

Pathologist Annotation Datasets for Evaluating Algorithms (PADEA)

Project summary: The project is creating pathologist annotated datasets of Tumor infiltrating lymphocytes density evaluations to support the validation of computational pathology, using the “High-Throughput Truthing” (HTT) demonstration project.

Justification

Tumor infiltrating lymphocytes (TILs) have been identified as a prognostic biomarker for breast cancer. Guidelines from professional societies are recommending clinicians to report the density of TILs in breast cancer tissue, which is error prone. There is a need to develop algorithms that are more precise and possibly more accurate. Given the growth of digital pathology and algorithms more broadly, there is also a need to develop and demonstrate data-collection and algorithm-validation methods for the purpose of regulatory submissions. These validation methods are imperative for these algorithms to be used in clinical practice and clinical trials.

Vision

Engage international experts to develop and demonstrate best practices for using pathologist annotations to evaluate computational pathology.

Mission

Quantitative image-based evaluations of pathologists that satisfy health providers and regulators for computational pathology to be used clinically.

Objectives

- ▶ Support breast cancer research and improve clinical practice.
- ▶ Qualify a data MDDT to encourage algorithm development.
- ▶ Improve the enterprise of digital pathology by demonstrating the creation of a validation dataset.

This project is being developed under the FDA's Office of Science and Engineering Laboratories (OSEL)'s leadership, led by Katherine Elfer and Brandon D. Gallas, with the participation of the co-authors of the following publications:

<https://doi.org/10.1117/1.JMI.9.4.047501>

<https://doi.org/10.3390/cancers14102467>



collaboration for
cancer classification