HTT update 20190402

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HTT Project Update:

As a reminder, HTT stands for high-throughput truthing, a project that was proposed for internal FDA funding. The original proposal and an overview can be found at https://nciphub.org/groups/eedapstudies/wiki/HighthroughputTruthingYear2. **The Pitch:** We are launching a project to crowdsource pathologists and collect data (images + pathologist annotations) that can be qualified by the FDA/CDRH medical device development tool program (MDDT). The MDDT qualified data would be available to any algorithm developer to be used to validate their algorithm performance in a submission to the FDA/CDRH.

In the last two months, we were awarded internal funding! More importantly, we have been getting this project off the ground. We have identified workgroups and leadership and have been fleshing out tasks and milestones. We have also identified funding mechanisms that collaborators will pursue individually and as a group. In that time, we have also been collaborating with the Medical Device Innovation Consortium (MDIC) to help with organization and administration. As we move forward, MDIC will also help engage and involve industry. MDIC is the only public-private partnership (PPP) developed to work with government and industry stakeholders in an effort to advance solutions that promote patient access to innovative medical technologies.

As a consequence of MDIC joining the collaboration, we are growing the scope of our plans beyond our original deliverable given in the pitch. Specifically we will pursue MDDT or mock 510(k) submissions for

- a WSI viewer, and
- a TILs in breast cancer algorithm.

These deliverables will make use of the data collected and qualified as described in the Pitch.

For more information, please refer to an updated executive summary and project overview:

- 20190402-HTTexecSummaryPublic.pdf (194 KB, uploaded by Sarah Dudgeon 5 years 3 weeks ago)
- 20190402-HTToverviewPublic.pdf (410 KB, uploaded by Sarah Dudgeon 5 years 3 weeks ago)

HTT Project Call for Collaboration:

After looking at the project overview, get in touch! We are eager to bolster our areas of expertise. Please contact Brandon.Gallas@fda.hhs.gov.

Quick info about FDA submissions for medical imaging algorithms

Click here for a document of links pointing to FDA guidance documents and other forms of communication. It was compiled by googling CDRH regulatory buzz words. We hope this document is useful. Caveat to all: You won't know what's required for your submission until you ask, try, and succeed.

Digital Health Update: Click Here Read the FDA's Discussion Paper on a Total Product Lifecycle Approach to Regulating Artificial Intelligence and Machine Learning Software as a Medical Device

- Submit comments to FDA-2019-N-1185 on regulations.gov by June 3, 2019.