

WSI Working Group

Brandon Gallas,
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Outline

- Getting Started
 - Organizing Committee
 - Membership
- Collaboration Website
 - How to join
 - Information posted
- Goals
- Next Steps
 - Steering Committee
 - Topic/Project Proposals

Organizing Committee

- Brandon D. Gallas PhD
- Marios A. Gavrielides PhD
 - Division of Imaging, Diagnostics, and Software Reliability
 - Office of Science and Engineering Laboratories
 - Center for Devices and Radiological Health
 - U.S. Food and Drug Administration
- Darren Treanor MB, BSc, PhD, FRCPath
 - Leeds Teaching Hospitals NHS Trust
 - University of Leeds
- Stephen M. Hewitt MD, PhD
 - Laboratory of Pathology
 - Center for Cancer Research
 - National Cancer Institute
 - National Institutes of Health



Brandon



Marios



Darren



Stephen

Marios A. Gavrielides

FDA/CDRH/OSEL/Division of Imaging, Diagnostics and Software Reliability

- Image Analysis, computer classifiers
 - HER2 assessment CAD
- Reader studies
 - With and without CAD
 - Digital vs. optical microscopy, exploring tasks
 - Ovarian cancer subtyping
- WSI color reproducibility
 - Impact on image analysis
 - Phantoms

Darren Treanor

Leeds Teaching Hospitals NHS Trust, University of Leeds

- Practising pathologist
- Runs Leeds digital pathology project
www.virtualpathology.leeds.ac.uk
- Research interests in digital pathology
 - workstation design
(including efficiency & accuracy)
 - image analysis
 - 3D pathology

Stephen M. Hewitt

NIH/NCI/CCR/Laboratory of Pathology

- Anatomic Pathologist
 - Translational /Clinical Trials Pathology
 - High Throughput Assays
- Association for Pathology Informatics: Program Chair
- Histochemical Society: Treasurer

- Active for over 10 years in the WSI Space
- FDA Consultant WSI/IHC
- FDA Collaborator on topics related to WSI

Brandon D. Gallas

FDA/CDRH/OSEL/Division of Imaging, Diagnostics and Software Reliability

FDA

- Applied Math, PhD
- Clinical Trials (Imaging)
 - Study Design and Analysis
 - Reader Variability
- Digital Mammography, CT
- Computer aids to clinicians
 - Depth of anesthesia (EEG)
 - Tumor detection (chest X-rays, colon CT, mammo.)
 - Cell classifiers (Digital Pathology)
- Digital Pathology

Resources

- <https://code.google.com/p/iMRMC>
 - Software to simulate, analyze, size and power reader studies
- <https://code.google.com/p/eeDAP>
 - Evaluation environment for digital and analog pathology

Membership

- 72 persons asked us to join
 - FDA
 - NIH
 - WSI Industry (and related industries)
 - Health Care Providers/Networks
 - Academia
- Transitioning from list of emails to collaboration hub

Collaboration Website

- https://NCIPHub/groups/wsi_working_group
- Demo process to join group
- Give quick tour of site
 - FDA Medical Device Development Tool Pilot
 - CDRH Experiential Learning Program (ELP)
 - Mock Submissions to FDA
 - Editorial

Short-term Goals

Excerpted from Editorial to J. Pathol. Inform.

- To form a group of interested parties
- To lay out the key technical performance metrics for WSI
 - gather information on the current state of the science, identify gaps in knowledge and unmet needs, and identify circumstances in which technical performance has been linked to diagnostic performance.
- To raise awareness of the issues among
 - pathologist users, vendors, regulators, and research and healthcare funding agencies

Long-Term Goals

Excerpted from Editorial to J. Pathol. Inform.

Facilitate and promote research to

- Develop, standardize, and explore the range of technical performance metrics in WSI
- Design and execute experiments investigating pathologist performance as a function of image quality
- Create and disseminate methods, tools, examples, and recommendations for evaluating technical and diagnostic performance
 - (phantoms, shared sets of slides, WSI images, protocols, study designs, analysis methods and source code)

Goals

Personal

- WSI working group will be a hub for
 - Community-based research
 - Recruiting readers and sites
 - Sourcing materials
 - Feedback on and sharing of study questions, designs, protocols, results

Next Steps

- Steering Committee
- Topic/Agenda/Project Proposals
 - Coordinate with ICC MIWG
- Face-to-face meeting
 - SPIE Medical Imaging, Feb?
 - Pathology Informatics, May?

FDA in the Community

- Standards
- Medical Device Innovation Consortium
 - Unique public-private partnership that enables pre-competitive collaboration between medical technology stakeholders
- Recent interactions with MITA
 - Dose Reduction in CT
- Quantitative Imaging Biomarkers Alliance (QIBA)
 - Metrology Papers
 - Profiles and Protocols
- The Lung Image Database Consortium (LIDC) and Image Database Resource Initiative (IDRI):
 - a completed reference database of lung nodules on CT scans

Quantifying dose reduction claims in CT

- Joint FDA-MITA task group developing framework for validation of claims:
 - Phantoms as stand-ins for the patient
 - Software for automated assessment
 - Rapid system evaluation without confounding factors of display and human inefficiency and variability
 - Statistical tools for measuring performance