eeDAP update 20171121

All Updates

Subject of this announcement: It's been a while since we last talked and I'd like to update you all about what has been happening. Below you will find info about

- New project: High-throughput truthing of microscope slides to validate artificial intelligence algorithms analyzing digital scans of pathology slides: leveraging data collected in international "grand challenges".
- Revised "Context of Use" and strategy for eeDAP MDDT
- Registration accuracy studies
- Material transfer agreement (MTA) to loan an eeDAP system to Memorial Sloan Kettering Cancer Center (MSKCC).
- MSKCC reader study on 14-head microscope!
- FDA visited Cold Spring Harbor Laboratory to help them install their own eeDAP system.
- FDA Commissioner Scott Gottlieb visited Dr. Brandon Gallas' digital pathology lab.

New project: High-throughput truthing of microscope slides to validate artificial intelligence algorithms analyzing digital scans of pathology slides: leveraging data collected in international "grand challenges"

This is a new project led by FDA. The kick-off started with an FDA internal-funding proposal. The idea is to marry high-throughput reader studies (like the one conducted on the 14-head microscope at MSKCC) with algorithms developed in grand challenges to produce regulatory-grade evaluations of the algorithms. Collaborators include MSKCC, CSHL, and challenge organizers Jeroen van der Laak and Mitko Veta. This project is generally open to new participants.

Click here for more information.

Revised "Context of Use" and strategy for eeDAP MDDT

The feedback from this group led us to strip down the eeDAP MDDT to make the context of use focus on the technical ability to register the glass slide and the WSI. We will not focus on using eeDAP itself to conduct reader studies and so we will not focus on the equivalence of images displayed by eeDAP compared to the proprietary WSI browser (color or user experience). This new focus should reduce the need for evidence/data; we should only need registration accuracy data. We hope to share a draft submission before the end of the year.

Registration accuracy studies

We have expanded our efforts to evaluate eeDAP's registration accuracy (<u>Link to discussion</u>). In the discussion you will find a summary of the planned experiments and preliminary results in an extended abstract submitted for the SPIE Medical Imaging conference (accepted as poster in the Digital Pathology track). Here is a timeline of plans:

- 12/1/17: Finish data collection.
- 1/1/18: Draft proceedings paper.
- 2/12/18: Present poster at SPIE Medical Imaging Conference.

MTA to loan an eeDAP system to MSKCC

FDA has executed a material transfer agreement with MSKCC, loaning an eeDAP system to allow MSKCC to try out the system.

 Here is a copy of the MTA: <u>MSK6501_FE.pdf</u> (433 KB, uploaded by Brandon D. Gallas 6 years 5 months ago)

MSKCC reader study on 14-head microscope!

On Nov. 3, 2017 Brandon Gallas and Qi Gong visited MSKCC to help Yukako Yagi conduct a study using eeDAP on a 14-head microscope. There were 11 pathologists participating. There were 40 regions of interest (ROIs) where they were asked to detect and mark the locations of mitotic figures. For each ROI, there were candidate mitotic figures identified during a preliminary study. There were 128 candidate mitotic figures in total. The participants were asked to classify these candidates as mitotic figures or not. The study was completed in 2 hours!

Click here for more information.

FDA visited Cold Spring Harbor Laboratory to help them install their own eeDAP system.

On Nov. 4, 2017 Brandon Gallas and Qi Gong visited Cold Spring Harbor Laboratory to help them install their own eeDAP system. It was a great visit, talking about immediate plans and the future. To get familiar with eeDAP, CSHL and Northwell pathologists will conduct a registration accuracy study of their own. It will be nice to report the translation of skills in a registration accuracy manuscript and the eeDAP MDDT submission. Additionally, we are also discussing a CRADA to allow Qi to visit from time-to-time to help with eeDAP hardware and programming.

BTW, Partha's lab is quite amazing. The quality of the mouse-brain images he is producing, and the volume at which he is producing them is exciting to see. Thank you for the tour, Partha.

FDA Commissioner Scott Gottlieb visited Dr. Brandon Gallas' digital pathology lab.

