MoFo Life Sciences: Five Key Takeaways from FDA's Transparency of AI/Ml-Enabled Medical Devices Virtual Workshop

By: Rachel Park and Stacy Cline Amin

On October 14, 2021, the Food and Drug Administration (FDA) held a virtual public workshop on transparency surrounding Artificial Intelligence/Machine Learning (AI/ML) enabled medical devices. The workshop focused on the role of transparency in enhancing the safe and effective use of AI/ML technology in the medical device space, with an emphasis on information-sharing methods for patients, caregivers, and providers.

Below are five key takeaways from the workshop:

1. Cultivating user awareness for both patients and healthcare providers will be a key area of focus for AI/ML-enabled device manufacturers and regulators going forward. In presentations and panel discussions, many panelists expressed concern as to whether healthcare providers would understand the limitations of AI/ML devices and be able to properly interpret and use the data in administering care.

2. Transparency and effective communication of AI/ML medical device labeling will be important to consider for all user types. Panelists discussed the idea of a nutrition facts label approach to AI/ML device labeling, using the analogy of food labeling to describe the balance of information and detail needed to enable users to make informed decisions.

3. Bias and systemic discrimination remain persistent issues in the AI/ML space. FDA and various industry stakeholders expressed commitment to ensuring that the data used to train AI/ML models are diverse and accurately reflect the patient population in which the technology will be used. Use of synthetic or artificial datasets to close the data gap and ensure devices are trained using ethnically diverse datasets has been a particularly relevant discussion.

4. Inequality, from both a patient and a manufacturer perspective, was a key topic of conversation during the workshop. Panelists discussed the potential for inequitable access to AI/ML devices across different patient populations, as well as the potential for unequal access to data amongst manufacturers in the industry.

5. Transparency surrounding tracking and reporting of device error or malfunctions will be an important topic of discussion as AI/ML-enabled devices are made available. Panelists discussed the potential for two-way communication between manufacturers and users, and FDA's role in promoting such transparency.

The recording of the webcast, transcript, and presentation slides will be posted on the Workshop webpage within the next few weeks. FDA will continue to receive and review comments and questions regarding transparency of AI/ML-enabled medical devices online on the public docket. Comments may be submitted on regulations.gov (Docket No. FDA-2019-N-1185) until November 15, 2021.

For questions on any of the topics discussed at this meeting, please contact the authors or a member of MoFo's FDA Regulatory + Compliance practice.