



**Calibration Slide for Histopathology task force  
Teleconference**

25 September 2014 • 15:00 (UK) / 10:00 (EDT)

The meeting was called to order at 10:00 am (EDT) by Craig Revie, chair of MIWG, with the following attendees:

Craig Revie	Karl Weinbuch
Brandon Gallas	Masahiro Nishibori
Debbie Orf	Masahiro Yamaguchi
Aldo Badano	Megumi Kondo
Allen Olson	Michael Flynn
Amit VasANJI	Nicholas Petrick
Catherine Conway	Nick Anderson
Craig Fenstermaker	Peyman Najmabadi
Chukka Srinivas	Phil Green
Dan Hosseinzadeh	Pinky Bautista
Darren Treanor	Po-Chieh Hung
Eric Glassy	Remy Tumber
Hong Wei	Robert Leif
James Chang	Shyam Kalavar
Jeremie Pescatore	Tinghui Yu
Wei-Chung Cheng	

After self-introductions and a check of the sound quality Mr. Revie reminded participants of forthcoming meetings, particularly CIC and IADP in November. He reviewed the agenda for the meeting as follows:

1. WSI Working Group overview (Brandon Gallas, FDA)
  - Questions and answers about the new WG
  - How should the ICC MIWG contribute?
2. Round-robin status update and next steps (Craig Revie)
  - Current status and plan to complete round-robin
  - Call for participants to review and compare results
3. Update on Digital microscope test materials and test methods white paper

He then handed the meeting to Brendan Gallas.

## **1. WSI Working Group of FDA**

Dr Brandon Gallas presented an overview of the WSI Working Group of the FDA [see attached]. He noted the contribution of ICC to medical imaging, which he wanted to foster and connect with, and was happy to share efforts. He introduced himself; he contributes lab support for the Center for Devices and Radiological Health at FDA. His own area of interest is reader variability and he has been developing a platform for running studies to compare pathologists viewing WSI images to pathologists using the microscope. The platform, called eeDAP, registers WSI images to the corresponding glass slides using a PC-controlled stage on a microscope that has a camera mounted on it. The software is written in Matlab.

Dr Gallas introduced the other members of the organizing committee (Dr. Marios Gavrielides, Dr. Stephen Hewitt, and Dr. Darren Treanor) who have helped initiate the Whole Slide Imaging working group, which commenced in May 2014. The group has been established, and most members have migrated to a collaborative website ([https://nciphub.org/groups/wsi\\_working\\_group](https://nciphub.org/groups/wsi_working_group) ).

The goals of the working group are submitted for publication at J. Pathol. Inform. One aim is to improve the pre-competitive space for different devices. Short term goals include key performance metrics for WSI, while long term goals include promoting research on such performance metrics. A broad range of issues is proposed for the group, and he wanted to avoid duplicating the effort of ICC MIWG.

Dr. Gallas answered a question and indicated that guidance on technical performance metrics from the FDA is imminent. He was unable to disclose the exact contents of the guidance but indicated that anyone in the business could probably identify the key imaging characteristics that would be discussed: colour, resolution, dynamic range and speed. He invited input from the MIWG WSI group and emphasised the desire for consensus.

He stated that he liked the direction of the ICC MIWG WSI group, anticipated future publications and welcomed a consensus document. He undertook to post a federal register announcement to ensure wide publicity for the activity.

In response to question about addressing colour in lifetime imaging, fluorescence and multi-spectral imaging, he invited contribution on these topics from ICC. Progress will depend on the inputs received.

## **2. Round-robin status update and next steps**

Mr Revie stated that the calibration assessment slide evaluation should be complete by the Boston meeting, and he will provide a summary of the results there.

Progress has been slower than expected. FFEI have produced a smaller slide for scanners that cannot handle the original design. He will set up a meeting of evaluation participants to review the results to date and resolve any differences before making public.

## **3. Update on Digital microscope test materials and test methods white paper**

Mr Revie reviewed the WSI guidelines draft and invited input.

Mr Revie thanked the attendees and reminded them of the next meeting on November 1 in Boston.

A full recording of the meeting is available at <http://www.npes.org/Portals/0/standards/2014-09-25%2010.02%20ICC%20MIWG%20--%20Whole%20Slide%20Imaging.wmv>

### **Action items from the meeting:**

FFEI calibration assessment slide

**MIWG-14-xx** Organise review of results and present at next meeting (Craig Revie)

**Actions from previous meetings:**

- MIWG-14-01**      Share slides and procedure for testing by other members of the group (Yukiko Yagi)
  
- MIWG-14-02**      Organise circulation of a single slide to vendors with measurement capability for a round robin test (Craig Revie)
  
- MIWG-14-03**      Circulate proposal for biopolymer-based calibration slide for consideration by the group for consortium funding or other development (Craig Revie).
  
- MIWG-14-04**      Provide suggestions for content to Phil Green (all)
  
- MIWG-14-05**      Participate in round-robin test of Sierra calibration assessment slide (interested members)

# WSI Working Group

Brandon Gallas,  
FDA/CDRH/OSEL/DIDSR

# 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](http://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](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