



To: MDDT Program Coordinator

RE: **MDDT Qualification Submission**

Dear Sir/Madam:

January 23, 2017

Please accept this **MDDT pre-qualification proposal**. The MDDT being proposed is a **Clinical Outcome Assessment** called **eeDAP, an evaluation environment for digital and analog pathology**. It is being submitted by Brandon D. Gallas in the FDA/CDRH's Division of Imaging, Diagnostic, and Software Reliability (DIDSR) in the Office of Science and Engineering Laboratories (contact information below). We are sharing the MDDT qualification effort and experience with the WSI Working Group (https://nciphub.org/groups/wsi_working_group).

The Context of Use for eeDAP is as follows:

eeDAP is a Clinical Outcome Assessment used in reader studies for whole slide imaging premarket submissions (PMA or 510k deNovo) to compare the accuracy or reproducibility of pathologist evaluations of digital images on a display to those of glass slides on a microscope. The pathologist evaluations of patient tissue are the clinical outcomes. The accuracy or reproducibility of the pathologist evaluations is the clinical outcome assessment; this assessment reflects image quality.

The eCopy is an exact duplicate of the paper copy.

Sincerely,

Brandon Gallas