

Presentation 2020: Project Description and Pilot Study

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Project Description and Pilot Study for A Pathologist-Annotated AI/ML Validation Dataset

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"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."



SCAN ME

Setting:

- Breast cancer pathology biomarker
- Artificial Intelligence for digital pathology
- Need high quality validation

Objectives:

- Validation dataset of: Images + Slides + Annotations *
- Pursue CDRH Medical Device Development Tool (MDDT) for dataset

Regulatory Impact:

- Clarify issues related to validating algorithms.
- Provide example for others to follow.

Methods:

- Reference standard: Noisy truth by pathologists.
- Pathologist training
- Multiple international clinical sites (generalizable results)
- Multiple regions of interest (ROI) per case (correlated data)

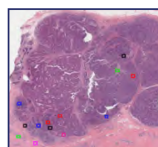
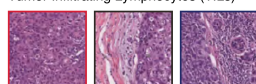
Statistical analyses must account for

- Pathologist variability
- Correlated ROIs



1 Set up Nested Data:

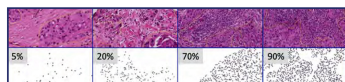
Slides / Regions of Interest
Tumor Infiltrating Lymphocytes (TILs)



2 Task 1: Label the ROI

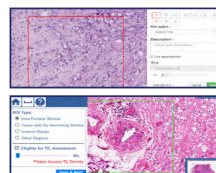
Task 2: Indicate Visual TIL Assessment Eligibility

Task 3: Record % TILs

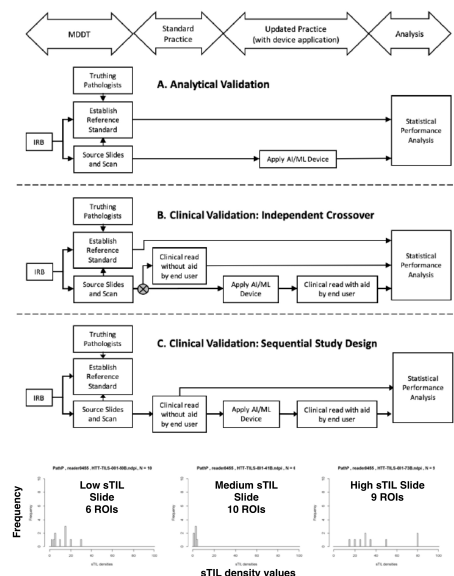


3 Digital Platforms:

PathPresenter, caMicroscope



Microscope Platform:
eeDAP



Poster File Downloadable Link: [PosterSummary.pdf](#) (1 MB, uploaded by Katherine N Elfer 3 years 5 months ago)

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Date: September 30, 2020

Location: Virtual, Scientific Computing Days, FDA