Welcome To Today's Webinar

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

Today's Topic:

Final Guidance, Patient Engagement in the Design and Conduct of Medical Device Clinical Studies

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Final Guidance:
Patient Engagement in the Design and Conduct of Medical Device Clinical Studies

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Final Guidance

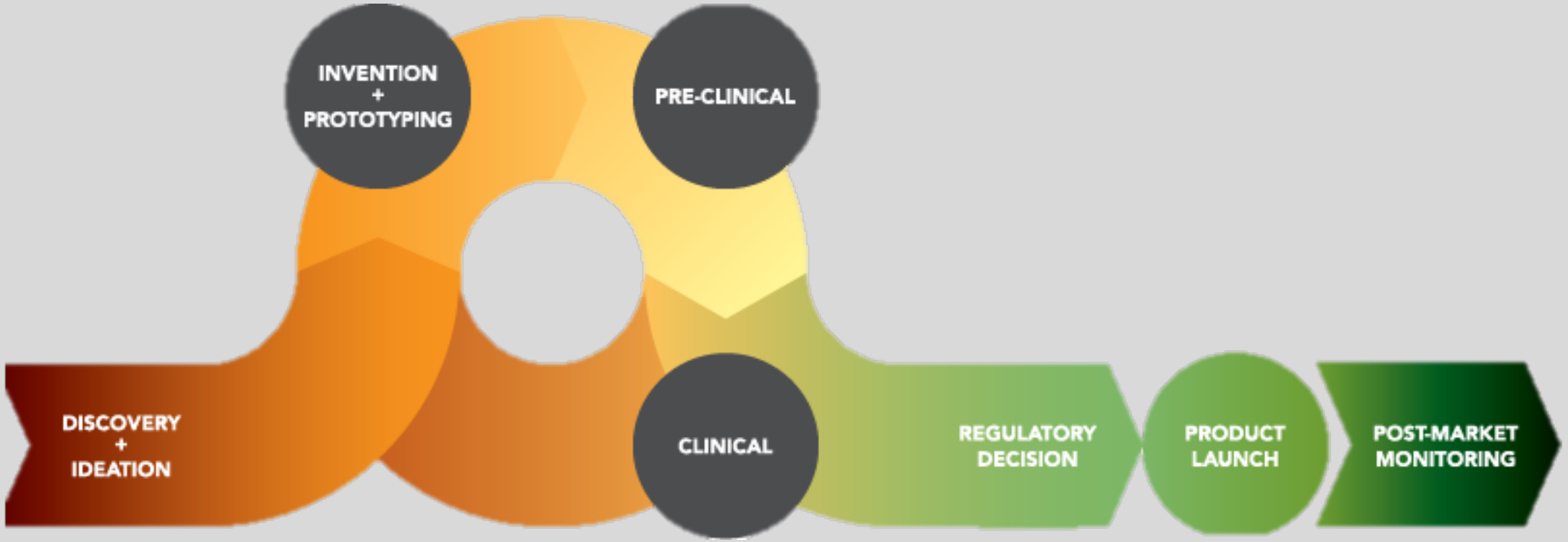
- **Patient Engagement in the Design and Conduct of Medical Device Clinical Studies**
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-studies
  - Docket Number: FDA-2019-D-3846

Learning Objectives

- Describe background, development and contents of the patient engagement guidance
- Discuss meaning of patient engagement and how patients as advisors can help improve clinical study design and conduct
- Review examples of opportunities to engage patients
- Identify helpful resources when developing patient engagement approaches in clinical studies

Background on Patient Engagement

Patient Input Across Total Product Lifecycle



Patient Engagement Guidance Development

PEAC = Patient Engagement Advisory Committee
CTTI = Clinical Trials Transformation Initiative

Key Terms and Definitions

- **Patient Engagement**
  - Intentional, meaningful interactions with patients that provide opportunities for mutual learning, and effective collaborations
- **Patients**
  - Individuals with or at risk of a specific disease or health condition whether or not they currently receive any therapy to prevent or treat that disease/condition
  - Are the individuals who directly experience the benefits and harms associated with medical products

Key Terms and Definitions

- **Study/Research Participants**
  - Individuals who are or become a participant in research, as a recipient of the test article, on whom or on whose specimen the test article is used, or as a control, and may include healthy individuals

- **Patient Advisors**
  - Individuals who have experience living with a disease or condition, and can serve in an advisory or consultative capacity to improve clinical study design and conduct
  - Are not study/research participants themselves or caregivers of study/research participants

Perceived Barriers and Challenges to PE in Clinical Studies

- Patients' perceptions that their input is not "allowed" or "valued"
- Challenges finding patient advisors
- Site investigators' reluctance to allow sponsors to engage with patients
- Logistical challenges of engaging with patient advisors
- Challenges determining which patient perspectives to include

Overview of Patient Engagement Guidance

Guidance Purpose

- Help sponsors understand how to voluntarily use patient engagement:
  - to elicit experience, perspectives, and other relevant information from patient advisors to improve the design and conduct of medical device clinical studies
- Highlight benefits of engaging with patient advisors early in device development process
- Illustrate which PE activities are generally not considered by FDA to constitute research or an activity subject to FDA's regulations, including regulations regarding IRB
- Address common questions and misconceptions about collecting and submitting to FDA PE information regarding the design and conduct of a medical device clinical study

Structure of Final Guidance

- Introduction with guidance objectives specified
- Scope
- Definition of patient engagement
- Questions and Answers on patient engagement in clinical studies
- Ways in which industry might engage with patients

Scope of Guidance

- **Focuses on application of patient engagement:**
  - By using patient advisors to inform and improve design and conduct of medical device clinical studies

- **Does not address:**
  - Study/research participant or patient advisor reimbursement or compensation
  - Promotion of investigational devices
  - Dissemination of clinical study results

Potential Benefits of Diverse Patient Advisor Input in Clinical Studies

- Faster study/research participant recruitment, enrollment, and study completion
- Greater study/research participant commitment and retention, resulting in decreased loss to follow-up
- Greater study/research participant adherence resulting in fewer protocol deviations and violations
- Greater study/research participation by diverse populations
- Fewer protocol revisions
- Streamlined data collection resulting in better quality data
- More relevant data on outcomes that matter to patients

Patient Engagement Activities

When Can Patient Advisors Be Involved?

Planning

During study plan development, especially in innovative areas or new targeted populations

Conduct

When significant recruitment and retention challenges occur

Future Efforts

To inform improvements for future studies

Some PE Activities that May Enhance Design and Conduct of Clinical Studies

- Informed consent improvement
- Flexible options for data collection and follow up visits
- Recruitment barriers and study delays
- Potential endpoints
- Patient-Reported Outcomes (PRO) concepts
- Patient Preference Information (PPI) study design

What Are Roles of IRBs and Other Institutional Groups in PE?

- **IRB Purpose**
  - Assure protection of rights and welfare of humans who are study research participants

- **No IRB Involvement – for PE activities with patient advisors**
  - Primarily involve interaction in a consultative or advisory capacity
  - FDA does not generally consider PE activities with patient advisors to constitute research or an activity subject to FDA's regulations on their own

- **IRB Involvement**
  - Interactions between study/research participants and investigators

Resources on Patient Engagement

How Can a Sponsor Receive Feedback from FDA on Patient Engagement Plan or Patient-Centered Study Design?

- **Q-Submission Program**
  - Final Guidance: Requests for Feedback and Meetings for Medical Device Submissions: The Q Submission Program
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

Summary

- Patient engagement in medical device clinical investigations has value and is appropriate in certain circumstances
- PE guidance provides an overview of potential value and summary of challenges and potential solutions related to involving patient advisors in design and conduct of clinical investigations
- We encourage early interaction with FDA to obtain feedback on your approach for incorporating patient input in design and conduct of device investigations
- More patient-centric device clinical studies may lead to improved efficiency and quality of clinical studies and greater uptake of results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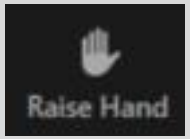
Let's Take Your Questions

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

  - Moderator will announce your name and invite you to ask your question
  - Unmute yourself when invited 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 presentation**
  - Email: DICE@fda.hhs.gov

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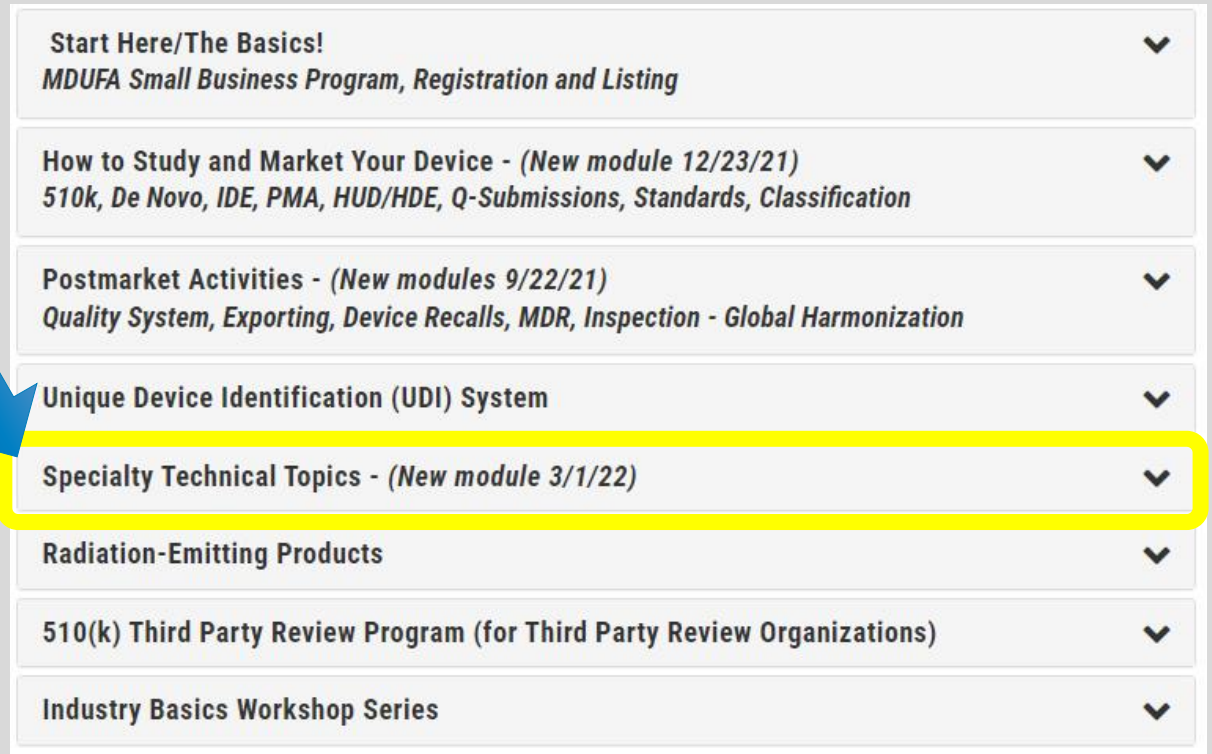


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