DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

PROPOSAL ELIGIBLE FOR MDDT PILOT PROGRAM: INCUBATOR PHASE MDDT TRACKING NUMBER: MDDT031

DATE: May 12, 2017

Food and Drug Administration
Attention: Brandon Gallas, Ph.D.
Mathematician
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Dr. Gallas:

We have evaluated the proposal you submitted for participation into the Medical Device Development Tools (MDDT) Pilot Program dated January 23, 2017. After careful review, we believe that your Proposal is eligible for acceptance into the Incubator Phase of the MDDT Pilot Program. This acceptance is based on our enthusiasm for the potential public health impact of your tool.

Because your proposed tool is not yet fully developed, we suggest engaging FDA via an Incubator Phase inquiry. The Incubator Phase provides the opportunity for interaction with FDA staff regarding development of the tool, prior to preparation of a prequalification or qualification package. The Incubator Phase inquiry should be submitted as an "informational meeting" Q- submission based on the guidance document: Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff, published in February 18, 2014. The cover sheet contents should follow the enclosure: Incubator Submission Cover Sheet. With this inquiry, you may ask specific questions of CDRH staff regarding the development and qualification plan of this tool. We will then provide collaborative feedback through teleconference or face-to-face meeting.

In your Incubator Phase inquiry, we recommend that you address the following:

1. The deployment and use of the eeDAP system. CDRH recognizes three types of MDDT, distinguished primarily by how the tool measures relevant parameters. You propose the eeDAP as a Clinical Outcome Assessment tool, but based on your product description and the co-registration capabilities of eeDAP when evaluating specific fields of view (FOVs), it may fit better as a Nonclinical Assessment Model. We will work with you to refine the Context of Use Statement and determine the most appropriate tool type for eeDAP.

2. The disadvantages of the eeDAP system. On page 9 of the submission, you describe the first of two major disadvantages as *"when collecting data in digital mode, the image is displayed with Matlab. As such, eeDAP doesn't evaluate the native image*

viewer's human factors and workflow components." There may be more than just the human factors and workflow components that are of concern. If the proposal is to have analytical and/or clinical studies conducted using eeDAP, it is not clear how the study data could be used to support the regulatory review of a whole slide imaging (WSI) device. FDA generally requires that analytical and/or clinical testing be conducted using the system (with the specified components) under review. As such, if eeDAP will serve as a surrogate for the WSI device submitted for review when conducting such studies, it will be necessary to submit technical performance documentation and testing for eeDAP.

Based on guidance received from CDRH staff during the Incubator Phase or completion of this tool, you may submit a prequalification package (PQP) to the MDDT Pilot Program. Prior to PQP submission, contact the MDDT Pilot Team at MDDT@fda.hhs.gov for more detailed instructions of what to include in that submission. Please reference your MDDT tracking number provided above on all correspondence.

If you have any additional questions regarding this letter, please contact the MDDT Pilot Team at MDDT@fda.hhs.gov.

Sincerely,

Joannie L. Adams-white -S

Digitally signed by Joannie L. Adams-white -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000974918, cn=Joannie L. Adams-white -S
Date: 2017.05.12 14:23:48 -04'00'

Joannie Adams-White
Senior Health Regulatory Project Manager
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Enclosures:
Incubator Submission Cover Sheet Template

Incubator Submission Cover Sheet Template

The Cover Letter for the Incubator Submission should contain the following elements to ensure proper document tracking:

Date:
Subject: (in bold print) **MDDT INCUBATOR PHASE INQUIRY**
MDDT Type: (in bold print)

- **NONCLINICAL ASSESSMENT MODEL**

MDDT Tracking Record Number: (in bold print), if previously assigned

Submission Type: (in bold print) **MDDT proposal**

Division: (in bold print) **Division of Molecular Genetics and Pathology**

Branch: (in bold print) **Molecular Pathology and Cytology Branch**

Lead reviewer: (in bold print) **Nick Anderson, Ph.D.**

MDDT Name(s): eeDAP: evaluation environment for Digital and Analog Pathology

Context of Use: Describe the intended context of use of the MDDT (1 to 2 sentences)

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Submissions to CDRH should be sent to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

For more information on formatting of an eCopy, please see:
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf .