

High-Throughput Truthing Year 3

Year 3: High-throughput truthing of microscope slides to validate artificial intelligence algorithms analyzing digital scans of pathology slides: data collection to create the medical device development tool (MDDT)

In Year 3 of the High Throughput Truthing project, the team will collect data at various collaborating sites and conferences.

Check out our completed work from [Year 1](#) and [Year 2](#) in the HTT project

- [Link to pathologist recruiting advertisement](#)
- Research collaboration agreement scope for collaborators providing slides and other materials
 - [CDRH RCA Gallas Template 7-23-2020.doc](#) (106 KB, uploaded by Brandon D. Gallas 3 years 7 months ago)

Pitch:

We are crowdsourcing pathologists to collect data (images + pathologist annotations) that can be qualified by the FDA/CDRH medical device development tool program (MDDT). If successful, the MDDT qualified data along with a statistical software package for data analysis would be available to any algorithm developer to be used to validate their algorithm performance in a submission to the FDA/CDRH.

Researchers from the U.S. Food and Drug Administration, alongside academic collaborators, are collecting pathologist annotations as data for AI/ML algorithm validation for tumor infiltrating lymphocyte (TIL) detection and quantitation. We are asking board-certified anatomic pathologists and anatomic pathology residents to score 80 ROIs as part of a research study. We anticipate that this task will take participants a total of 30 minutes. The data are intended to inform the agency's approach to novel algorithm validation, ensuring high quality commercial products with a faster FDA-pipeline to approval.

[Complete the HTT Data Collection Training](#)

Consent Form:

[HTT IRBInformedConsent.pdf](#) (47 KB, uploaded by Brandon D. Gallas 4 years 3 months ago)

[Begin Data Collection](#)

Exit Survey:

Please complete [this Survey](#) when you finish data collection, and help us improve the HTT

project.

Get Involved:

- Supply glass slides and their scanned versions
- Help create a Continuing Medical Education course in conjunction with this project
- Host an analog (microscope + eeDAP) data collection event at your clinical site
- Help spread the word, recruit your colleagues to participate in online data collection

Thank you. For more information contact:

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on behalf of the High-Throughput Truthing (HTT) Project