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: Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder

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Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder

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Draft Guidance

- **Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder**
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-considerations-studies-devices-intended-treat-opioid-use-disorder

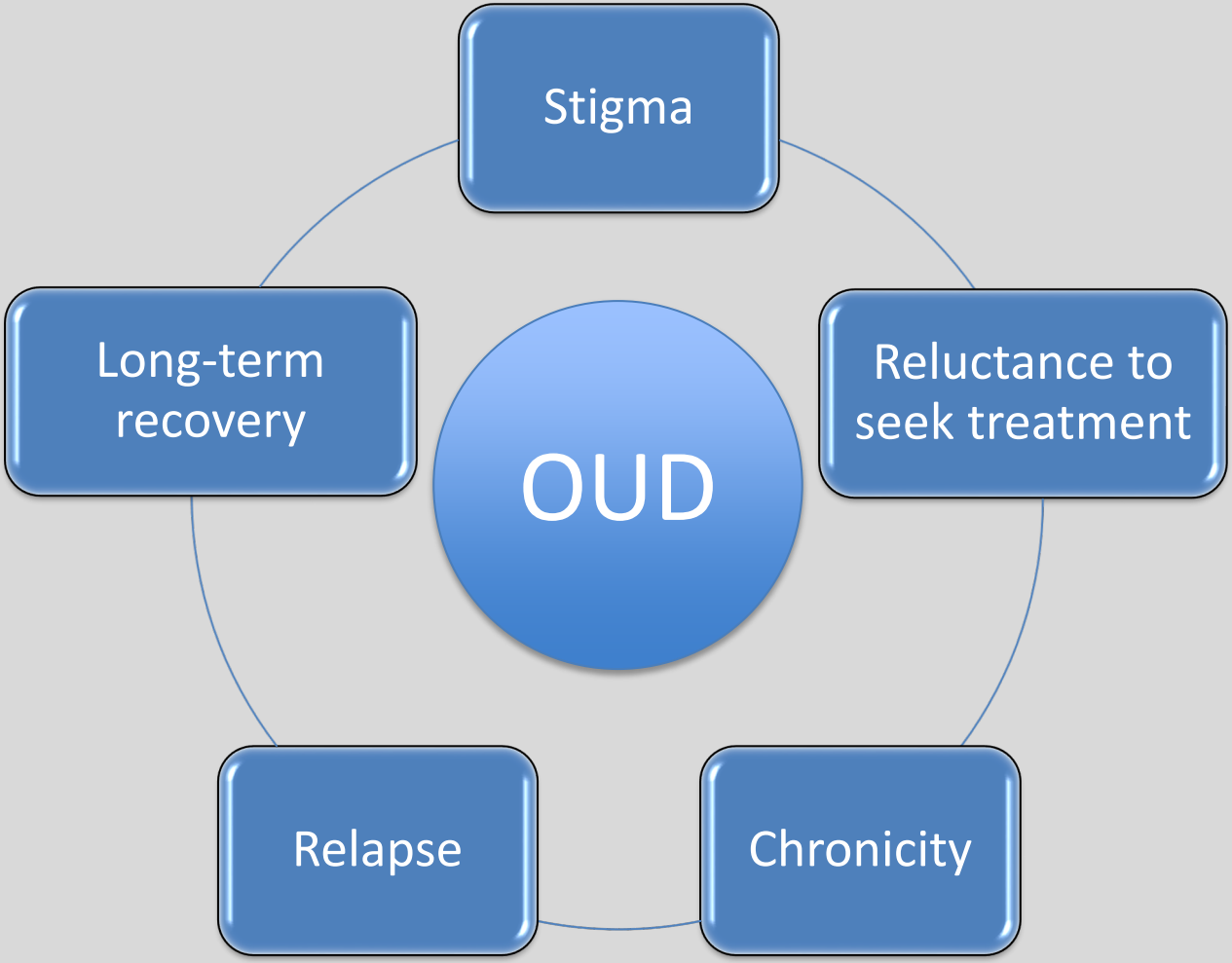
Learning Objectives

- Describe the challenges in designing pivotal Opioid Use Disorder ("OUD") device studies
- Identify the purpose and scope of the draft guidance
- List the important design features to consider for the design of pivotal studies of devices intended to treat OUD ("OUD device studies")

The Complexity of OUD

Opioid Epidemic and OUD

- The opioid crisis is a public health emergency (PHE)
- PHE most recently renewed on March 31, 2023
- FDA is committed to addressing this PHE:
- Part of FDA Overdose Prevention Framework


Stigma
Reluctance to seek treatment
Chronicity
Relapse
Long-term recovery
OUD

Purpose and Scope of Guidance

Purpose

- Provides recommendations for the design of pivotal clinical studies for devices intended to treat OUD and used to support future marketing authorization

Scope

- Only devices intended to treat OUD
- Excluded:
  - Early feasibility/preliminary studies
  - Devices intended to detect opioid use
  - Devices intended to diagnose/determine risk of developing OUD
  - Devices intended to treat pain
  - Combination products

Recommendations for Pivotal OUD Device Studies

General Principles

- Well-controlled studies:
  - 21 CFR 860.7 (Determination of safety and effectiveness)
  - See "Design Considerations for Pivotal Clinical Investigations for Medical Devices"
- Discussion through Q-Submission (Q-Sub)
  - See "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program"

Clinical Study Design Recommendations

Patient Population & Treatment Assignment

Recording Medication Use

Monitoring Drug Use

Study Length and Evaluation

Participant Retention & Missing Data

Clinical Outcomes

Patient Population and Treatment Assignment

- Defined, representative study population
  - See "Collection of Race and Ethnicity Data in Clinical Trials"
- Use a sham control to minimize bias and uncertainty

Recording Medication Use

- Need to mitigate inaccurate reports of drug use
- Record baseline medications
  - Prescribed drug(s)
  - Dose
  - Duration
  - Timing of drug use
  - Medication changes

Monitoring Drug Use

- Self-reports and objective measures, such as:
  - Random and schedule urine tests
  - Drug levels in blood or saliva
  - Use of drug detection technologies
- Quantitative methods take precedence over self-reported information

Study Length and Evaluation

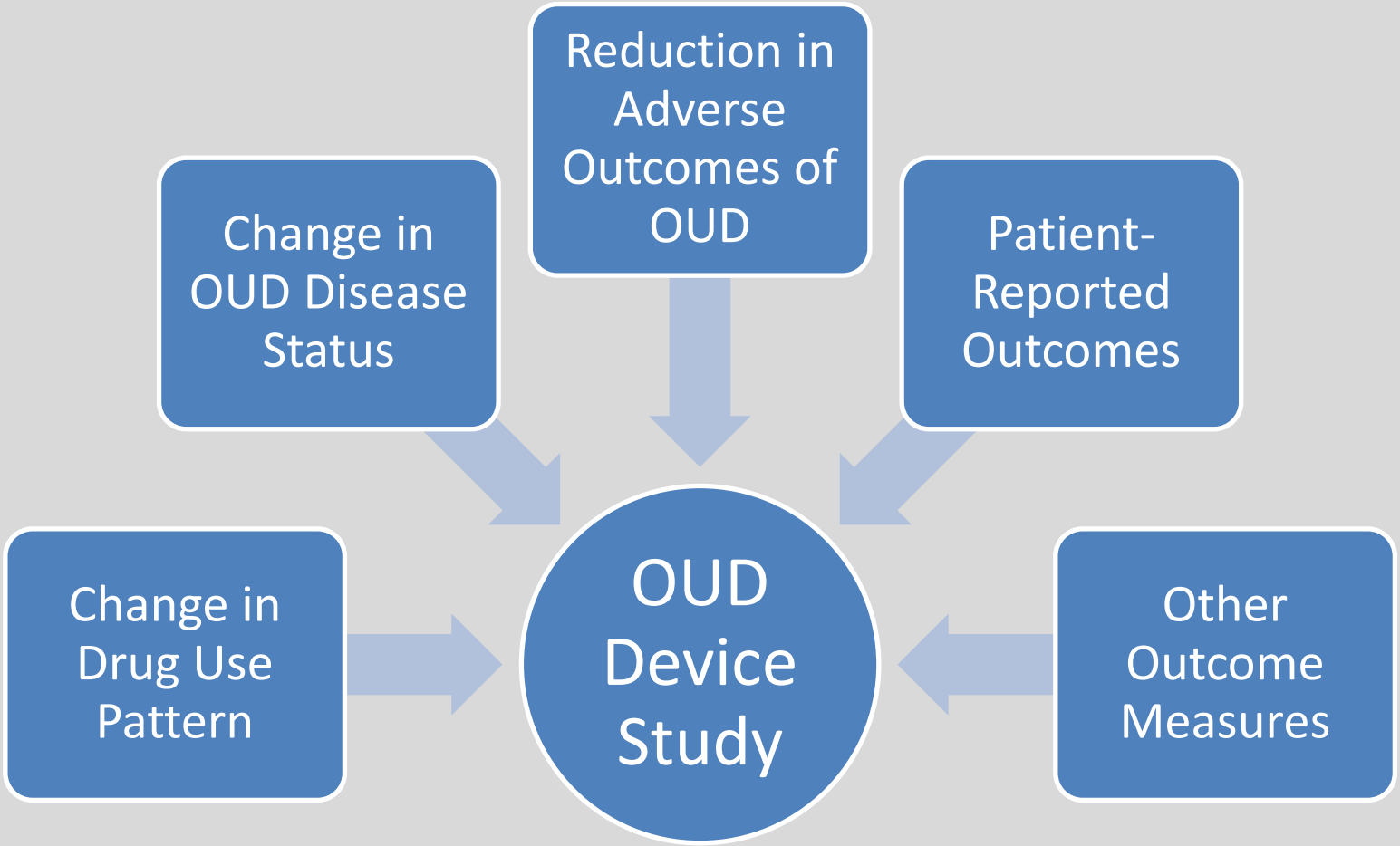
- Minimum of 6 months treatment duration
- Include procedures to account for:
  - Participant retention
  - Missing data

Participant Retention and Missing Data

- Maximizing study participation is critical
- Missing data introduces a high degree of uncertainty in study results
- Need methods/procedures to address, detect, and correct missing data

Clinical Outcomes

- Generate valid scientific evidence
- Demonstrate clinically significant benefits
- Primary outcomes
  - Main source of effectiveness evidence
- Secondary outcomes
  - Help confirm or explain primary outcomes
- Consistent with the Center for Drug Evaluation and Research (CDER) guidance
  - "Opioid Use Disorder: Endpoints for Demonstrating Effectiveness of Drugs for Treatment Guidance for Industry"


Reduction in Adverse Outcomes of OUD
Change in OUD Disease Status
Patient-Reported Outcomes
Change in Drug Use Pattern
OUD Device Study
Other Outcome Measures

Resources

Slide Number	Cited Resource	URL
12	21 CFR 860.7 – Determination of safety and effectiveness	www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-860/subpart-A/section-860.7
12	Design Considerations for Pivotal Clinical Investigations for Medical Devices	www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-pivotal-clinical-investigations-medical-devices
12	Requests for Feedback and Meetings for Medial Device Submission: The Q-Submission Program	www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program
14	Collection of Race and Ethnicity Data in Clinical Trials	www.fda.gov/regulatory-information/search-fda-guidance-documents/collection-race-and-ethnicity-data-clinical-trials
19	Opioid Use Disorder: Endpoints for Demonstrating Effectiveness of Drugs for Treatment Guidance for Industry	www.fda.gov/regulatory-information/search-fda-guidance-documents/opioid-use-disorder-endpoints-demonstrating-effectiveness-drugs-treatment-guidance-industry

A Note about Draft Guidances

- You may comment on any guidance at any time
  - see 21 CFR 10.115(g)(5)
- Please submit comments on draft guidance before closure date
  - to ensures that FDA considers your comment on a draft guidance before we work on final guidance
- Draft guidance is not for implementation

Submit Comments to Dockets by: October 26, 2023

- **Draft Guidance: Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder**
  - Docket: FDA-2023-D-0466
  - www.regulations.gov/docket/FDA-2023-D-0466

Summary

- Spur innovative options to combat opioid epidemic
- Provide recommendations for OUD device studies:
  - Generate valid scientific evidence from well-controlled studies
  - Demonstrate clinically meaningful benefits
  - Provide reasonable assurance of safety and effectiveness
- Complexity of OUD necessitates:
  - Collaboration with FDA (Q-Submission process)
  - Discussion of alternative study designs and methods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Additional Panelists

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Let's Take Your Questions

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

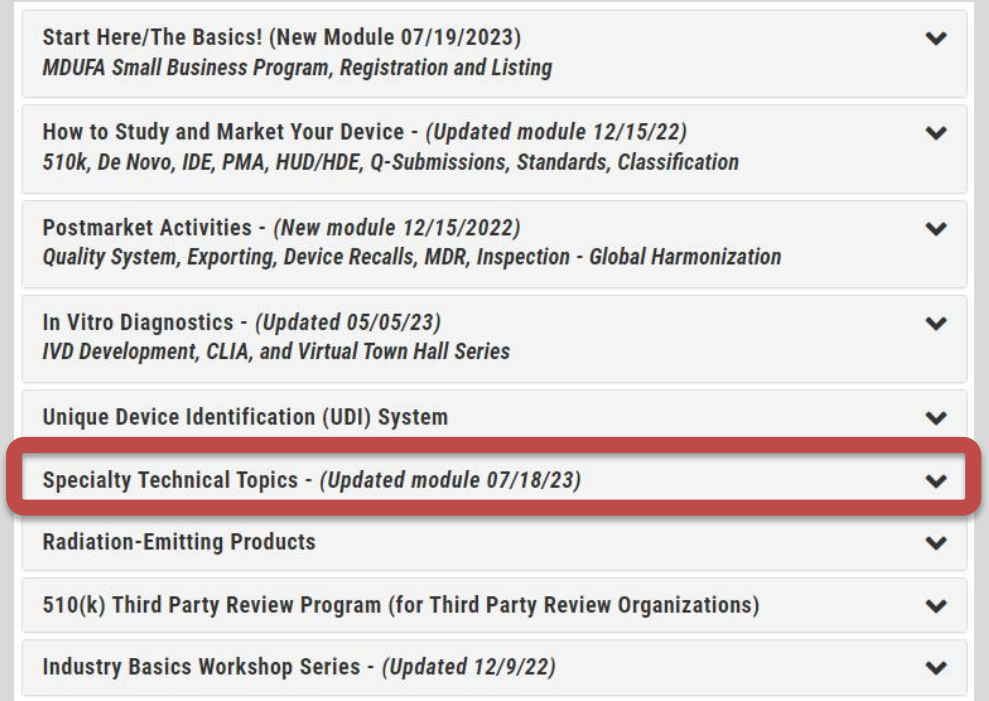
  2. Moderator will announce your name and invite you to ask your question
  3. Unmute yourself when prompted in Zoom to ask your question

- **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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