U.S. FOOD & DRUG ADMINISTRATION

Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes

Today's Topic:
Qualification of Medical Device Development Tools (MDDTs)

September 12, 2023

Qualification of Medical Device Development Tools, Guidance

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U.S. Food and Drug Administration

Guidance

- **Qualification of Medical Device Development Tools, Guidance for Industry, Tool Developers, and Food and Drug Administration Staff, issued on July 17, 2023**
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/qualification-medical-device-development-tools
  - www.federalregister.gov/documents/2021/11/04/2021-24061/content-of-premarket-submissions-for-device-software-functions-draft-guidance-for-industry-and-food

- **Medical Device Development Tools (MDDT) Webpage**
  - www.fda.gov/medical-devices/medical-device-development-tools-mddt

MDDT Guidance

- Streamlines framework and process for qualification of an MDDT
- Does not discuss individual MDDT submissions
- Does not address specific evidentiary or performance expectations of an MDDT submission

Learning Objectives

- Define medical device development tools (MDDTs)
- Discuss MDDT qualification and its benefits
- Describe the qualification decision framework
- Discuss other regulatory considerations and related recommendations
- Discuss how to submit an MDDT proposal package

MDDT Program

- Voluntary
- Reduces regulatory burden in evaluating medical devices
- Facilitates development and timely evaluation of medical devices
- Supports regulatory submissions and decision-making
- Tool submitters may be a person, group, consortium, or organization (including the federal government)

What is an MDDT?

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

Examples of MDDTs

Non-clinical Assessment Model

Non-clinical test model or method that measures or predicts parameters of interest in regard to safety, effectiveness, or device performance

Biomarker Test

Test or instrument used to detect or measure a biomarker. Biomarkers are a defined characteristic measured as an indicator of normal biological processes, pathogenic processes, or biological responses to an exposure or intervention, including therapeutic interventions

Clinical Outcome Assessment

Assessment of a clinical outcome reported by a clinician, a patient, a non-clinician observer or through a performance-based assessment.

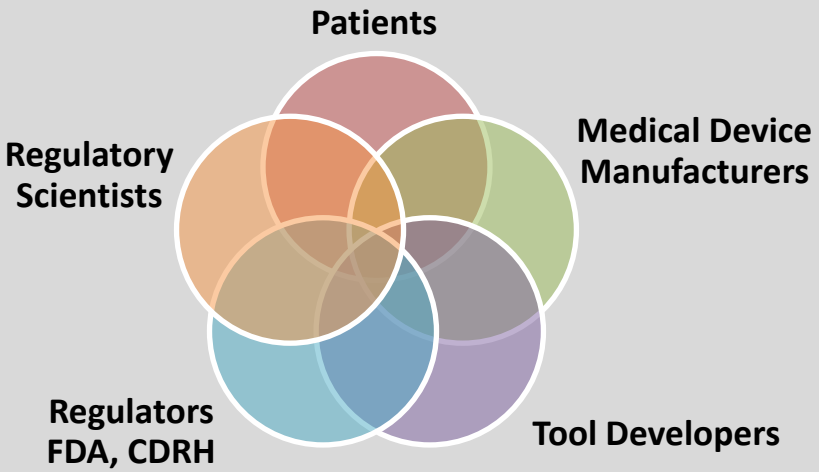
What is MDDT Qualification?

- A conclusion, based on CDRH review of the MDDT Qualification Package
- Signifies that the MDDT can be relied upon to facilitate regulatory decision making when used according to qualified context of use

What is MDDT Qualification?

- CDRH reviewers should accept MDDT for qualified context of use
  - Without need to reconfirm suitability and utility of MDDT when used in the regulatory submission
- Developers are encouraged to make their qualified MDDTs publicly available

Benefits of MDDT Qualification



- Bridges gaps between research and development
  - Innovation
  - Collaboration
- Can be applied to multiple device submissions
  - Efficiency in CDRH Review
  - Minimizes uncertainty in review process
- Reduces individual resource expenditure

Key Components of MDDT Qualification Framework

MDDT Description

Context of Use

Regulatory Utility

Strength of Evidence

Assessment of Advantages and Limitations

Context of Use

- Statement that fully, clearly describes the way to use the MDDT and its medical device development-related purpose
- A complete context of use should address:
  - Output/measure/assessment from MDDT
  - Role of MDDT in regulatory evaluation (such as for use in clinical studies)
  - Phase of development where MDDT may be used (such as design evaluation, animal testing, or early clinical studies)

Types of Evidence to Support Qualification

- Design Verification
- Simulation Results from Computational Models
- Bench or Animal Performance Data (such as full test reports and protocols)

Types of Evidence to Support Qualification

- Clinical Data (full test reports and protocols, all appropriate pre-specified statistical analyses to demonstrate relationship between tool and context of use)
- Human Factors Testing

Assessment of Advantages and Limitations

- For proposed context of use and plan for evidence generation, identify advantages and limitations
- Advantages
  - Should highlight impact of tool use in support of regulatory decision making
- Limitations
  - Should accurately detail conditions under which tool should not be used or may not provide meaningful assessment of safety, effectiveness, or performance of a medical device

Qualification Process

Proposal Phase	Qualification Phase
1) Determine suitability of MDDT based on ability to facilitate regulatory decision making. 2) Review **Qualification Plan** with performance criteria and plan for collecting and gathering evidence in support of proposed and context of use.	1) Evaluate strength of evidence in **Qualification Package** to determine whether evidence meets the performance criteria and supports the Qualification Plan for proposed context of use. 2) Qualify tool if the evidence supports the proposed context of use.

FDA only intends to qualify tools where FDA can make public certain high-level information about the existence of qualified tools and their utility

Key Content to Include in Proposal Phase

MDDT Description	Concept of Interest/Description of principle Method and mode of measurement
Context of Use Statement	Use within regulatory submission Specific output(s), measure(s), endpoints, timing of assessments, etc.
Performance Criteria	Performance characteristics of measurement outputs Measurement properties (reliability, meaningful change, etc.) Scientific justification for strength of evidence collected to support qualification
Qualification Plan	Methods and Performance data to be collected Design verification and validation/validity evidence to be collected Relationship between measurement outputs/validity evidence to context of use
Assessment of Advantages and Limitations	Advantages should highlight impact of tool use on regulatory decision making Limitations should highlight conditions under which tool cannot provide a meaningful assessment

Key Content to Include in Qualification Phase

Proposal	Contents of Proposal including: • Tool description • Context of use statement • Performance criteria • Qualification plan
Tool Evidence	Evidence Clinical Outcome Assessment (COA) Dossier
Assessment of Advantages and Limitations	Advantages should highlight impact of tool use on regulatory decision making Limitations should highlight conditions under which tool cannot provide a meaningful assessment

Regulatory Considerations and Related Recommendations

- Some MDDTs may meet definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act
  - impacted by how MDDT is intended for use
- Unlikely a device if:
  - only for use in device development or evaluation
  - not for use in diagnosing or treating patients or study subjects

Regulatory Considerations and Related Recommendations

- Likely a device if:
  - MDDT is intended for use in diagnosing or treating, or aiding in the diagnosis or treatment of subjects in a clinical study
- Likely a device but not an MDDT if:
  - a product intended for use in diagnosing or treating, or aiding in diagnosis or treatment of patients in clinical settings outside clinical studies

Regulatory Considerations and Related Recommendations

- 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
  - MDDTs are not meant to replace standards development and recognition process
  - MDDTs are not meant to replace device-specific FDA guidance

Summary of Evidence and Basis of Qualification (SEBQ)

- SEBQ includes:
  - Brief description of tool and principle of operation
  - Qualified context of use
  - Summary of evidence to support qualification
  - Assessment of advantages and limitations
  - Contact information for tool developer
- SEBQ does not include proprietary information

MDDT Proposal Submission Process

- Any tool developer, medical device sponsor, or others, such as research organizations and academia can voluntarily submit a proposal
- No Fees
- MDDT Proposal Submission Content
  - www.fda.gov/medical-devices/medical-device-development-tools-mddt/medical-device-development-tool-mddt-proposal-submission-content

MDDT Proposal Submission Process

- We recommend you use CDRH Premarket Review Submission Cover Sheet
  - Facilitates correct login and prompt routing to appropriate CDRH review group
- Identify requests as an “MDDT” in the cover letter
- MDDT proposals and qualification packages are tracked with a universal tracking number (UTN)
  - Previously were Informational Meeting Q-Submissions

MDDT Proposal Submission Process

- Submission Methods:
  - Electronically through the CDRH Customer Collaboration Portal
    - www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal
  - Mail to the CDRH Document Control Center
    - www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-medical-device-submissions
- Email questions to MDDT@fda.hhs.gov

Summary

- MDDT Program is voluntary pathway to qualify regulatory science tools.
- MDDTs are tools that assess safety, effectiveness or performance of a medical device.
- MDDTs are not intended to replace standards development and recognition or device specific guidance.
- FDA intends to publicly disclose SEBQ for qualified tools.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Let's Take Your Questions

- **To Ask a Question:**
  1. Raise your hand in Zoom 

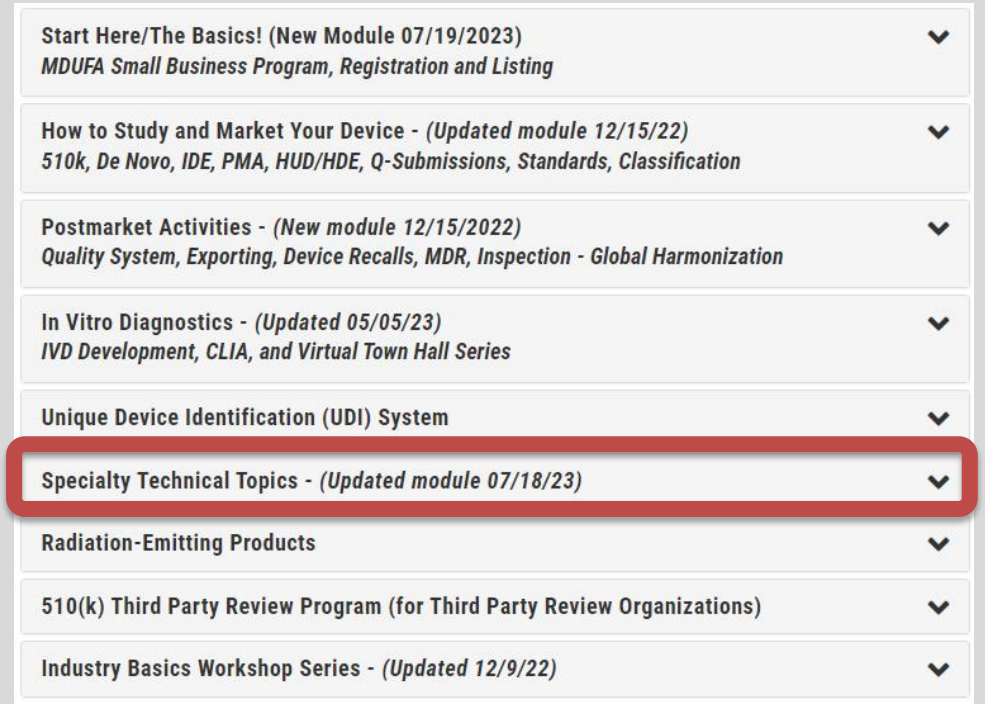
  2. Moderator will announce your name and invite you to ask your question
  3. Unmute yourself when prompted in Zoom to ask your question

- **When Asking a Question:**
  - Ask one question only
  - Keep question short
  - No questions about specific submissions

- **After Question is Answered:**
  - Mute yourself and lower your hand
  - If you have more questions - raise your hand again

Thanks for Joining Today!

- **Presentation and Transcript will be available at CDRH Learn**
  - www.fda.gov/Training/CDRHLearn
- **Additional questions about today's webinar**
  - Email: DICE@fda.hhs.gov
- **Upcoming Webinars**
  - www.fda.gov/CDRHWebinar

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