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 FDA CDRH’s AI 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 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
Jeff Shuren, CDRH, US FDA

1:00 pm Session 1 – Frameworks for Regulating AI/ML Medical Device Software
Objective: FDA has done considerable work rethinking 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 – both where the process is working well, where there are challenges, and where there are gaps in the regulatory science.

1:45 am 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 SaMD and SiMD. Topics will include the recently released harmonized GMLP document from FDA, Health Canada, and the UK, as well as other GMLP frameworks from national and international public and private entities.

2:30 pm Break

2:35 pm Session 3: Evaluating Real-World Performance of AI/ML SaMD
Objective: This session will focus on what evaluations will be needed to understand real-world performance of these devices. Discussion will outline the various categories of real-world performance (RWP) measures, and where real-world data (RWD) and real-world evidence (RWE) may be useful in supporting these evaluations, and where there are challenges 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.
3:20 pm  Business Roundtable

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

3:50 pm  Summary and Next Steps

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

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