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

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Clinical Outcome Assessments
Biomarker Tests
Nonclinical Assessment Models

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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


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

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Questions?

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