Introduction to Medical Device Development Tools (MDDTs)

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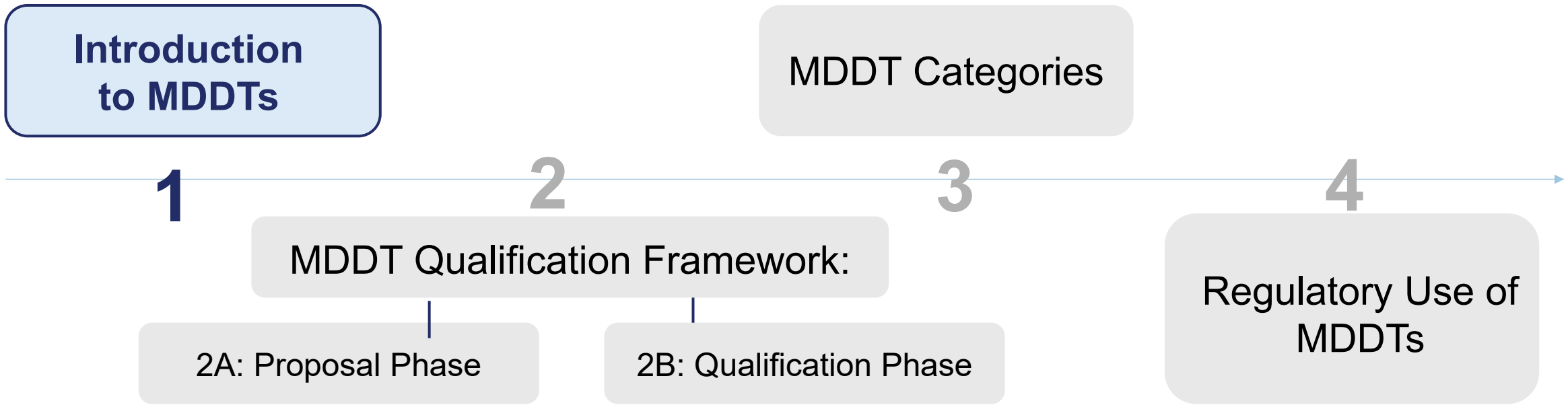
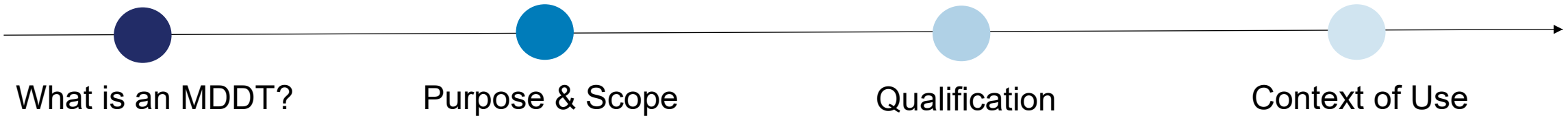
Medical Device Development Tool (MDDT) Series

Module 1



Module 1:
Introduction to Medical Device Development Tools (MDDTs)



Module 1
Learning Objectives

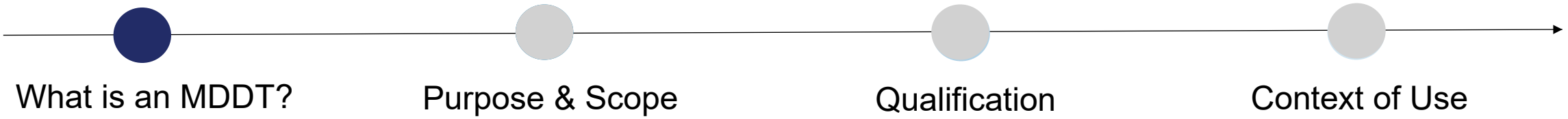
Introduction to MDDTs

- Define what is an MDDT
- Describe the purpose and scope of the MDDT Program
- Explain how MDDT Qualification works
- Define Context of Use (COU)

What is an MDDT?

An MDDT is a ***method, material, or measurement*** used to assess the ***safety, effectiveness, or performance*** of a medical device. An MDDT is scientifically substantiated and can be qualified for use in device evaluation to support regulatory decision-making within a specified context of use.

"Qualification of Medical Device Development Tools", Guidance for Industry, 2023



What is an MDDT? (continued)

Qualified for use in device evaluation

Scientifically substantiated

Supports regulatory decision-making

MDDTs Address Regulatory Challenges

The MDDT program was created to:

- Incorporate advancing regulatory science **innovation**
- Increase **predictability** during device evaluation
- Improve **efficiency** and **transparency**
- Encourage **collaboration** in developing tools and supporting evidence

What is an MDDT? | Purpose & Scope | Qualification | Context of Use

The MDDT Program: Purpose

To qualify scientifically substantiated tools that can **support regulatory decision-making** within a specific context of use for medical devices.

To ensure validated tools can be used **across multiple submissions** without repeated FDA evaluation.

To enhance **predictability, consistency, and efficiency** in device development and review.

The MDDT Program: Scope

In Scope

- Assess **safety, effectiveness or performance**
- Has a defined **Context of Use (COU)**
- Clear **regulatory utility**

Out of Scope

- Only assesses **drugs or biologics**
- **Does not aid** in regulatory evaluation or decision-making
- Confidential or **non-public use**

What is MDDT Program Qualification?

MDDT qualification is FDA's determination that

"…within a specified ***context of use****, the results of an assessment that uses an MDDT can be relied upon in* ***device evaluation*** *and to support* ***regulatory decision-making****"*

Once qualified, the tool can be used by sponsors in multiple device development programs and regulatory submissions.

FDA's MDDT Webpage

What is an MDDT? | Purpose & Scope | Qualification | Context of Use

Two Phases of MDDT Qualification

1. Proposal Phase

Define and Plan

- Determine tool suitability
- Review Qualification Plan

2. Qualification Phase

Evaluate and Decide

- Evaluate strength of evidence supporting Context of Use (COU)
- Qualify tool if evidence supports the proposed COU

What is an MDDT? | Purpose & Scope | Qualification | Context of Use

What is Context of Use (COU)?

Every MDDT is qualified for a specific **COU**

Describes:

- ***What*** the tool measures or assesses
- ***How*** it is used in medical device development
- ***How*** it will be used to assess a medical device
- ***Which phase*** in device development it can be used
- ***Limitations*** of the tool

Taken together, these elements define the COU: by describing what the tool measures or produces, how and when it is used in medical device development, how it is used to assess a device, and its limitations.

What is an MDDT? | Purpose & Scope | Qualification | Context of Use

Example COU: CardioSim-Stress

Fictitious Non-Clinical Assessment Model

CardioSim-Stress provides a quantitative analysis of the maximum principal stress and cumulative fatigue damage on a virtual coronary stent model for de novo coronary lesions when subjected to physiological cardiac cycle loading conditions. The output is a predictive report detailing the structural integrity over a simulated 10-year implantation period. CardioSim-Stress is intended to supplement physical bench testing and short-term implantation studies during design verification and may reduce test duration in long-term implantation studies.

CardioSim-Stress is not a standalone replacement for physical fatigue testing or other nonclinical studies. It is validated only for coronary stents made of L605 cobalt-chromium alloy with strut thicknesses between 80µm - 120µm. CardioSim-Stress is based on healthy adult coronary artery anatomy and does not account for patient-specific anatomical variations or severe disease states.

This is a **hypothetical** COU created for educational purposes only. It does not represent an actual qualified MDDT.

What is an MDDT? | Purpose & Scope | Qualification | Context of Use

COU Content Considerations

WHAT it measures

- *inputs*
- *outputs*

HOW and by **WHOM** it is used

- *phase of device development*
- *intended users*
- *study type & population*

Regulatory Role

- *nonclinical or clinical, pre- or post-market context*
- *what the tool supports or supplements*

Limitations & Constraints

- *population exclusions*
- *conditions & environment of use*
- *input parameter boundaries*

What is an MDDT? | Purpose & Scope | Qualification | Context of Use

CardioSim-Stress COU Example

WHAT
it measures

*…**quantitative analysis of the maximum principal stress and cumulative fatigue damage** on a virtual coronary stent model when subjected to simulated physiological cardiac cycle loading conditions.*

HOW and
BY WHOM
it is used

*…output is a **predictive report** detailing the stent's structural integrity over a simulated **10-year implantation period**.*

What is an MDDT? | Purpose & Scope | Qualification | Context of Use

CardioSim-Stress COU Example (continued)

HOW and **BY WHOM**

*…intended to **supplement physical bench testing and short-term implantation studies** during the **design verification phase**…*

Regulatory Role

*…**supplement physical bench testing** and short-term implantation studies during the design verification phase and **may reduce test duration** in long-term implantation studies.*

What is an MDDT? | Purpose & Scope | Qualification | Context of Use

CardioSim-Stress COU Example (continued)

Limitations & Constraints

- *Not intended to replace fatigue testing or other nonclinical studies*
- *Only for stents made from L605 cobalt-chromium alloy with strut thicknesses 80μm -120μm.*
- *Based on a healthy adult coronary artery anatomy*
- *Does not account for patient-specific anatomical variations or severe disease states.*

Strong Context of Use

COU Principle	CardioSim-Stress Example
Clear Definition of Outputs	Predictive report of structural integrity over 10 years
Device Development Phase	Used in design verification & performance testing
Device Scope	L605 coronary stents (80–120µm)
Defined Regulatory Purpose	Supplement bench testing; *may* reduce long-term implantation test duration
Explicit Limitations	Does not replace physical fatigue testing; Not applicable for patient-specific anatomical variations

What is an MDDT? Purpose & Scope Qualification Context of Use

Module 1 Summary

An MDDT is a method, material, or measurement used to assess the safety, effectiveness, or performance of a medical device. It is scientifically substantiated and can be qualified for use in device evaluation to support regulatory decision-making within a specified context of use.

The purpose of the MDDT Program is to qualify tools that can be used in the development and evaluation of medical devices within a specified context of use.

The scope of the MDDT Program covers tools that are used to assess the safety, effectiveness, or performance of a medical device, have a defined Context of Use and clear regulatory utility.

MDDT Qualification occurs through a two-phase process (Proposal and Qualification).

The COU describes what the tool measures, how and when an MDDT is to be used in regulatory evaluation, and what are the limitations of the tool.

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Resources

Slide Number	Cited Resource	URL
1-6	"Qualification of Medical Device Development Tools", Guidance for Industry, 2023	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/qualification-medical-device-development-tools
1-11	FDA MDDT webpage	https://www.fda.gov/medical-devices/medical-device-development-tools-mddt

Your Call to Action

Visit the Medical Device Development Tools (MDDT) **website** to

- Learn more about the MDDT Program and qualification process
- View the list of qualified MDDTs available for public use

Review other modules in this series:

- Module 2: MDDT Qualification Framework
- Module 3: MDDT Categories
- Module 4: Regulatory Use of MDDTs

Apply to the MDDT Program by putting together a submission

Contact the MDDT Program with questions about qualification, engagement, or next steps: MDDT@fda.hhs.gov