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