

Date:

Subject: MDDT PROPOSAL

Submission Type: Q-SUBMISSION: INFORMATIONAL MEETING REQUEST

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/medical-devices/how-study-and-market-your-device/ecopy-program-medical-device-submissions>