



Leidos Biomedical Research, Inc.

October 15, 2018

Brandon D. Gallas, PhD
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Division of Imaging, Diagnostics, and Software Reliability

Re: Letter of Support for MDDT Proposal

Dear Dr. Gallas,

I am writing to express my enthusiastic support for your funding proposal entitled "High-throughput truthing of microscope slides to validate artificial intelligence algorithms analyzing digital scans of same slides: data (images + annotations) as an MDDT." This work will focus on the qualification of data (images + annotations) by the FDA/CDRH medical device development tool (MDDT) program and "crowdsourcing pathologists" at 1-2 conference "data-collection" events and via the web. The MDDT qualified data would be available to algorithm developers to be used to validate their algorithm performance in their submission to the FDA

I am the director of the Cancer Imaging Program – Imaging Cancer Informatics unit and Technical Manager of The Cancer Imaging Archive (TCIA) which is supported by the National Cancer Institute and provides a vast, freely accessible, open archive of cancer-specific medical images and metadata. The archive, including software, processes, data, and staff, is housed at University of Arkansas for Medical Sciences.

As the core mission of TCIA is to make highly valuable data sets available to the cancer research community, TCIA would be well suited to provide infrastructure to support the hosting of images and for viewing and to host annotation software to support the primary application of your proposal to evaluate TILs (tumor infiltrating lymphocytes).

Sincerely,

A handwritten signature in black ink, appearing to read "John Freymann".

John Freymann (Contractor)
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Applied/Developmental Research Directorate
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