FDA Update – Center for Devices and Radiological Health

"Introduction to the Medical Device Development Tool (MDDT) Program"

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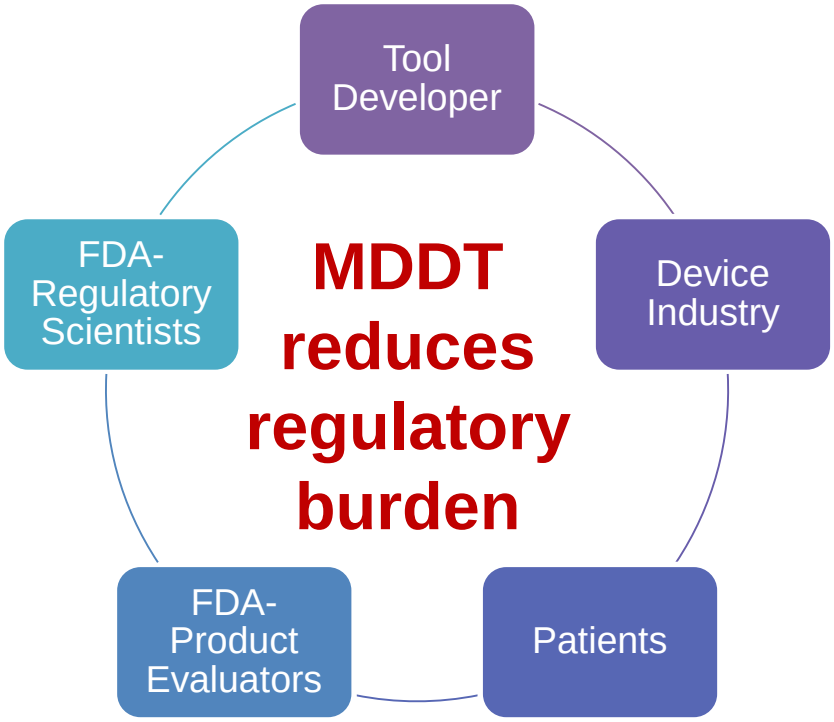
Medical Device Development Tool (MDDT) Program: Benefit of Qualifying Tools

Promotes Efficient Medical Device Development



- Fosters innovation
- Encourages collaboration
- Reduces resource expenditure
- Qualified MDDT applied in multiple device submissions
- Efficiency in CDRH regulatory review resources
- Minimizes uncertainty in regulatory review process

What Is An MDDT?

- **Medical Device Development Tool (MDDT)** is a method, material, or measurement used to assess the effectiveness, safety, or performance of a medical device
  - A MDDT is scientifically validated and qualified for a specific ***Context Of Use*** (COU)
  - COU describes the way the MDDT should be used, purpose in device evaluation and/or regulatory submission, and specific output/measure from the tool
  - Qualification is a FDA conclusion that within the COU a MDDT can be relied upon to have a specific interpretation and application in medical device development and regulatory review
  - CDRH reviewers should accept the MDDT outcomes within the qualified context of use (COU)) without the need to reconfirm the suitability and utility of the MDDT when used in a regulatory submission

MDDT Types

COA

- Patient selection for clinical studies
- Clinical study outcomes
  - Objective and subjective

BT

- Objective measure of biologic process or response to an intervention
- Patient selection
- Predict or identify outcomes

NAM

- Models to measure/predict a parameter of interest
- Reduce / Replace animal testing
- Reduce test duration or sample size

Clinical Outcome Assessments

Biomarker Tests

Nonclinical Assessment Models

MDDT Exciting Growth Opportunities

- The MDDT program is seeking new MDDT submissions in the following key areas:
  - Surrogate outcomes for clinical trials
  - Biomarker Tests for physiological safety (e.g., electrical hazard, light/EM radiation hazard, biocompatibility, toxicology)
  - Bench Testing Evaluation Methodologies
  - Modeling and Computational Tools
  - Phantom Tools
  - Software Simulation Tools
  - Patient Preference Tools

Resources for More Information

Inquiries for additional information email: MDDT@fda.hhs.gov

- FR notice announcing the MDDT Program (8/10/2017): https://www.federalregister.gov/documents/2017/08/10/2017-16827/qualification-of-medical-device-development-tools-guidance-for-industry-tool-developers-and-food-and

- MDDT Guidance Document: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm374432.pdf

- MDDT Public Webpage: http://www.fda.gov/MedicalDevices/ScienceandResearch/MedicalDeviceDevelopmentToolsMDDT/default.htm

- Q-Submission Guidance Document: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm311176.pdf

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Questions?

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