

2020 GLOBAL CONFERENCE ON REGULATORY SCIENCE

MACHINE LEARNING AND DATA SCIENCE

Oct 20-21, 2020 | 10am - 3:30pm ET | Virtual Meeting

Working Group: Digital Pathology, AI and Image-Based Biomarkers in Research and Clinical Practice

This workshop will cover emerging digital pathology technologies, image-based biomarkers and diagnostics, construction of multiplexed tissue and tumor atlases, use of digital pathology in clinical and research settings, and the regulation of new devices and tests. We will have two live (virtual) meetings and then develop a white paper subsequently.

Anatomic pathology is one of the most important diagnostic modalities but it relies on technologies that are little changed in nearly a century: direct inspection of stained tissue sections using transmitted light microscopy. In the last few years however, pathology has become increasingly digital and is being transformed both by new measurement methods (such as multiplexed high-resolution imaging) and use of machine-learning or artificial intelligence (ML/AI) methods to interpret images and improve diagnosis. These developments will have a particularly large impact on precision medicine because they promise to combine the traditional strengths of histopathology with the molecular information needed to refine diagnostic and prognostic categories and specify optimal targeted therapies. However, the introduction of unfamiliar and untested imaging and ML/AI technologies brings substantial challenges with respect to evaluating performance and ensuring compliance with regulations.

WORKSHOP TOPICS

- Current and emerging computational and imaging technologies, including ML/AI algorithms
- Research and translational applications of digital pathology and multiplexed imaging
- Clinical use of digital pathology in areas such as cancer immunoprofiling
- Standardization of formats, algorithms and test suites and implementation of FAIR data policies in research
- Evaluation and regulation of digital pathology as a clinical service and companion diagnostic

WORKSHOP DELIVERABLES:

- Joint discussion of challenges and opportunities in use of digital pathology in research and clinical applications among individuals involved in patient care, federal funding, regulatory review, manufacture of instruments and development of commercial algorithms
- Preparation of a whitepaper on digital pathology for submission to a peer-reviewed, open-science journal. The organizers will oversee writing of this paper and workshop participants can be involved as *active* co-authors or contribute to review of the paper pre-publication.

Sponsored by: The HMS Laboratory of Systems Pharmacology, the Departments of Pathology at the Brigham and Women's Hospital and the Dana-Farber Cancer Institute, and the Human Tumor Atlas Network, a National Cancer Institute Cancer Moonshot Program.

WORKING GROUP TIMES

10/20 3:30pm-5pm &
10/21 3:45pm-5:15pm

THE CONFERENCE

Hosted by *Harvard-MIT Center for Regulatory Science*, the [2020 Global Conference on Regulatory Science](#) will convene academic scientists and physicians, international regulators, industry experts and patient groups to explore emerging topics at the intersection between regulatory science and therapeutic development.



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