



Cold Spring Harbor Laboratory

Partha Mitra, Ph.D., Professor

Dr Brandon Gallas, Ph. D
Food and Drug Administration
Friday Oct 19, 2018

Dear Brandon,

I write in strong support of your internal proposal for a study on “*High-throughput truthing of microscope slides to validate artificial intelligence algorithms analyzing digital scans of same slides: data (images + annotations) as an MDDT*”. I am looking forward to collaborative interactions and we have set up your eeDAP device at CSHL to aid the study in question. Over the last year, as you know we have made considerable progress, with your help, in modifying eeDAP to enable the recording stage position, so that we can study the behavior of an AP physician performing diagnoses *in situ*.

As part of this study we plan to compare the performance of human Anatomic Pathologists with automated or semi-automated algorithms on tasks involving detection of relevant objects in Whole Slide Imaging data of cancer tissues. A staff computer scientist as well as a neuroscientist will participate in this study. I am collaborating with Dr Adam Kepecs, a Professor at CSHL, and Dr Jim Crawford, Professor and Chair of Laboratory Medicine at Hofstra/Northwell. Dr Crawford will be providing the slides with tissues which we will scan using Nanozoomer WSI scanners in my lab, as well as expertise in Anatomic Pathology. My laboratory has considerable expertise in AI/Machine Vision methods as applicable to tissue images, developed previously in the context of Neuroanatomical image data. I am also collaborating in this context with Prof. Mohanasankar Sivaprakasan of the Health Care Technologies Innovation Center at IIT Madras, Chennai, India.

I do not see us at CSHL making a marketing submission directly in relation to the eeDAP study (the subject of this letter), which is being conducted in the public domain like the rest of our academic research. The focus of this research project is scientific and algorithmic. However, I am interested in ultimately developing algorithms that have practical clinical utility. I cannot rule out the possibility that I will at some future date participate in a submission to the FDA for a digital pathology software application. I do not expect however that this will impact our current study in any way.

I wish you success with your funding application and the collaborative research that this will enable.

Sincerely,

Partha P Mitra
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