



Date: 18 January 2019

Subject: MDDT Incubator Phase Inquiry

MDDT Type: Nonclinical Assessment Model (NAM)

MDDT Tracking Number: **MDDT031**

Submission Type: **MDDT proposal (The eCopy is an exact duplicate of the paper copy.)**

Division: **Division of Molecular Genetics and Pathology**

Branch: **Molecular Pathology and Cytology Branch**

Lead Reviewer: **Nick Anderson**

MDDT Name: **eeDAP, evaluation environment for digital and analog pathology**

**Context of Use:**

eeDAP allows an investigator to design a study in which pathologists can evaluate pre-specified fields of view (FOVs) and features on a glass slide using a microscope. The FOVs and features are pre-specified by referring to a digital scan of the corresponding slide (a whole slide image: WSI) and identifying the (x,y) position of the center of the FOV or the feature.

**Dear Sir/Madam:**

It has been a while since FDA has accepted our proposal of the eeDAP (evaluation environment for digital and analog pathology) into the MDDT incubator phase (12 May 2017). We apologize for the delay and are ready to take the next steps.

Sincerely,

A handwritten signature in black ink that reads "Brandon Gallas". The signature is written in a cursive, flowing style.

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Silver Spring MD 20993-0002  
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