AI/Machine Learning: Regulation, Development, and Real-World Performance Evaluation

Virtual Public Meeting
March 22, 2022

12:30 pm – 4:00 pm ET

Meeting Objective: This webinar will spotlight updates and progress since the January 2021 release of U.S. Food and Drug Administration’s Center for Device and Radiological Health’s (FDA CDRH) AI/ML Action Plan. Each panel will focus on one aspect of the Action plan, starting with an overall framework for regulating AI, development of Good Machine Learning Practices, and post-market evaluation of AI/ML Software as a Medical Device (SaMD).

12:30 pm Welcome and Overview
Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy

12:35 pm Fireside Chat
Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy
Jeffrey Shuren, CDRH, US FDA

1:00 pm Session 1: Frameworks for Regulating AI/ML Medical Device Software
Objective: FDA has done considerable work thinking through efficient regulatory processes around AI/ML and medical device software more generally. This session will focus on consideration for regulating AI/ML-enabled devices. Panelists will discuss the regulatory processes for AI/ML-enabled products, including change control plans – where the process is working well, where there are challenges, and where there are gaps in the regulatory science.

Panelists:
Matthew Diamond, US FDA
Berkman Sahiner, US FDA
Mona Flores, NVIDIA
Pat Baird, Philips
Kathleen Blake, American Medical Association
Cynthia Chauhan, Heart Failure Society of America

Moderator: Christina Silcox, Duke-Robert J. Margolis, MD, Center for Health Policy
1:45 pm  **Session 2: Good Machine Learning Practices in the US and Globally**

*Objective:* This session will focus on emerging good machine learning practices (GMLP) for the development of AI/ML-enabled medical device software. Topics will include the recently released harmonized GMLP guiding principles document from FDA, Health Canada, and the UK, as well as other GMLP initiatives from national and international public and private entities.

Panelists:
- **Janet Hendry**, Health Canada
- **MiRa Jacobs**, US FDA
- **Johan Ordish**, Medicines and Healthcare products Regulatory Agency (UK)
- **Scott Thiel**, Hologic
- **Linda Ricci**, US FDA

Moderator: **Suresh Balu**, Duke Health

2:30 pm  **Break**

2:35 pm  **Session 3: Evaluating Real-World Performance of AI/ML SaMD**

*Objective:* This session will focus on what may be needed to understand the real-world performance of these devices and how these data can be used to support long-term evaluation and monitoring of AI/ML-enabled devices coming to market as well as tracking performance of modifications to these algorithms over time. Discussion will outline the various categories of real-world performance (RWP) measures, where real-world data (RWD) and real-world evidence (RWE) may be useful in supporting these evaluations, and where there are challenges collecting, accessing, or using RWD. This session will highlight an upcoming Duke-Margolis white paper on the accessibility of RWD for evaluations of AI SaMD, among other topics.

Panelists:
- **Andrew Auerbach**, University of California, San Francisco
- **Vinay Pai**, US FDA
- **Robbert Zusterzeel**, IQVIA
- **Barbara Evans**, University of Florida
- **Nick Petrick**, US FDA

Moderator: **Rachele Hendricks-Sturrup**, Duke-Robert J. Margolis, MD, Center for Health Policy
3:20 pm  Business Roundtable

Objective: This roundtable session will look at how businesses are considering the current regulatory landscape and evaluation of AI/ML-enabled medical devices, as well as implementing good machine learning practices and post-market evaluation of products.

Panelists:
Jen Baird, Fifth Eye
David Golan, Viz.ai
Jodi Daniel, Crowell and Moring

Moderator: Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy

3:50 pm  Summary and Next Steps

Mark McClellan, Duke-Robert J. Margolis, MD, Center for Health Policy

This meeting is partially funded by a grant from the Gordon and Betty Moore Foundation