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CDRH Final Guidance: Qualification of Medical Device Development Tools (MDDT)

Thursday, August 24, 2017
1:00 – 2:30 PM

MDDT Working Group

Presenter:
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PURPOSE

August 10, 2017: the FDA published guidance document that finalizes the Medical Device Development Tools (MDDT) Pilot Program.

The purpose of this webinar is to help clarify the Agency's recommendations related to the content of the guidance document.

FDA's Medical Device Development Tool webpage:
https://www.fda.gov/medicaldevices/scienceandresearch/medicaldevicedevelopmenttoolsmddt/default.htm

OUTLINE

- Introduction
- Benefits of MDDT qualification
- What is an MDDT?
- What is qualification?
- Qualification decision framework
- Phases of qualification
- Regulatory considerations and additional recommendations

INTRODUCTION

MDDT Program

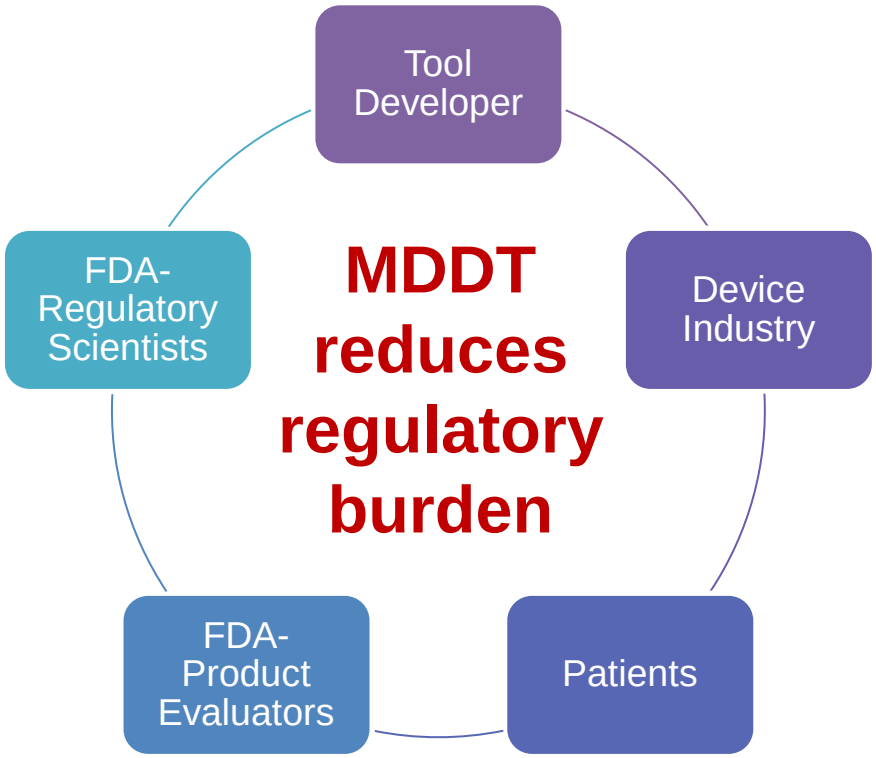
- Voluntary
- Reduces regulatory burden in evaluating medical devices
- **Facilitates development and timely evaluation of medical devices**
- Supports regulatory submissions and decision-making (i.e. study population enrichment, reduce or minimize the use of animals [i.e. simulation])
- Tool submitters: person, group, consortium, or organization (including the federal government)

Guidance

- Describes framework and process for qualification of an MDDT
- Finalizes draft version (November, 2013)

This Guidance does not discuss individual MDDT submission nor address specific evidentiary or performance expectations of an MDDT submission

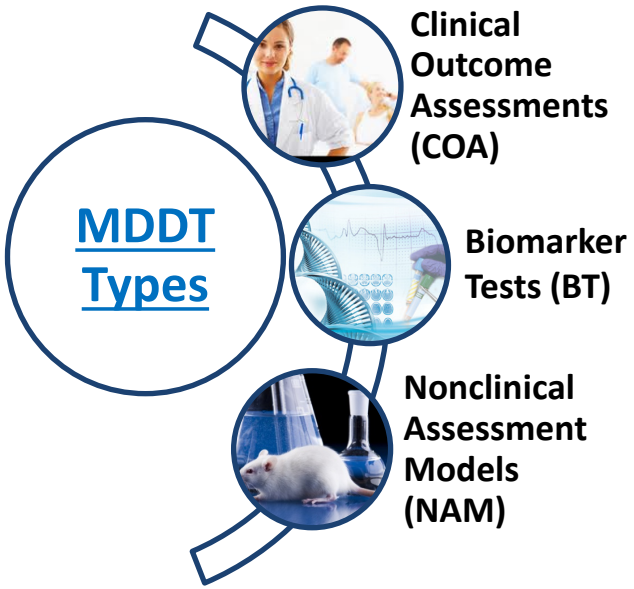
What are the benefits of MDDT qualification?



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

What is an MDDT?

- Method, material, or measurement to assess effectiveness, safety, or performance of a medical device
- Scientifically validated and can be qualified for use in device evaluation and support regulatory decision-making



COAs: Instruments that measure how a patient feels or functions (i.e. patient-reported outcome (PRO) for pain severity)

BTs: Test or instrument used to detect or measure a biomarker (i.e. instrument or method for measuring blood pressure)

NAMs: Non-clinical test model or method measures or predicts device function or *in vivo* device performance (i.e. *in vitro* models to replace animal testing)

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 (for the qualified context of use) **without the need to reconfirm the suitability and utility of the MDDT** when used in regulatory submission

- We encourage developers to make their qualified MDDTs publicly available

CDRH Qualification Decision Framework

Key considerations for qualifying a proposed MDDT:

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

Context of Use

Context of Use (COU): Key aspect of qualification

- Describes 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 (i.e. for use in clinical studies)
  - Phase(s) medical device development in which tool measurements can be used (i.e. design evaluation, animal testing, clinical studies)

Evidence to Support Qualification

Amount and strength of evidence needed to support qualification of MDDT will vary depending on COU and tool type

- Type of evidence needed may include but not limited to as appropriate:
- design verification
- simulation results from computational models
- bench or animal performance data (i.e. full test reports and protocols)
- clinical data (including as above, all appropriate pre-specified statistical analyses to demonstrate relationship between tool and COU)
- human factors testing

Assessment of Advantages/ Disadvantages of an MDDT

- ✓ Qualification depends on **probable advantages outweighing probable disadvantages** of using the tool in the course of developing and/or evaluating a medical device

- ✓ **Type**, **Magnitude**, and **Likelihood** of Advantages & Disadvantages will be assessed, as well as **Mitigation** of Disadvantages

- ✓ CDRH intends to place emphasis on regulatory, public health, and/or clinical impact

Overview of the MDDT Qualification Process

Presenter:

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Policy Analyst/Jurisdiction Officer (acting)
Office of Device Evaluation
Center for Devices and Radiological Health

Presenter:
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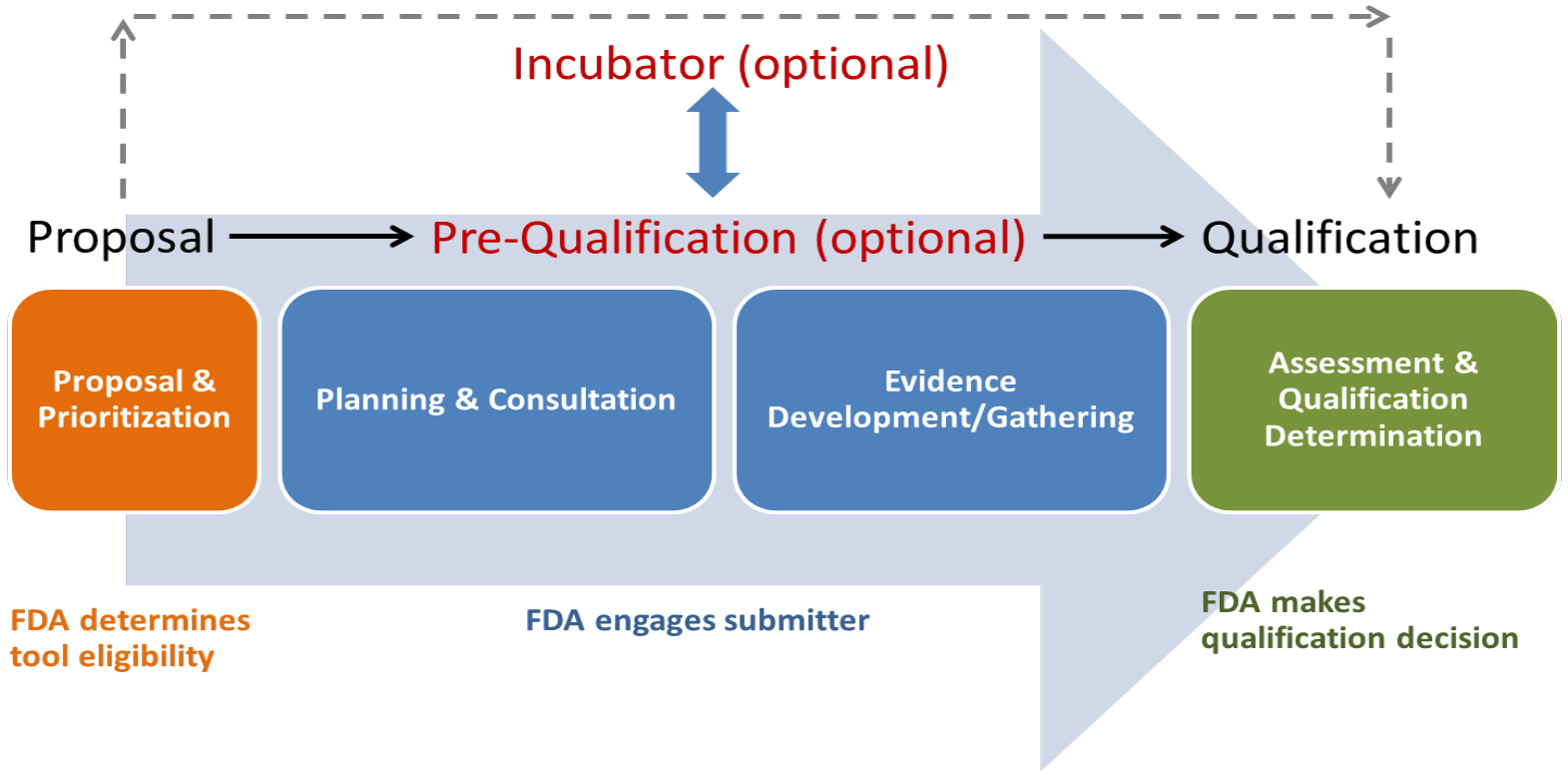
CDRH Qualification Process

A. Proposal Phase

B. Incubator Phase (Optional)

C. Pre-Qualification Phase (Optional)

D. Qualification Phase



Proposal Phase

- Submitters should submit complete proposal package which includes:
  - MDDT description
  - Tool Justification
  - Context of Use
  - Tool readiness
  - Role of MDDT in regulatory evaluation

- CDRH reviews proposals and determines acceptance
  - Accepted proposals: CDRH recommends suitable next phase (incubator, pre-qualification, or qualification) for submission
  - Not accepted proposals: CDRH provides the factor(s) contributing to this decision

- Submitters notified of the decision regarding proposal acceptance in writing approximately 60 days from receipt of proposal

Incubator Phase (Optional)

When submitters are invited to participate in incubator phase they will need to submit an incubator inquiry package (IIP):

- similar content to the proposal package
- updated tool development plan including a timeline
- list of questions for CDRH
- Response to any questions sent by CDRH in the proposal acceptance letter

CDRH may also recommend whether the tool is ready to advance to pre-qualification or qualification phase

Pre-Qualification Phase (Optional)

- Submitters may submit a pre-qualification package

- The package should include a complete plan for gathering the necessary evidence to support tool qualification-
    - Detailed protocols of all studies and tests to be completed to support qualification.
    - A statistical analysis plan when needed

- CDRH conducts expert review of tool description, proposed COU, and evidence plan, and provides feedback addressing any potential studies or protocol modifications that could improve evidence plan

- Tool advances to qualification phase when a tool submitter has demonstrated that evidence plan appears adequate to support proposed COU

Qualification Phase

Submitters should provide complete qualification package that includes:

- all descriptive elements and protocols as described in the proposal and pre-qualification sections
- statement if tool has been previously submitted to MDDT Program or through the Drug Development Tool Program
- MDDT description
- all evidence needed to support qualification
- discussion of how strength of evidence supports qualification
- assessment of advantages and disadvantages for tool use

Qualification Phase, cont.

The qualification package should also include the following to facilitate proper use of the MDDT:

- Tool developer contact information
- Tool data usage by sponsors in regulatory submissions

Appendix 1 of the MDDT guidance provides more details on how to submit a complete qualification package

Regulatory Considerations and Related Recommendations

Presenter:

Hilda F. Scharen, MSc.
CAPT, USPHS
Director, Medical Device Development Tools
Office of the Center Director, Center for Devices and Radiological Health

Regulatory Considerations and Related Recommendations

Some MDDTs may meet the definition of a device in section 201(h) of the FD&C Act.

- Whether an MDDT is a medical device under section 201(h) of the FD&C Act will often depend on how it is intended to be used
- If the MDDT product is only for use in device development/evaluation and is not for use in diagnosing or treating patients or study subjects, it is unlikely it would be a device
- If the MDDT is intended for use in diagnosing or treating, or aiding in the diagnosis or treatment of subjects in a clinical study, it would likely be a device
- A product intended for use in diagnosing or treating, or aiding in the diagnosis or treatment of patients in clinical settings outside clinical studies would likely be a device, but would not be an MDDT

Regulatory Considerations and Related Recommendations, cont.

MDDT Qualification versus Clearance or Approval of Medical Device

- Type of evidence needed to support MDDT qualification is not the type of evidence needed to support marketing authorization for a medical device

MDDT qualification versus consensus standards and device-specific FDA guidance

- MDDT not meant to replace consensus standards and recognition process

Communication to Public of FDA Qualification Decisions

- FDA intends to publicly disclose a **Summary of Evidence and Basis of Qualification (SEBQ)** if the FDA qualifies the tool

- An SEBQ includes:
  - brief description of tool and its principle of operation
  - qualified context of use
  - general summary of evidence to support qualification and discussion of strength of that evidence
  - brief assessment of advantages and disadvantages of using MDDT for its qualified context of use
  - information on how a device developer can contact tool developer to access the tool

- Any tool submitter with questions about the content and detail FDA intends to provide in an SEBQ should raise those with FDA during the proposal phase

Questions?

For questions related to MDDT, please contact the CDRH MDDT Working Group: MDDT@fda.hhs.gov

For general questions, please contact the Division of Industry and Consumer Education: DICE@fda.hhs.gov

Slide Presentation, Transcript and Webinar Recording will be available at:

http://www.fda.gov/training/cdrhlearn

Under the Heading: How to Study and Market Your Device; Sub-heading: Cross-Cutting Premarket Policy

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