

## HTT update 20220531

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We are pleased to announce some recent accomplishments of the High-throughput truthing project (HTT).

A list of all previous updates can be found [on this page](#). Our publications and presentations are organized [in this Zotero library](#). Our data is being shared [in this GitHub repository](#).

The HTT project's **objective** is to create a validation dataset fit for a regulatory purpose. Pursuing this objective is expected to inform regulatory frameworks and be instructive to others to develop their own validation datasets. For more detailed information about the project and/or to register as a pathologist-data-collector, please visit <https://ncihub.org/groups/eedapstudies/>.

The HTT project has been accepted as a project of the Truthing and Validation Workgroup of **Plcc**.

- Plcc is The Pathology Innovation Collaborative Community.
- Plcc is pronounced "Pie" CC.
- [Link to the Truthing and Validation workgroup](#).
- [Link to the FDA Collaborative Communities Program](#).

The HTT project was also accepted as a project of the W.H.O. International Collaboration for Cancer Classification and Research (IC3R).

- The IC3R project is named PADEA (Pathologist Annotation Datasets for Evaluating Algorithms) to allow the effort to grow to other applications beyond TILs evaluation.
- [Link to IC3R "Projects" page](#).

To contact us with any questions or join our efforts: [Contact Us HERE](#)

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## Updates

### May 2022

- 5/27: Upcoming Presentation to College of American Pathologists (CAP) AI Committee
  - New CAP Committee chaired by Raj Dash
- Recruiting: FDA/CDRH/OSEL/Division of Imaging Diagnostics and Software Reliability (DIDSR)
  - DIDSR is recruiting at all levels, Full Time Employees and Fellows

- Published Manuscript: “Development of Training Materials for Pathologists to Provide Machine Learning Validation Data of Tumor-Infiltrating Lymphocytes in Breast Cancer”
  - Authors: Victor Garcia, Katherine Elfer, Dieter Peeters, Anna Ehinger, Bruce Werness, Amy Ly, Xiaxion “Bill” Li, Matthew Hanna, Kim Blenman, Roberto Salgado, Brandon Gallas
  - Published 17 May 2022 in Cancers Special Issue “Tumor Infiltrating Lymphocytes (TIL) in Solid Tumors: Emerging Insights.”
  - [Open Access Link](#)
- Presentation: “Development of Pathologist Training Materials using Consensus Driven Annotations of sTIL Assessment in Breast Cancer”
  - Presenter: Victor Garcia
  - Pathology Informatics Summit 2022
  - Presented 11 May 2022 in Pittsburgh, PA
  - [View Abstract & Slides Here](#)
- Expert Annotations now on DIDS/HTT repository and other updates
  - Expert Panel annotations (“camc-expert”) now publicly available on [DIDS/HTT](#)
  - R Markdown and PDF Output used for figures in Garcia, et. al Cancers manuscript also available
- Published Manuscript: “Three-Way Mixed Effect ANOVA to Estimate MRMC Limits of Agreement”
  - Authors: Si Wen and Brandon Gallas.
  - Published 11 May 2022 in Statistics of Biopharmaceutical Research
  - <https://doi.org/10.1080/19466315.2022.2063169>

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## April 2022

- Tutorial by Brandon Gallas : “Tutorial on Reader Study Designs and MRMC Analysis”
  - Brandon presented at an FDA Internal Training on 8 April 2022
  - Slides Available: <https://ncihub.org/groups/eedapstudies/wiki/DeviceAdviceAIMLImaging>
  - Presentation info on eeDAP Studies Zotero
- Poster Presentation: “Tools for collecting pathologist annotations and understanding interobserver variability”
  - Presenter: Katherine Elfer
  - American Association for Cancer Research (AACR) Annual Conference 2022
  - Presented 8 April 2022 in New Orleans
  - [See Poster Here](#)

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## March 2022

- FDA-PIcc Discussion Series: Can AI Grand-Challenges inform Regulatory Science in Anatomic Pathology?
  - Speakers: Roberto Salgado, MD and Francesco Ciompi, PhD
  - Project Page: <https://pathologyinnovationcc.org/projects/project-ai-grand-challenges>
- Submitted Manuscript, “Tools to collect and analyze crowd-source pathologist annotations for validating machine learning algorithms”
  - Elfer K, et. al. submitted to the Journal of Medical Imaging
- Submitted Manuscript, “Development of Training Materials for Pathologists to Provide Machine Learning Validation Data of Tumor-Infiltrating Lymphocytes in Breast Cancer”
  - Garcia V., et. al. submitted to Cancers Special Issue “Tumor Infiltrating Lymphocytes (TIL) in Solid Tumors: Emerging Insights.”

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## February 2022

- Published Manuscript, “FDA fosters innovative approaches in research, resources and collaboration”
  - Authors: Brandon D. Gallas, Aldo Badano, Sarah Dudgeon, Katherine Elfer, Victor Garcia, Jochen K. Lennerz, Kyle Myers, Nicholas Petrick & Ed Margerrison
  - Link to Journal: <https://www.nature.com/articles/s42256-022-00450-2>
  - Link to shareable online viewable copy: <https://rdcu.be/cHCIY>

Zotero [Published 23 February 2022 Presentations]