

## Presentation 2022: FDA OCE Webinar - Validating Models in Digital Pathology: Overview of HTT Project - Gallas

### FDA Oncology Center of Excellence Interest Group Webinar

26 October 2022

#### Title

Developing a dataset to validate computational models that analyze digital pathology images to assess tumor-infiltrating lymphocytes (TILs) in breast cancer

#### Slides and Video

- [20221026-OCE-HTToverview-Gallas-20221026-ToShare.pdf](#) (4 MB, uploaded by Brandon D. Gallas 1 year 6 months ago)
- <https://vimeo.com/767440412>

#### Abstract

This presentation will provide an overview of the High Throughput Truthing (HTT) project. The HTT project aims to develop a dataset of slides, images, and measurements of a quantitative prognostic biomarker fit for a regulatory purpose. The context is breast cancer, the biomarker is the density of stromal tumor-infiltrating lymphocytes (sTILs) in hematoxylin and eosin-stained invasive breast cancer specimens, and the purpose is to validate computational models. We will discuss the results of a pilot study of more than 30 crowd-sourced pathologists and a deep-dive study of challenging pilot-study cases with our collaborating expert pathologists. Unexpected outcomes of these studies are pathologist training materials that identify pitfalls and include annotations and commentary from our collaborating experts. The training materials will improve the biomarker estimates from crowd-sourced pathologists and can pave the way for regular reporting of the density of sTILs for breast cancer patients. The training materials have been shaped into two forms: written and interactive. The interactive component includes an sTILs density estimation test with feedback and a proficiency test. We will demonstrate these tests and our method to determine the proficiency test score. The proficiency test score will set the stage for evaluating a computational model, as we prepare to launch our pivotal study.

#### Presenter

- Brandon D. Gallas, PhD
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### Bio

Brandon D. Gallas provides mathematical, statistical, and modeling expertise to the evaluation of medical imaging devices at the FDA. His main areas of research are image quality, computer-aided diagnosis, imaging physics, and the design, execution, and statistical analysis of reader studies (<https://www.doi.org/10.5281/ZENODO.6628838>). Recently, he has been investigating pathologist performance and agreement using whole slide imaging devices and the microscope (<https://ncihub.org/groups/eedapstudies>). These studies are enabled by an evaluation environment that registers the digital images to the glass slides (<https://github.com/DIDSR/eeDAP/releases>). Dr. Gallas also participates in the Pathology Innovation Collaborative Community (<https://digitalpathologyalliance.org/>), a regulatory science initiative to harmonize and standardize digital pathology processes to speed up innovation to patients.