# MDDT Proposal Cover Sheet Template

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

Date:
Subject: (in bold print) **MDDT PROPOSAL**
MDDT Type: (in bold print)

- **CLINICAL OUTCOME ASSESSMENT**
- **BIOMARKER TEST, or**
- **NONCLINICAL ASSESSMENT MODEL**

Submission Type: (in bold print) **Q-SUBMISSION**: **INFORMATIONAL MEETING REQUEST**
*Please clearly indicate that the submission is an Informational Meeting request on the CDRH Premarket Review Submission Cover Sheet.*

Division (if known; in bold print): **DIVISION OF ___**

Branch (if known; in bold print): **__ __ DEVICES BRANCH**

Lead reviewer (if known; in bold print): **NAME**

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

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

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

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 . The eCopy for the MDDT Proposal should meet the technical standards outlined in Attachment 1 of the referenced guidance.