U.S. FOOD & DRUG ADMINISTRATION

Principles of the Medical Device Development Tools (MDDT) Program

Hilda F. Scharen, MDDT Program Director

US FDA: Center for Devices and Radiological Health (CDRH)

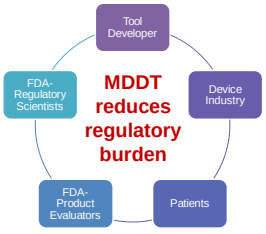
Outline

- KEY CONCEPTS
  - Vision for the MDDT Program
  - Benefits of MDDT Qualification
  - What is an MDDT?
  - What is a Context of Use?
  - Types of MDDTs
  - Non Clinical Assessment Models needs
  - MDDT Program Phases

VISION FOR POTENTIAL UTILITY

- Voluntary Program for Tool Developers
- Tool submitters can be: person, group, consortium, or organization (including FDA)
- To expedite medical device innovation, development and regulatory approval/clearance through qualifying and making MDDTs publically available and by collaborating with tool developers, device industry and other stakeholders

What are the Benefits of MDDT Qualification?



- Innovation
- Collaboration
- Reduce individual resource expenditure
- Bridge gaps between research and development
- Qualified MDDT applied in multiple device submissions
- Efficiency in CDRH review resources
- Minimizes uncertainty in review process

4

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 tool that is scientifically validated and qualified for a specific ***context of use*** (COU) for use in device development and to support regulatory decision-making

5

Context of Use (COU)

- Key aspect of Qualification
- Describes the way MDDT should be used, purpose, and conditions under which MDDT is qualified
- Complete COU should include:
  - Tool or product area in which MDDT is proposed to be qualified
  - Specific output/measure from MDDT
  - Role of MDDT in regulatory evaluation
  - Phase(s) of medical device development in which tool measurements can be used (i.e. design evaluation, animal testing, clinical studies)

6

MDDT Types

COA Reflects how an individual feels or functions (subjective)
- Clinical Study endpoints

Clinical Outcome Assessments

BT
- Objective measure of biologic or pathogenic process or response to an intervention
- Patient selection for clinical studies
- Predict or identify outcomes

Biomarker Tests

NAM
- Models (computational and animal) to measure/predict a parameter of interest
- Reduce / Replace animal testing
- Reduce test duration or sample size

Nonclinical Assessment Models

7

Non-Clinical Assessment Models

Non-clinical test model or method that measures or predicts imaging device function

- Computation / Simulation Models
  - Structural (Functional) Algorithms for Image Feature Analysis
  - Disease Progression Algorithms for Image Trend Analysis
- Imaging Phantoms
  - OCT
  - Adaptive optics
- Reference Standard Validated Image Databases

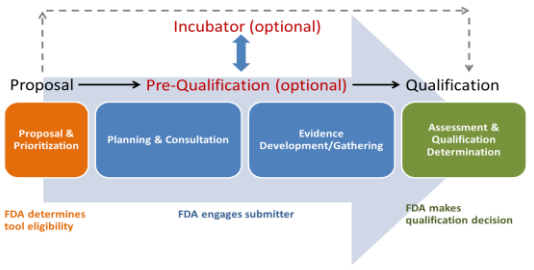
8

What is MDDT Qualification?

- Qualification is a conclusion, based on FDA review, that **within the context of use (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
- CDRH encourages tool developers to make their qualified MDDTs publicly available

9

QUALIFICATION PROCESS



10

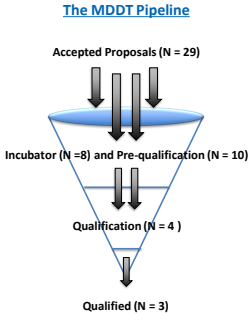
CDRH Qualification Decision Framework

Key considerations for qualifying a MDDT:

- MDDT description
- Context of use
- Public Health Impact
- Strength of evidence
- Assessment of advantages and disadvantages

11

Current MDDT Tools



Potential MDDTs enter as ***Proposals***

An ***Accepted Proposal*** can then enter into one of three phases:

- ***Incubator*** – Tool Development with FDA consultation
- ***Pre-qualification*** – Planning of evidence development and gathering
- ***Qualification*** – Decision if strength of evidence supports context of use adequately

4/2/19 12

Resources

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

13

Thank You for Your Interest in the MDDT Program

U.S. FOOD & DRUG ADMINISTRATION