



CBDS Digital Health Series

“Regulatory Considerations and Algorithm Assessment Methods for Devices Leveraging Artificial Intelligence and Machine Learning (AI/ML) in Medical Imaging”

Nicholas Petrick, PhD

Host: Xenophon Papademetris

Zoom: <https://yale.zoom.us/j/92130271030>



Artificial intelligence and machine learning (AI/ML) tools are quickly becoming ubiquitous in modern society. While the introduction of AI/ML based digital health tools, especially those directly supporting medical decision making, have seen slower migration to the clinical setting compared to other sectors, clinical decision support tools are increasing available. The number of digital health tools on the market is growing quickly with the potential for some of these tools to transform current clinical decision-making processes. New types of radiological AI/ML tools include detection tools to aid in localizing potential disease, diagnostic tools to aid in the assessment of disease, triage tools to aid in prioritization of time-sensitive imaging studies for clinical review, and optimization tools to improve image acquisition. Many of the current computer assist tools have the potential to evolve towards autonomous operation which can introduce new safety and effectiveness concerns. A continuing challenge for the FDA is the regulation of AI/ML-based devices in a least burdensome manner while ensuring their safety and effectiveness.

In this talk, I will introduce FDA’s medical device regulatory processes with the goal of demystifying how medical devices, especially radiological devices, are regulated in the U.S. I will describe several computer-assist technologies and will go on to discuss specific methods for assessing and evaluating algorithms designed to aid medical image interpretation. This latter discussion of evaluation methods will focus on how to assess an algorithm’s standalone performance and how to assess an algorithm’s ability to aid clinical decision making. I will also include a discussion of research efforts within my laboratory focused on efficiently utilizing limited sized datasets in AI/ML and methods for efficient assessment of medical imaging and AI/ML devices.

Dr. Nicholas Petrick is the Deputy Director for the Division of Imaging, Diagnostics and Software Reliability within the U.S. Food and Drug Administration, Center for Devices and Radiological Health and is a member of the FDA Senior Biomedical Research Service. He earned his B.S. degree from Rochester Institute of Technology in Electrical Engineering and his M.S. and Ph.D. degrees from the University of Michigan in Electrical Engineering Systems. His research includes development of AI/ML for medical imaging and digital health, quantitative imaging methods and assessment methodologies for AI/ML and imaging devices.

Wednesday, December 16, 2020
4:00 to 5:00 p.m.

