

Dear all,

We are writing to invite you to contribute to the high-throughput truthing project (HTT).

The HTT project's objective is to **a)** create a validation dataset fit for a regulatory purpose and **b)** apply statistical methods to evaluate variance in ground truth for a given dataset. Pursuing this objective is expected to inform regulatory frameworks and be instructive to others to develop their own validation datasets. Specifically, the project deals with the assessment of tumor infiltrating lymphocytes (TILs) in H&E-stained breast cancer slides – board-certified pathologists were asked to quantify TILs by viewing regions of interest (ROIs) on breast biopsy and core H&Es under a standardized microscope setup. Initial work on the project has been accepted for publication in the Journal of Pathology Informatics (pre-publication copy available at <https://arxiv.org/abs/2010.06995>).

For more information please visit <https://ncihub.org/groups/eedapstudies/>.

Please see below for instructions on how to help:

- **Digital Data Collection:** We are looking for data collectors to provide annotations on our digital platforms.
 - Pathologists or pathology residents: complete the training and registration [HERE](#).
- **In-Person Data Collection:** We are recruiting data collectors and host sites for collecting microscope-mode data using the eeDAP platform:
 - Summer-Early Fall 2021: We are recruiting data collectors to contribute at Yale School of Medicine (Dr Kim RM Blenman (kim.blenman@yale.edu))
 - Summer-Early Fall 2021: We will soon be recruiting data collectors to contribute at Stony Brook Medicine (contact TBD)
 - Target for host sites: 5 readers per batch, 8 total batches, just over 1 hour per batch (can be broken into half batches of ~30 minutes each)
 - [LINK to eeDAP Manuscript](#)
 - [LINK to eeDAP GitHub Repo](#)
- **Sourcing Glass Slides:** We are sourcing glass slides of TILs in breast cancer for our pivotal study.
 - We have executed a research collaboration agreements (RCA) for slide sourcing at one site and are nearing completion of an RCA with another site.
 - We have a template research plan for all Research Collaboration Agreements
 - We'd like to identify at least one more U.S. site that can provide slides.

If you want to help, please contact:

Katherine Elfer, Project Coordinator (Katherine.Elfer@fda.hhs.gov) and

Brandon Gallas, Project Lead (Brandon.Gallas@fda.hhs.gov).