June 21, 2019

Food and Drug Administration
Center for Devices and Radiological Health
Office of Science and Engineering Laboratories
Attention: Brandon Gallas, Ph.D.
Mathematician
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: MDDT Name: eeDAP System
MDDT Type: Non-Clinical Assessment Model
Q-Submission Number: Q190346
Dated: January 18, 2019
Received: February 19, 2019

Dear Dr. Gallas:

The Proposal you submitted for participation into the Medical Device Development Tools (MDDT) Program dated January 18, 2019 (Incubator Phase date: May 12, 2017) has been reviewed by the Center for Devices and Radiological Health for consideration for entry to the MDDT Program. After careful review of your Proposal, we recommend the discussions concerning the MDDT for eeDAP System be advanced to the pre-Qualification Stage and request that you submit a pre-Qualification Package (PQP).

On August 10, 2017, CDRH issued the MDDT Final Guidance which represents the FDA's current thinking on this topic. Your participation in this Program may provide ways for improving the guidance.

The PQP 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: Pre-Qualification Package Cover Sheet.

The PQP should contain the following information which is also outlined in the guidance.

I. Complete submitter contact information including name(s), affiliation, mailing address, email address, phone and fax numbers.

II. Description of the MDDT

   a. Measurement(s) provided

   b. Describe tool principle and method of measurement

III. Context of Use, including the disease and/or device area for application of MDDT

IV. Type of Evidence to Gather

V. Strength of Evidence
   a. Tool Validity
   b. Plausibility
   c. Extent of Prediction
   d. Capture

VI. Assessment of Advantages & Disadvantages

VII. Estimated timeline for submitting the Qualification package
   a. Identify any areas where further development or discussion with FDA is needed

VIII. Q-submission Details
   a. Meeting format for the interactive discussion (e.g., in-person, teleconference)
   b. Three preferred dates and times you are available to meet
   c. Planned attendees

Within section IV. Type of Evidence to Gather or V. Strength of Evidence, please include a detailed evidence plan that includes the following:

A detailed study protocol to include study methods including sample size with justification, statistical analysis plan and study acceptance criteria.

Furthermore, please include in your pre-Qualification package a response to the comments from the Review Team based on the review of your Incubator phase submission that were communicated as written feedback on June 21, 2019.

If you have any questions or concerns, please feel free to contact Shyam Kalavar at shyam.kalavar@fda.hhs.gov or at 301-796-6807.

Sincerely,

Reena Philip -S

Reena Philip, Ph.D.
Director
Division of Molecular Genetics and Pathology
OHT 7: Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Enclosures:
Pre-Qualification Package Cover Sheet Template

Pre-Qualification Package Cover Sheet Template

The Cover Sheet for the MDDT Pre-Qualification package should contain the following elements to ensure proper document tracking:

Date:

Subject: MDDT PRE-QUALIFICATION PACKAGE

Submission Type: Q-SUBMISSION: INFORMATIONAL MEETING REQUEST

Q-SUBMISSION Number: Q######

Office:

Division/Team:

Assistant Director Name (Optional):

MDDT Name: *Identify the specific MDDT (by name) that is being submitted*

MDDT Type: *Select one*

CLINICAL OUTCOME ASSESMENT TOOL
BIOMARKER TEST
NON CLINICAL OUTCOME MEASUREMENT

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

Submitter: *Complete submitter contact information including name(s), affiliation, mailing address, email address and phone number.*

Submissions to CDRH should be sent to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) - W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

For more information on formatting of an eCopy, please see:
https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm