FDA Update – Center for Devices and Radiological Health

“Introduction to the Medical Device Development Tool (MDDT) Program”

Jennifer Goode, BS
Biocompatibility Program Advisor
FDA/CDRH, Office of Device Evaluation

ICCVAM Public Forum
Thursday May 24, 2018
Bethesda, MD
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

MDDT reduces regulatory burden
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
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

Acknowledgements

Hilda Scharen, M.Sc., CAPT, USPHS
Director, Medical Device Development Tools (MDDT)
Questions?

Jennifer.Goode@fda.hhs.gov