Discussion on the FDA Medical Device Development Tools (MDDT) program

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What is an MDDT?

- The Medical Device Development Tool (MDDT) program is a way for the U.S. Food and Drug Administration (FDA) to qualify tools that medical device manufactures can choose to use in the development and evaluation of medical devices.
- Device manufacturers generally need to both demonstrate the safety and efficacy of their novel device, but also support and validate the use of validation tools, often purpose built.
- The MDDT program aims to standardize the “measuring stick” that is used to evaluate certain medical devices.
- There are three types of MDDTs:
  - Biomarker Tests (BT)
  - Non-Clinical Assessment Model (NAM)
  - Clinical Assessment Outcome (CAO)

Value of an MDDT

- MDDTs allow for increased predictability for medical device developers, by making it clear the FDA will accept assessments from a qualified MDDT in support of demonstrating safety, effectiveness, or performance of a medical device.
- MDDTs have the potential to improve efficiency and transparency of medical device approval process, by facilitating use of validated and qualified tools across multiple medical device submissions and manufacturers.
- NIH innovators might consider leveraging some of their findings to qualifying an MDDT to be licensed to other device manufacturers as a potential product.
- However, a challenge the MDDT program faces is that it is entirely optional and there is no explicit regulatory benefit to leveraging an MDDT in a submission.

MDDT Categories

- There are three categories of MDDTs:
  - **Biomarker Test (BT)** is a test or instrument used to detect or measure a biomarker. Unlike qualified biomarkers used in drug development, MDDTs also include the mechanism by which the biomarker is captured and/or evaluated.
  - **Non-Clinical Assessment Model (NAM)** is a non-clinical test model or method that measures or predicts parameters of interest to evaluate the device safety, effectiveness, or device performance.
  - **Clinical Outcome Assessment (COA)** describes or reflects how a person feels, functions, or survives and can be reported by a healthcare provider, a patient, a non-clinical observer or through performance of an activity or task.

Getting an MDDT Qualified by CDRH

There are two primary phases to the MDDT process:

Phase	Goal	Information Submitted
Proposal Phase	Determine if the MDDT is suitable for qualification through the MDDT program.	Submit a complete Qualification Plan for collecting and gathering evidence for qualification of the tool, a description of the MDDT, and context of use.
Qualification Phase	Determine whether, for a specific context of use, the tool is qualified based on the evidence and justifications provided.	Submit the data collected according to the Qualification Plan as part of the Full Qualification Package, which the FDA reviews for the qualification decision.

Source: https://www.fda.gov/medical-devices/medical-device-development-tools-mddt#qualification

Innovator support for developing an MDDT

- Like NIH, CDRH has its own Small Business Innovation Research (SBIR) grant program.
  - These grants may be applicable to a broad variety of efforts such as development of Voluntary Consensus Standards, research methods, and Medical Device Development Tools.
- Contact FDA's MDDT Program
  - Email questions to MDDT@fda.hhs.gov

Resources

- Medical Device Development Tools (MDDT) | FDA
- Medical Device Development Tool (MDDT) Guidance | FDA
- Qualification Process for Drug Development Tools - Guidance for Industry | FDA

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