U.S. FOOD & DRUG ADMINISTRATION

CDRH Medical Device Development Tools (MDDT) Program

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- MDDT Submission Process
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Why the MDDT Program?

Qualification through MDDT Pathway

Using MDDTs to support marketing applications

MDDT Program qualifies tools to advance medical device development

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)

Medical Device Manufacturers

- Reduce individual resource expenditure
- Minimize uncertainty in review process

Regulators (FDA/CDRH)

- Efficiency in CDRH Review
- Acceptance of Tool in Regulatory Review

Regulatory Scientists & Tool Developers

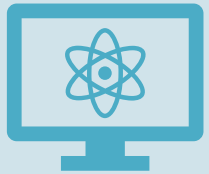
- Bridge gap between research and development
- Further innovation & Collaboration

Patients

- Enable Patient Voices to be incorporated [PROs]

MDDT Qualification plays many roles in the medical device ecosystem

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 Common MDDTs

Non-clinical Assessment Models

A non-clinical test model or method that measures or predicts device function or in vivo device performance.

- *e.g., computational models, animal models, phantoms.*

Biomarker Test

A defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or biological responses to an exposure or intervention, including therapeutic interventions.

- *e.g., measures of molecular, histologic, radiographic, or physiologic characteristics.*

Clinical Outcome Assessment

Assessment of a clinical outcome reported by a clinician, a patient, a non-clinician observer or through a performance-based assessment. May include digital health technologies.

Other

Tools that do not fit directly into any particular category, however can be used to support regulatory decision making

- *e.g., databases.*

Qualification Process

Proposal Phase (~90 Days)

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.

Qualification Phase

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

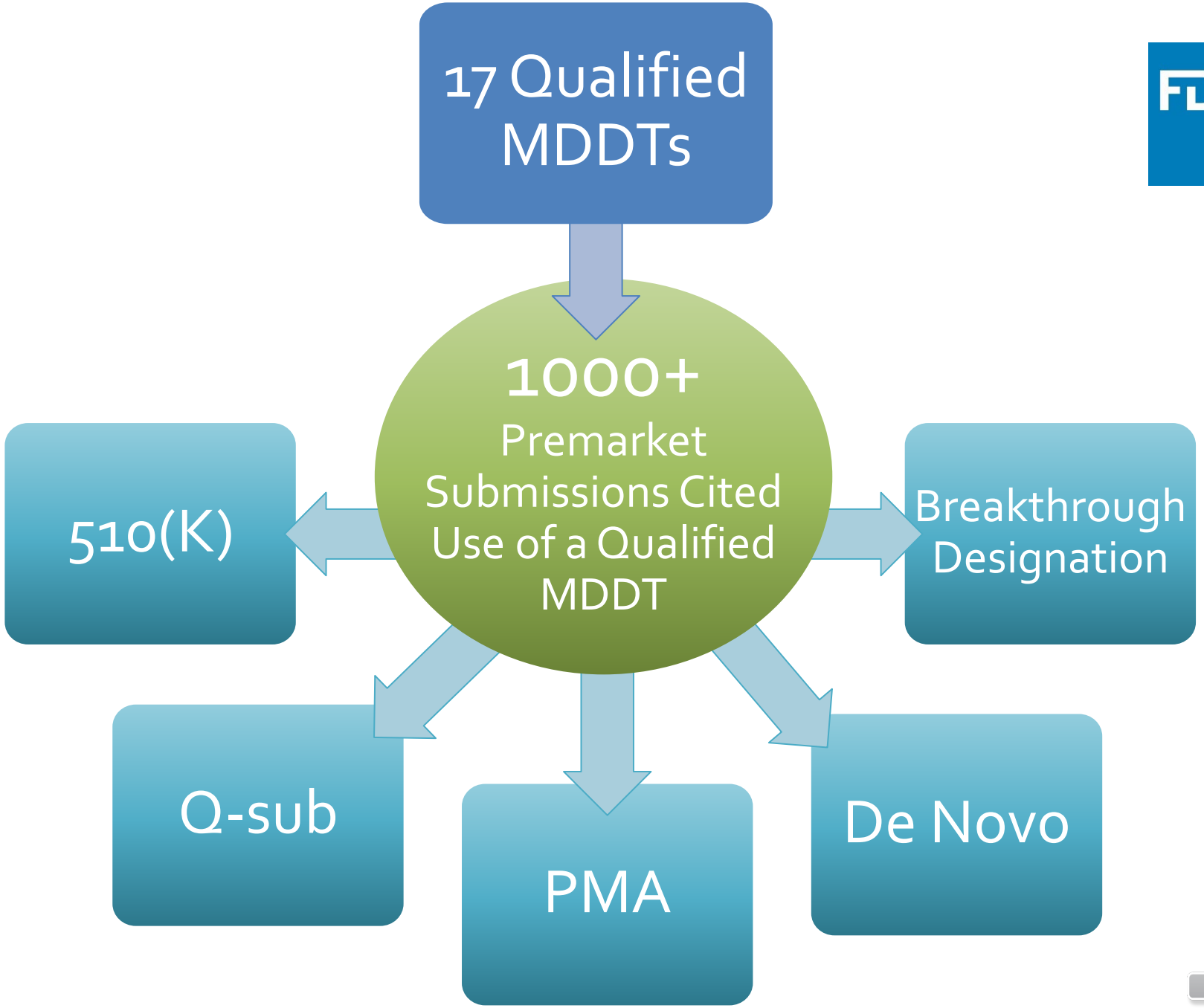
Summary of Evidence and Basis of Qualification (SEBQ)

- 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
- 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

Qualified MDDTs are routinely cited by Sponsors



17 Currently Qualified MDDTs

COA (7)

- Assessment of IntraOcular Lens Implant Symptoms (AIOLIS) instrument (5/16/22)
- FACE-Q | Aesthetics(4/26/22)
- Patient-Reported Outcomes with LASIK Symptoms and Satisfaction (PROWL-SS) (6/17/21)
- BREAST-Q Reconstruction Module (8/20/20)
- Insulin Dosing Systems: Perceptions, Ideas, Reflections, and Expectations (INSPIRE) Questionnaires(6/24/20)
- Minnesota Living with Heart Failure Questionnaire (MLHFQ)(3/19/18)
- Kansas City Cardiomyopathy Questionnaire (KCCQ)(10/19/17)

BIO (2)

- Apple Atrial Fibrillation History Feature (5/1/24)
- OSIRIX CDE Software Module (3/12/19)

NAM (7)

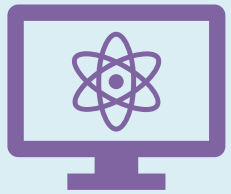
- Accelerated Testing to Prove Long-Term Material Biostability (8/9/23)
- Computational Tool Comprising Visible Human Project Based Anatomical Female CAD Model and Ansys HFSS/Mechanical FEM Software for Temperature Rise Prediction near an Orthopedic Femoral Nail Implant during a 1.5 T MRI Scan (3/30/23)
- CHemical RISk Calculator (CHRIS) - Color Additives (11/28/23)
- Virtual MRI Safety Evaluations of Medical Devices (11/16/21)
- IMAnalytics with MRIxViP1.5T/3.0T And BCLib (5/20/21)
- Rubric for Applying CVSS to Medical Devices (10/20/20)
- Tissue Mimicking Material (TMM) for Preclinical Acoustic Performance Characterization of High Intensity Therapeutic Ultrasound (HITU) Devices (7/10/29)

Other (1)

- The University of California San Francisco (UCSF) Lethal Arrhythmia Database (LAD) (3/28/24)

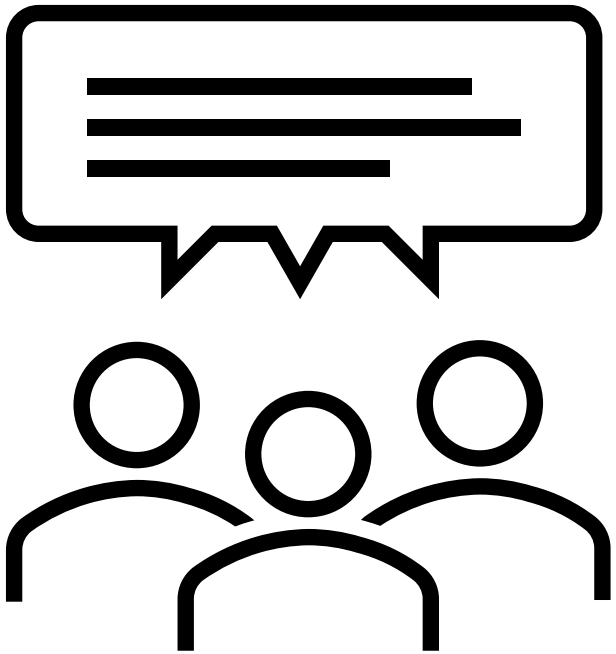
Summary

MDDT PROGRAM IS A VOLUNTARY PATHWAY TO QUALIFY REGULATORY SCIENCE TOOLS



MDDTS ARE TOOLS THAT ASSESS SAFETY, EFFECTIVENESS OR PERFORMANCE OF A MEDICAL DEVICE.

DEVICE MANUFACTURERS ARE ENCOURAGED TO USE IN SUPPORT OF THEIR PREMARKET APPLICATION.



Resources

MDDT Program & Qualified tools

MDDT Webpage

MDDT Guidance

Questions or Concerns:
MDDT@fda.hhs.gov