

To Dr. Brandon Gallas and the FDA Critical Path Proposal Review Committee,

I support Dr. Brandon Gallas' proposal, "High-throughput truthing of microscope slides to validate artificial intelligence algorithms analyzing digital scans of same slides: data (images + annotations) as an MDDT." I believe he has an excellent plan for conducting studies to create regulatory grade annotation data for a medical device development tool (MDDT). I am willing to participate and recruit pathologists from my organization. The evaluation of tumor infiltrating lymphocytes (the primary application) appears very promising for prognosing cancer, and the pathologist community needs training in this area.

Additionally, I have a grant to organize a speaker series on AI in digital pathology and I'd like to invite Dr. Gallas to speak and conduct a data-collection event as part of that. I believe we can get a respectable turn out of pathologists to hear about the project and be study participants. My team is also very active in the development, investigation, and deployment of AI in digital pathology. I believe we can provide algorithm expertise and outputs to support the development of the reader studies and performance evaluation. If I can, I will also use my network to help the project conduct studies at conferences where the pathologists go. These are excellent opportunities to get pathologists to participate in the studies.

My CCIPD team has developed pioneering computer aided diagnosis, pattern recognition, image analysis tools for diagnosis and prognosis of different types of cancers (prostate, breast, medulloblastoma, oropharyngeal) based on quantitative and computerized histomorphometric image analysis of digitized histologic biopsy tissue specimens. This novel approach involves quantitatively mining the histologic image data for hundreds of image features via sophisticated image segmentation, feature extraction, machine learning and pattern recognition methods and then predicting the risk of disease recurrence and patient prognosis. We have also pioneered new ways of combining histomorphometric imaging features with "omics" derived biomarkers for improved and integrated prediction of prostate cancer outcome. We have published over 140 peer-reviewed journal papers, over 160 peer-reviewed conference papers, and have over 70 patents awarded or pending.

The aims of this project are what the community needs. It engages pathologists, giving them a voice and role in the regulatory process. If the community is involved in creating the validation data and evaluating algorithms, there will be confidence in the technology.

Sincerely,



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