Transparency of Artificial Intelligence/ Machine Learning (AI/ML)-Enabled Medical Devices:
FDA Virtual Public Workshop

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CDRH Digital Health Center of Excellence, US FDA

www.fda.gov/digitalhealth
Continuing Our Collaborative Approach

Evolving Role of AI in Radiological Imaging
February 28-28, 2020

PEAC Meeting
February 2020

AI Radiology Workshop
February 2020

Collaborative Communities
September 2019

Discussion Paper
April 2019

AI/ML Action Plan
January 2021

Today's Workshop
October 14, 2021

Requesting Your Continued Input
Please submit your comments regarding the workshop to www.regulations.gov Docket No. FDA-2019-N-1185 by November 15, 2021
Presentation Outline

• Brief Overview of AI/ML-Enabled Devices

• Workshop Focus:
  1. What Does Transparency Mean?
  2. Why is Transparency so Important?
  3. How Can We Promote Transparency?
AI/ML-Enabled Medical Devices

Artificial Intelligence (AI):
A branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviors such as learning, making decisions and making predictions.

Machine Learning (ML):
A subset of AI that allows computer algorithms to learn through data, without being explicitly programmed, to perform a task.

AI/ML-Enabled Medical Device:
A medical device that uses machine learning to achieve its intended medical purpose.

Descriptions adapted from IMDRF Artificial Intelligence Medical Devices Key Terms & Definitions
Proposed document posted for public consultation Sept 2021 through Nov 29, 2021
http://www.imdrf.org/consultations/cons-aimd-mlmd-ktd.asp
Examples of AI/ML-Enabled Medical Devices

FDA News Release
FDA Authorizes Marketing of First Cardiac Ultrasound Software That Uses Artificial Intelligence to Guide User

February 7, 2020

Caption Guidance™ (Caption Health, Brisbane AU). Figure from www.captionhealth.com

FDA News Release
FDA Authorizes Marketing of First Device that Uses Artificial Intelligence to Help Detect Potential Signs of Colon Cancer

April 9, 2021

GI Genius™ (Medtronic Inc., Minneapolis, Minnesota, USA). Figure from Hassan C et al. Gut. 2019.
# FDA Resources on AI/ML-Enabled Medical Devices

**Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices**

<table>
<thead>
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AI/ML-Enabled Medical Devices: Opportunities & Challenges

OPPORTUNITIES

• Significant positive impact on health care
  • Earlier disease detection
  • More accurate diagnosis
  • New insights into human physiology
  • Personalized diagnostics and therapeutics
• Applications across all medical fields
• Ability to learn, adapt, and improve performance

CHALLENGES

• Fit-for-purpose data sets for development and testing, including diversity
• Identification and minimization of bias
• Opacity of some algorithms
• Providing oversight for an adaptive system
• Ensuring transparency to users
Working Definition of Transparency

TRANSPARENCY:
Degree to which appropriate information about a device
– including its intended use, development, performance, and, when available, logic – is clearly communicated to stakeholders

*Working definition of Transparency, above, for purposes of this workshop adapted from ISO/IEC JTC1 SC42 WG1 25059 (draft)
Transparency is Fundamental to a Patient-Centered Approach

1. Allows patients, providers, and caregivers to make informed decisions
2. Supports proper use of a device
3. Promotes health equity
4. Facilitates evaluation and monitoring of device performance
5. Fosters trust and promotes adoption
Continuing to Improve Transparency

• What are the needs of specific stakeholders?
• What is the appropriate information to communicate?
• What is the best way to communicate that information?
  ➢ How can device labeling be improved?
  ➢ How can other public-facing information be improved?
  ➢ What else can be done to promote transparency?

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