML-Based SaMD

Outlines five next steps to advancing access:

1. Update the proposed AI/ML regulatory framework
2. Strengthen FDA’s role in harmonizing GMLP
3. Foster a patient-centered approach
4. Support development of regulatory science methods
5. Advance real-world performance pilots
Understanding Transparency

Transparency is crucial to help providers and patients make informed decisions about their use of a device with AI/ML capabilities.

Source: The Medical Futurist
Transparency for All Users

Common User Questions:

• How does it work?
• How does it influence care?
• Will it work for my patient in a particular environment?
• What is being done with my data?
• What do I need to know?
• What are the benefits? Risks? Limitations?
Collaborating with You

Our Goal is to Hear from You!

- Establishing safety and effectiveness
- Considerations for achieving transparency for users
- Lessons learned in the real world
- Possible means of promoting transparency