

## HTT update 20191209

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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 eight months we:

- established collaborating institutions
- completed IRBs, finalized data collection protocol
- created data collection and image viewing infrastructure
- tested the infrastructure and data workflow

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

- [20190402-HTTexecSummaryPublic.pdf](#) (271 KB, uploaded by Brandon D. Gallas 2 years 4 months ago)
- [20190402-HTToverviewPublic.pdf](#) (410 KB, uploaded by Brandon D. Gallas 2 years 4 months ago)

Brandon gave a talk to the ACR Imaging Data Commons team. His ppt is available here:

The project was pitched to the Alliance. The ppt is available here:

### MDDT Submission:

The FDA Medical Device Development Tool ([MDDT](#)) program accepts submissions into its program at various levels of completion. On Nov 15 2019 we submitted to the proposal phase of the program, for a tool in the earliest stages of development.

View the proposal here: (file:00\_MDDTproposal\_TILsAnnotatedDataset\_Gallas.pdf not found)

Once accepted into the program, we will continue developing the MDDT in partnership with the

FDA.



## The Alliance for Digital Pathology

[The Alliance for Digital Pathology](#) is a collaborative and voluntary group interested in the evolution of regulatory science as it applies to digital pathology. They seek participation from all stakeholders (industry, vendors, academic medical centers, patient advocates, regulatory bodies, associations, etc.) to come together and identify key elements necessary to move the field of digital pathology forward.

The purpose of the Alliance is to accomplish concrete practical deliverables and relevant strategic aims in order to sustain and expand the existing collaborative infrastructure.

- **Meetings:** The Alliance has held three meetings already, with a fourth scheduled for February 27 & 28. This meeting is scheduled to include HTT data collection.
  - July 22, 2019: The Alliance is Formed  
Over 50 attendees from various entities were in attendance. Attendees shared an interest to encourage innovation and commercialization by developing evaluation tools, methods and standards, and clarifying regulatory pathways in digital pathology and specifically in the AI space were present. A temporary alliance has been established between the different participating entities with the intent to grow the alliance to incorporate additional stakeholders.  
[key presentations](#) by FDA, MDIC, DPA, and The Alliance for Digital Pathology are uploaded to the Alliance website.
  - Oct 5, 2019: The Alliance Solicits Project Proposals  
The aim of the meeting was to:

1. Have key stakeholder presentations to inform the members
  2. Share and discuss the aims of this temporary alliance/initiative
  3. Derive 8 concise regulatory sciences deliverables in pre-selected content areas via a breakout session
  4. Enable networking among the members/participants.
  5. Share the content in the public domain
  6. [Presentations and results](#) of the breakout sessions are on the Alliance website.
- Nov 4, 2019: The Alliance Moves Project Proposals Further, and Hears from New Stakeholders  
The aim of the meeting was to:
    1. Share and discuss progress in the Alliance
    2. Enable networking among the members/participants
    3. Have a full day to share and work on deliverables
    4. Take the content of the prior breakout sessions, continue development and derive practically relevant deliverables
    5. Share the content in the public domain
    6. Please find the [presentations and the results](#) of the breakout sessions on the Alliance website. The project overviews can be found in the [full program](#)
  - Feb 27-28, 2019: The Alliance Hears from Other Stakeholders, and Collects Data
    1. Tentative plan: 27 February 2020, 2-5pm
      - Hear about challenges and solutions from pharma, big-data companies, payors, and industry regulatory affairs personnel
      - Reception
    2. Tentative plan: 28 February 2020, 9am-5pm
      - Hands-on development of projects (scope, deliverables, resource needs, leaders)
      - Data collection for HTT project
      - Looking for pathologists to register to participate!

- **Future Communications:** While the WSI Working Group updates happen far less frequently, the Alliance sends updates regularly.  
[join the Alliance and receive updates](#)