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

Resources shared during the meeting

Virtual Public Meeting
March 22, 2022
12:30 pm – 4:00 pm ET

FDA Resources:

- U.S. FDA Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan.

Duke-Margolis Resources:


Other Resources:

Panel 1:

- Trustworthy Augmented Intelligence in Health Care: https://link.springer.com/article/10.1007/s10916-021-01790-z
- Federated learning for predicting clinical outcomes in patients with COVID-19: https://www.nature.com/articles/s41591-021-01506-3


Panel 2:


Business Roundtable:

• https://startupceoreflections.com/effectively-engaging-the-fda/
• https://startupceoreflections.com/the-fda-are-people-too/
• https://startupceoreflections.com/comparing-the-fda-510k-and-de-novo-device-pathways/

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