Recruiting Pathologists to Truth Images

Preceding USCAP

Friday, February 28th
JW Marriott Los Angeles LIVE, Gold 4 Ballroom
30 min. sessions between 9am-5pm

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 you to score 80 ROIs as part of a research study. We anticipate that this task will take you 30 minutes plus intake and 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 enter the tumor-associated stromal TIL density, which is a number from 0-100. Once you have determined stromal TIL density for each FOV, you will type or click the value using the software's guided user interface (Figure 2). Please see the attached PDF document for study training materials on TIL density evaluations which may be completed ahead of time.

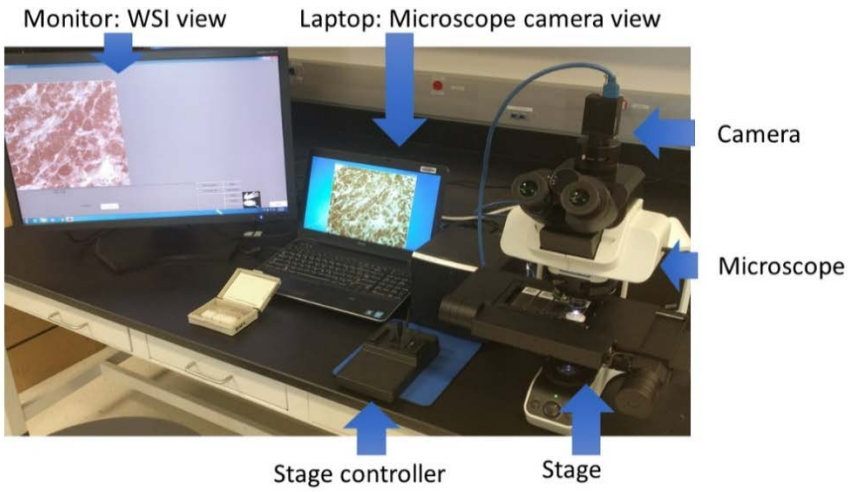

Figure 1: Microscope Setup. Computer controlled stage automatically navigates to next FOV.

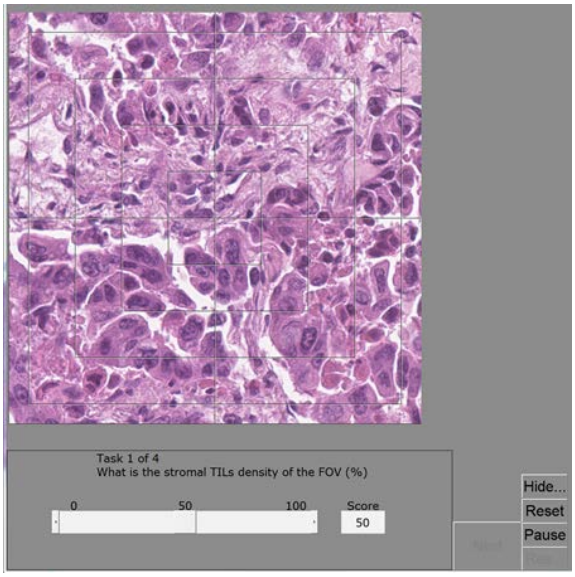

Figure 2: Data capture system for TIL evaluation with slider bar or keyboard data entry.

Please complete this form to sign up for data collection and a WebEx demonstrating the data collection.

In co-operation with a meeting of 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/HighThroughputTruthingYear3/File:HTTatUSCAP.pdf

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. See more here.

Training for TIL evaluation:
TILs evaluation manuscript, TILs training slides – Participating pathologists can review the training slides (required to participate), and read the related manuscript if possible. These 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:
Click here to view the consent form.

Brandon D. Gallas, PhD
Mathematician
Division of Imaging, Diagnostics, and Software Reliability (DIDSR)
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)
10903 New Hampshire Ave, WO-62 Rm 4104, Silver Spring, MD 20993
Email: brandon.gallas@fda.hhs.gov
Phone: 301-796-2531