

## 20181002 Update

Summer is over, the new fiscal year is started (for the US gov), and we are planning our next year of research in FDA's Office of Science and Engineering Laboratories, and hopefully in collaboration with members of the WSI WG community. A reminder here is that OSEL is the research arm of CDRH and does not necessarily reflect any specific policy/decision making of CDRH's regulatory offices (OIR or ODE).

- Brandon Gallas will give a **WebEx reprise of his presentation** given at the European Congress of Pathology on 9 September 2018
  - "Evaluating Computational Pathology at the US FDA and Related Research." ([Link to presentation.](#))
  - WebEx Date and Time: **Thursday at 11am on 11 October 2018** ([Link to WebEx info.](#))

In addition to the ECP presentation, I plan to summarize my research plans for the coming year. Primarily, I plan to collect data (images and annotations) and propose it to be qualified by the FDA/CDRH as a Medical Device Development Tool (MDDT) to be used in submissions to the FDA to validate algorithms. I will also outline other WSI- and algorithm-related projects by other investigators in my division:

- Marios Gavrielides plans to examine issues related to the stand-alone assessment of computer-aided diagnosis systems for primary diagnosis, with an application to ovarian cancer subtyping.
- Anant Agrawal plans to develop a phantom for technical assessment of WSI systems using nanoscale 3D printing.
- Berkman Sahiner and Weijie Chen plan to expand the evaluation of artificial intelligence and machine learning devices to less structured post-market reference standards and higher risk/higher impact autonomous use.

is is conducting a **pilot reader study** at the Annual Meeting of the American Society of Clinical **Baltimore on 3-5 October 2018.**

lot is to support the data MDDT project mentioned above.

athologists' tasks are to evaluate lymphocytes in lung tumors.

find the booth, hear about the study, and participate!

pe to follow up the pilot with a pivotal study at the San Antonio Breast Cancer Symposium or other with many pathologists. If you are a conference organizer or are leadership in a professional society and o help make this happen, please contact Brandon.

atory Science with Computational Modeling for Medical Devices at the FDA's Office of Science and [link to paper.](#)). You will be surprised by what is happening at the FDA.

-related research, it's time to hear from the WSI WG. What are you doing? What are your concerns? What discussions should we be having? Several WSI WG members have asked what happened to the discussions on the technical performance assessment of WSI scanners, especially as image quality impacts training and deployment.

**Engage and engage the 145 WSI WG members?**

Committee member Marios Gavrielides ideas ([Marios.Gavrielides@fda.hhs.gov](mailto:Marios.Gavrielides@fda.hhs.gov)). He will summarize the issues and plan future discussions.