HTT update 20190124

Wiki Main Page

All Updates

Subject of this announcement:

- Update on eeDAP MDDT: Incubator Inquiry (Draft)
- High-throughput truthing (HTT) project info

How does a government employee address collaborators and friends during a shutdown? I have no idea. I don't even know how to respond to the simplest questions like, "How's it going?"

Update on eeDAP MDDT: Incubator Inquiry (Draft)

Anyhow, after many weeks of being furloughed I have been recently designated as "partially exempt". I am allowed to work on regulatory consults and already submitted Medical Device Development Tools (MDDTs). In particular, I can work on the eeDAP MDDT! The eeDAP MDDT has been languishing thanks to other deadlines and new work. Now it is at the top of my to-do pile.

- Here is a review of the eeDAP MDDT project (LINK), including a timeline of updates (LINK).
- Key progress: We have conducted two registration accuracy studies that are evidence to support the MDDT qualification (approval).
- NEW/NOW progress: We have drafted an MDDT inquiry about the eeDAP proposal that we will submit to the FDA for feedback on next steps. Here are contents:
    - **Cover letter:**
    - 001_coverLetter.pdf (187 KB, uploaded by Brandon D. Gallas 5 years 1 month ago)
    - **Body:**
    - 002_body.pdf (160 KB, uploaded by Brandon D. Gallas 5 years 1 month ago)
    - **Registration accuracy conference proceedings:**
    - 003_Gong2018_Proc-SPIE_v10581p1058118.pdf (485 KB, uploaded by Brandon D. Gallas 5 years 1 month ago)
    - **Original proposal:**
    - 004_originalProposal.pdf (17 MB, uploaded by Brandon D. Gallas 5 years 1 month ago)
    - **Proposal acceptance letter:**
    - 005_MDDT031_Proposal_Acceptance_Incubator.pdf (154 KB, uploaded by Brandon D. Gallas 5 years 1 month ago)

g for feedback on the MDDT inquiry to the FDA. Please send me comments or ask for an extension by Monday 11-Feb-2019.

ughput truthing (HTT) project info

HTT work, while the sales pitch for the CP project proposal was about creating MDDT datasets, many e project origins were to explore and demonstrate the role that eeDAP can play in the regulatory ifically, the planned data-collection events would explore and demonstrate eeDAP regulatory use cases: scope to collect reference evaluations that can be compared to evaluations using the digital WSIs or to m algorithms. As such, we are going to proceed with the data-collection events and postpone the work ate MDDT data sets until after the shutdown.

tus of HTT work, the data-collection events? We have identified providers of glass slides and images. ified caMicroscope and the Cancer Imaging Archive as the infrastructure to be used for WSI VSI annotations are needed for study prep and data collection in digital mode. We have outlined drafts of and data collection workflows. We have identified several events where we can conduct the reader

get done? Establish IRBs and agreements to govern the sharing of slides and images and to allow for tion. Set up and test infrastructure. Develop study prep and data collection workflows. We will miss the conduct a data-collection event at USCAP (local for FDA in 2019). No money. No prep. So sad. That have a little breathing room to work out the IRBs and agreements.

ur attention. I'm so sorry that I have not been responsive to emails. I'm not supposed to work on them if within the scope of my exempted duties. I hope you understand.

allas, PhD

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