U.S. FOOD & DRUG ADMINISTRATION
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Project Description and Pilot Study for A Pathologist-Annotated AI/ML Validation Dataset

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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

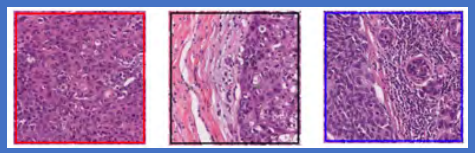
Regulatory Impact:
- Clarify issues related to validating algorithms.
- Provide example for others to follow.

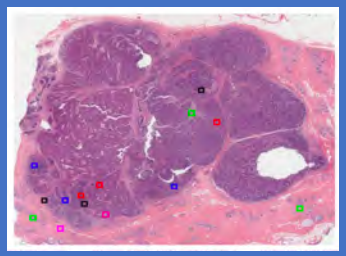
Methods:
- Reference standard: Noisy truth by pathologists.
- Pathologist training
- Multiple international clinical sites (generalizable results)
- Multiple regions of interest (ROI) per case (correlated data)

Statistical analyses must account for
- Pathologist variability
- Correlated ROIs

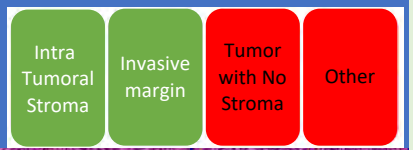
"We are crowdsourcing pathologists to collect data (images + pathologist annotations) that can be qualified by the FDA/CDRH medical device development tool program (MDDT). If successful, the MDDT qualified data along with a statistical software package for data analysis would be available to any algorithm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

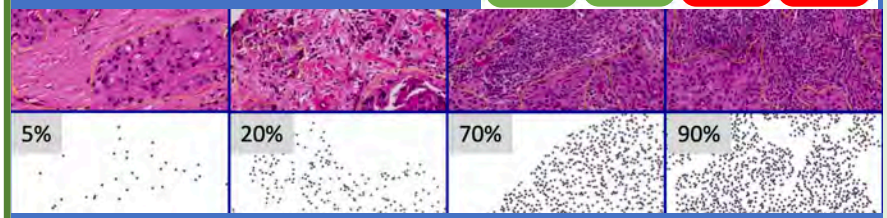
1 Set up Nested Data:
Slides / Regions of Interest
Tumor Infiltrating Lymphocytes (TILs)



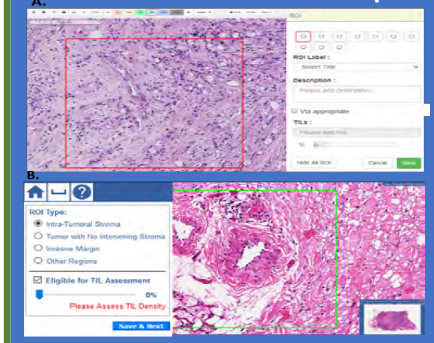


2 Task 1 Label the ROI
Task 2 Indicate Visual TIL Assessment Eligibility
Task 3 Record % TILs





3 Digital Platforms:
PathPresenter
caMicroscope



Microscope Platform:
eeDAP