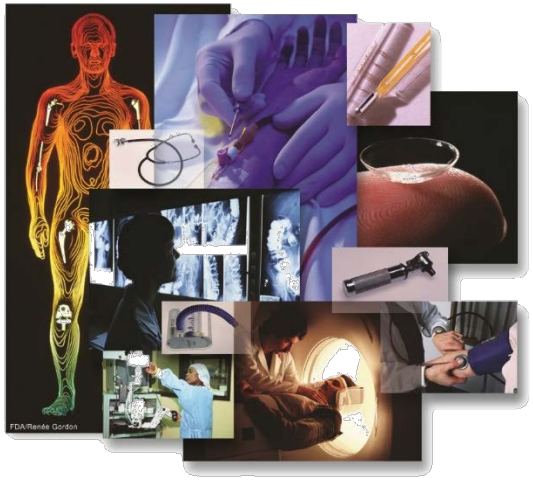

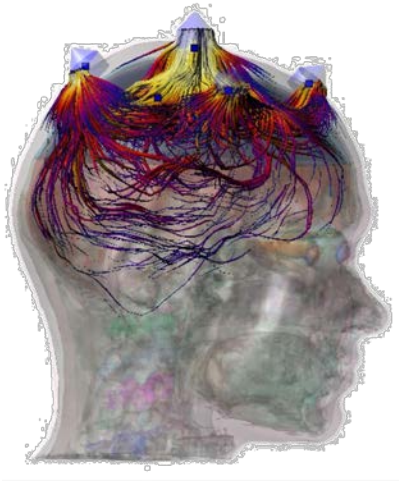

Medical Device Development Tools (MDDT) Program

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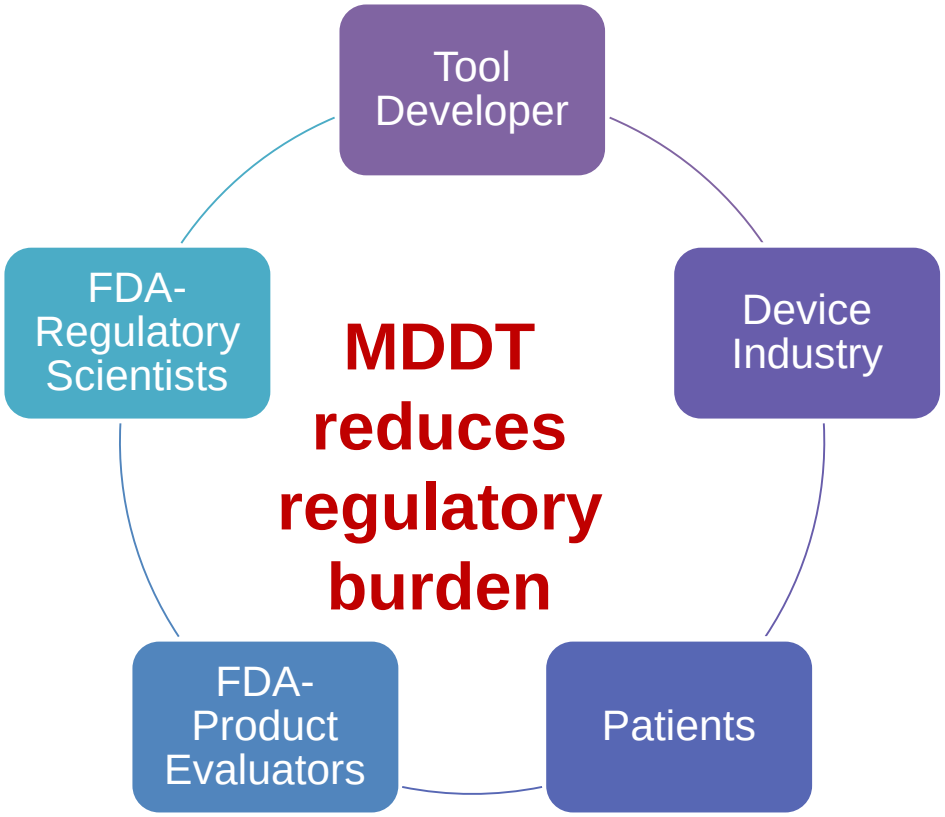
Medical Device Development Tool Program

Promotes Efficient Medical Device Development



Benefit of Qualifying Tools

- Fosters innovation
- Encourages collaboration
- Reduces resource expenditure
- Qualified MDDT applied in multiple device submissions
- Promotes 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

Clinical Outcome Assessments

BT

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

MDDT Program Creation

- Before the creation of the MDDT program…tools used by developers were evaluated on case-by-case basis — for each medical device submission
- **Now** with the creation of the voluntary MDDT Program we are creating both efficiency and transparency in the review process for submitters and reviewers:
  - Qualifying tools for a specific use, FDA facilitates application for multiple medical device submissions and manufacturers
  - Qualified MDDT used in a regulatory submission can be relied upon in device evaluation and to support regulatory decision-making without the need to reconfirm the suitability and utility of the MDDT tool.
  - Submitters have assurance that a qualified tool used within its COU will be accepted by FDA without the need to reconfirm the suitability and utility of the tool.

MDDT Qualified Tools

Name of Tool	Summary of Evidence and Basis for Qualification (SEBQ)	Product Area(s)	Tool Type	
Rubric for Applying CVSS to Medical Devices	Tool description	Cybersecurity	NAM	10/20/2020
BREAST-Q Reconstruction Module	Qualified COU	Plastic Surgery	COA	08/20/2020
Insulin Dosing Systems: Perceptions, Ideas, Reflections, and Expectations (INSPIRE) Questionnaires	Summary evidence to support qualification	Automated Insulin Dosing (AID)	COA	06/24/2020
IMAnalytics with MRIxViP1.5T/3.0T And BCLib	Brief assessment advantages vs. disadvantages	Active implanted medical devices (AIMDs)	NAM	12/12/2019
Tissue Mimicking Material (TMM) for Preclinical Acoustic Performance Characterization of High Intensity Therapeutic Ultrasound (HITU) Devices	Tool developer contact information	Imaging	NAM	07/10/2019
OSIRIX CDE Software Module		Neuro	BT	03/12/2019
Minnesota Living with Heart Failure Questionnaire (MLHFQ)		Cardio	COA	03/19/2018
Kansas City Cardiomyopathy Questionnaire (KCCQ)		Cardio	COA	10/19/2017

MDDT QUALIFICATION PROCESS

Proposal Phase	Qualification Phase
The goal of the proposal phase is to determine if the MDDT is suitable for qualification through the MDDT program. Those interested in seeking qualification should submit a complete ***Qualification Plan*** for collecting & gathering evidence for qualification of the tool a description of the MDDT, and context of use.	The goal of the qualification phase is to determine whether, for a specific context of use, the tool is qualified based on the evidence and justifications provided. In this phase the data collected according to the Qualification Plan is submitted as the ***Full Qualification Package*** and is reviewed for qualification decision.

Resources

- To submit a proposal, download this Proposal Phase Template and follow the instructions to format the cover sheet and qualification plan contents

- MDDT Final Guidance published – August 2017

- MDDT Program & Qualified tools:
  MDDT Webpage

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