

Digital Health Center of Excellence

Empowering digital health stakeholders to advance health care

FDA



Transparency of Artificial Intelligence/Machine Learning-enabled Medical Devices

Virtual Public Workshop

October 14, 2021



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Center for Devices and Radiological Health (CDRH)

U.S. Food and Drug Administration

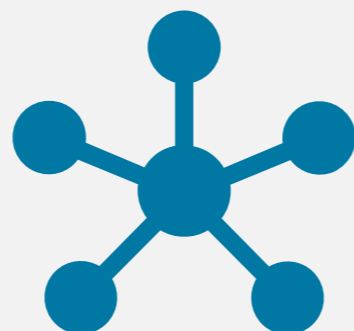
This Workshop



**Direct response to stakeholder feedback,
including the 2020 FDA Patient Engagement
Advisory Committee meeting**



**Fulfilling part of FDA's January 2021 Action
Plan focused on AI/ML-enabled medical
devices**



Broad stakeholder engagement is encouraged

Workshop Goals

- Identify unique considerations in achieving transparency for users of AI/ML-enabled medical devices and ways in which transparency might enhance the safety and effectiveness of these devices
- Gather input from various stakeholders on the types of information that would be helpful for a manufacturer to include in the labeling of and public facing information of AI/ML-enabled medical devices, as well as other potential mechanisms for information sharing.



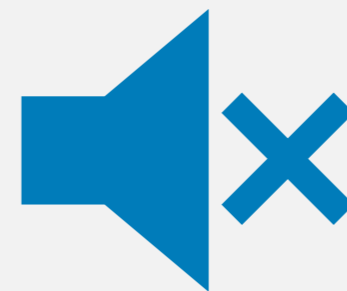
Agenda

10:00 am	Welcome and Opening Remarks
10:30 am	Session I. The Meaning and Role of Transparency <i>(Presentations, panel discussion, and Q&A)</i>
12:00 pm	Lunch
12:30 pm	Open Public Comment Session
1:20 pm	Break
1:30 pm	Session II. Promoting Transparency <i>(Presentations, panel discussion, and Q&A)</i>
3:15 pm	Closing Remarks
3:30 pm	Adjourn

Logistics



Click on either window to enlarge it in the webcast viewer



All attendees will remain muted throughout the entire webcast



The FDA Studio will monitor for any technical problems and work to address them as they are able



To ask a question, click on the thought bubble icon in the webcast window

Workshop Materials

After the workshop, you can find the following materials on the workshop webpage:

- ✓ The webcast
- ✓ The transcript
- ✓ The presentation slides

Submitting Comments

- Instructions found on the workshop website.
- Please submit your comments regarding the workshop to



www.regulations.gov/

Docket No. FDA-2019-N-1185

By November 15, 2021

- The resulting discussions from the workshop and comments received in the docket will be taken into consideration.