Recruiting Pathologists to Truth Images

Researchers from the U.S. Food and Drug Administration, alongside academic colleagues, are collecting pathologist annotations as data for AI/ML algorithm validation for tumor infiltrating lymphocyte (TIL) detection and quantitation. We are asking pathologists to score at least one full batch of 80 ROIs as part of a research study. We anticipate that one batch will take 30 minutes plus 30 minutes of training that can be done ahead of time. 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.

Specifically, you will be presented pre-selected fields of view (FOV) digitally or on a microscope (Figure 1). For each FOV, you will label the FOV and enter the percent of tumor-associated stroma and the tumor-associated stromal TIL density, which are numbers from 0-100.

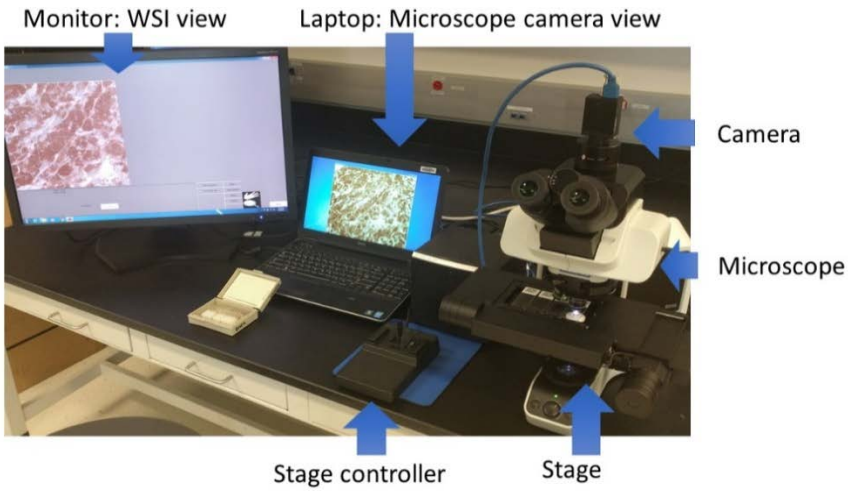

Figure 1: Microscope Setup. Computer controlled stage automatically navigates to next FOV.

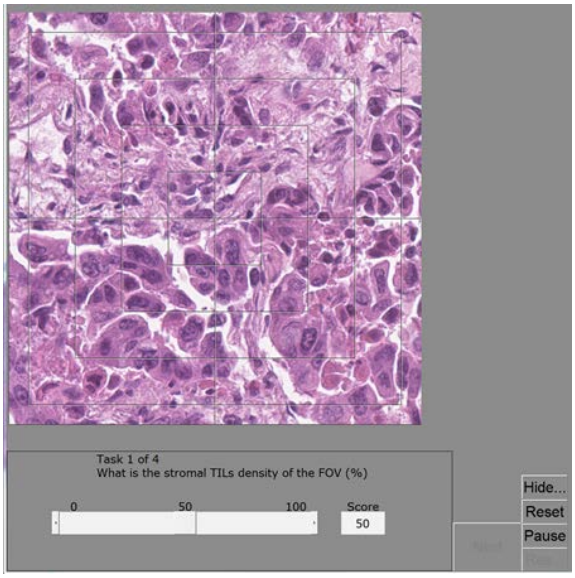

Figure 2: Data capture system for TIL evaluation with slider bar or keyboard data entry.

Please visit this wiki page for information about the project, data-collection training, IRB participation consent, and to begin data collection: https://ncihub.org/groups/eedapstudies.

In co-operation with the Alliance for Digital Pathology.

All the best,
Brandon Gallas, PhD, (brandon.gallas@fda.hhs.gov)
FDA/CDRH/OSEL Division of Imaging, Diagnostics, and Software Reliability
on behalf of the High-Throughput Truthing (HTT) Project

This announcement with more information about the project (including training materials) can be downloaded from

- https://ncihub.org/groups/eedapstudies/wiki/HTTdataCollectionTraining

More about the project:
We are crowdsourcing board-certified anatomic pathologists and residents to digitally record TIL densities in demarked regions of interest of Breast Cancer biopsy glass slides and corresponding whole slide images using microscope and digital viewing modes, respectively. Resulting data (images + pathologist annotations) may be qualified by the FDA/CDRH medical device development tool program (Link to info about the MDDT program). The MDDT qualified data, alongside a statistical analysis software package, would be available to any algorithm developer to be used to validate their algorithm performance in a submission to the FDA/CDRH. We are organizing data-collection events at meetings with high pathologist attendance and at dedicated workshops held by collaborating sites. More information about the project can be found here: https://ncihub.org/groups/eedapstudies.

Training for TIL evaluation:
Please visit this wiki page for training materials, including documents covering the study, clinical task, and the platform.

- https://ncihub.org/groups/eedapstudies/wiki/HTTdataCollectionTraining

Participating pathologists can watch a recording of the original training webinar or review the training slides of the clinical evaluation of sTILs (required to participate). The recording also includes an overview of the project at the beginning and a tutorial for using the data-collection platforms. There is also a related manuscript that provides depth and context for the training. The clinical training materials were created by the TILs in breast cancer working group.

Related Reference
eeDAP – Annotations will be collected in digital and microscope modes. For the microscope mode, we will use eeDAP, an Evaluation Environment for Digital and Analog Pathology (eeDAP), a registration system between the microscope and digital whole slide images.

Consent Form:
The informed consent for can be found here: https://ncihub.org/groups/eedapstudies/wiki/HTTinformedConsent.

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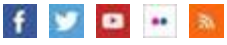

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