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
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.
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>10:00 am</td>
<td>Welcome and Opening Remarks</td>
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<tr>
<td>10:30 am</td>
<td>Session I. The Meaning and Role of Transparency <em>(Presentations, panel discussion, and Q&amp;A)</em></td>
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<tr>
<td>12:00 pm</td>
<td>Lunch</td>
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<tr>
<td>12:30 pm</td>
<td>Open Public Comment Session</td>
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<tr>
<td>1:20 pm</td>
<td>Break</td>
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<tr>
<td>1:30 pm</td>
<td>Session II. Promoting Transparency <em>(Presentations, panel discussion, and Q&amp;A)</em></td>
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<tr>
<td>3:15 pm</td>
<td>Closing Remarks</td>
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<td>3:30 pm</td>
<td>Adjourn</td>
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*All times in ET*
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.