Welcome to today's
FDA/CDRH Webinar

Thank you for your patience while we register all of today's participants.

If you have not connected to the audio portion of the webinar, please do so now:

Dial: 800-369-1937

International Callers Dial: 1-312-470-7075

Passcode:5211887

Strengthening the Medical Device Clinical Trial Enterprise

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Office of Device Evaluation

Center for Devices and Radiological Health

Please help us help you

- CDRH would like to better understand your training and communication needs regarding medical device clinical trials
- We will be asking you to complete a short survey
- Results will inform our future clinical trials outreach efforts
- Survey link: https://www.research.net/s/fdamdct

Survey link: https://www.research.net/s/fdamdct

Outline

- Overview of CDRH's 2014-15 Strategic Priorities
- Clinical trial enterprise priority
- CDRH's recent efforts and results
- Focus on Early Feasibility Studies (EFS)
- Future plans

Survey link: https://www.research.net/s/fdamdct

CDRH Strategic Priorities 2014/2015

- **Strengthen the Clinical Trial Enterprise**
- **Strike the Right Balance Between Premarket and Postmarket Data Collection**
- **Provide Excellent Customer Service**

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Strengthening the Clinical Trial Enterprise

- Goal: Improve the efficiency, consistency, and predictability of the IDE process to reduce the time and number of cycles needed to reach appropriate IDE full approval for medical devices, in general, and for devices of public health importance, in particular.
- Goal: Increase the number of early feasibility/first-in-human IDE studies submitted to FDA and conducted in the U.S.

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The IDE Challenge

- The IDE review process is an important part to protecting subjects in investigational device studies
- We also recognize, the sooner an IDE is approved, the sooner a potentially important technology can be available to US patients
- The IDE process has at times led to avoidable bottlenecks in the process
- We can and should look for ways to improve the process of FDA's decision making for IDEs

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What is CDRH doing?

- **Established Clinical Trials Program and Clinical Trials Director (CTD)**
- **Established SOP for CTD involvement and review of certain IDE decisions. Focus on:**
  - Ensuring CDRH is “in the right place”
  - Ensuring flexibility is applied where appropriate
  - Increased communication with sponsors
- **Established Early Feasibility Study (EFS) coordinators within Clinical Trials Program**

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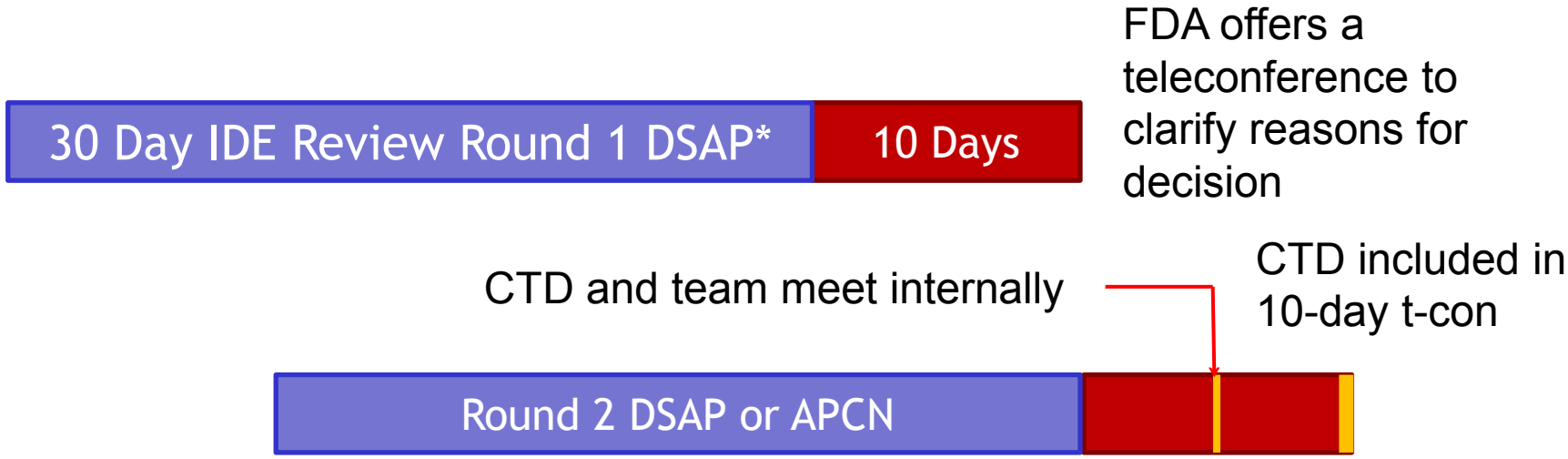
IDE SOP Provisions

30 Day IDE Review Round 1 DSAP*	10 Days

FDA offers a teleconference to clarify reasons for decision

* For Round 1 disapproval (DSAP) and approval with conditions (APCN) decisions, the clinical trials director (CTD) may review and request to meet with review team.

IDE SOP Provisions



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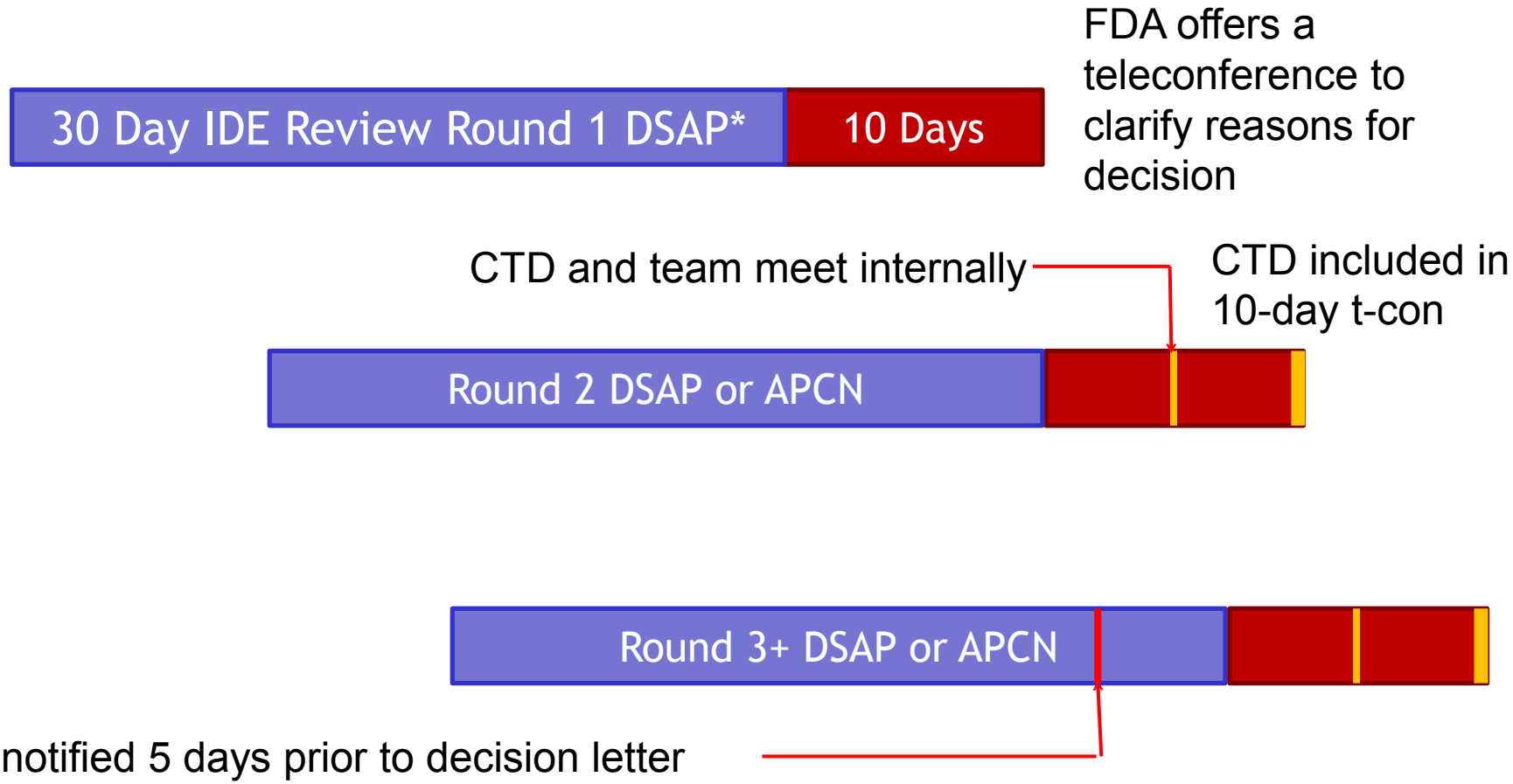
IDE SOP Provisions



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Clinical Trials Program Outcomes

- Helps ensure consistency in decision-making
- Facilitates sharing of best practices across divisions
- Encourages higher levels of interaction
- Helps prepare sponsor to respond
  - 10-day meeting

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FY2014 Goals and Results

By September 30, 2014, compared to FY13 performance, CDRH sought to:

- **Reduce the number of IDEs requiring more than two cycles to an appropriate full approval decision by 25%**
  - Result: 34% reduction
- **Reduce the overall median time to appropriate full IDE approval by 25%**
  - Result: 53% reduction

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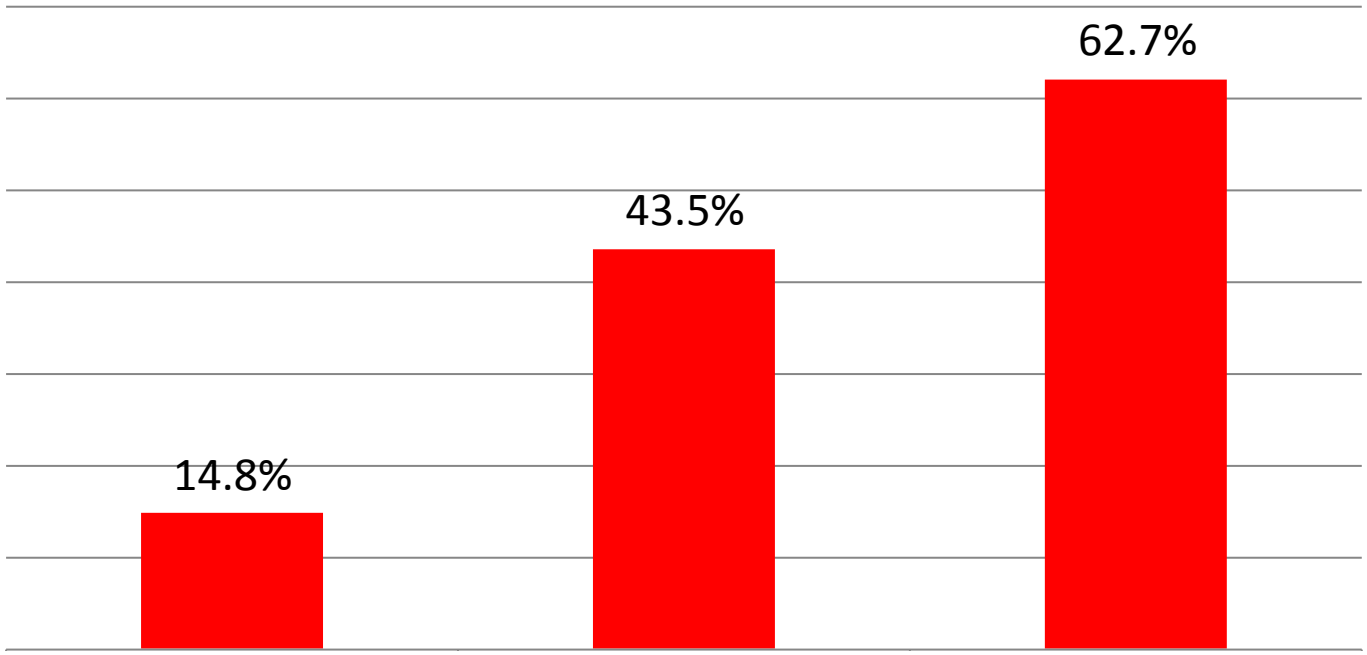
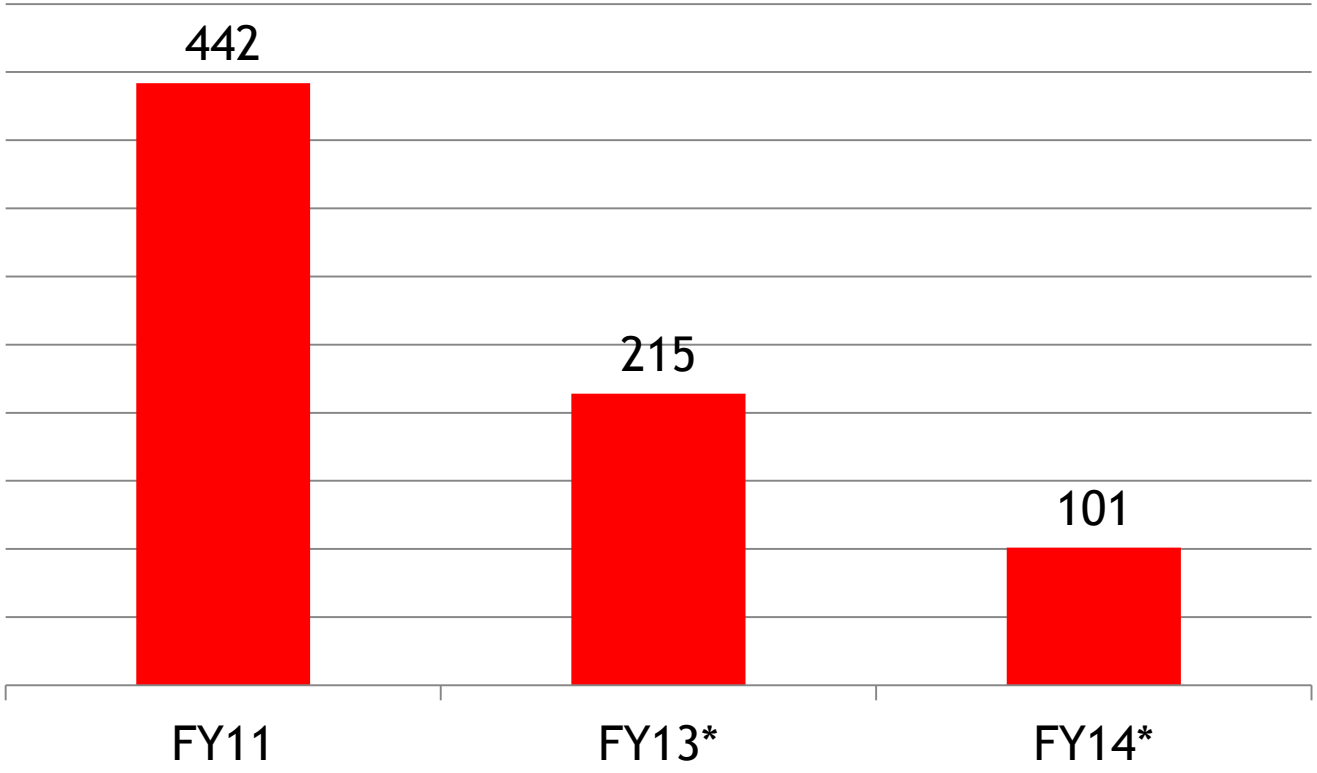
FY14 Performance



* Values calculated on 10/31/13 and 10/31/14 respectively

FY14 Performance

Median Days to Full IDE Study Approval



* Values calculated on 10/31/13 and 10/31/14 respectively

FY2015 Goals

By June 30, 2015, compared to FY13 performance, CDRH seeks to:

- Reduce the number of IDEs requiring more than two cycles to an appropriate full approval decision by 50%
- Reduce the overall median time to full appropriate IDE approval to 30 days.
- Increase the number of early feasibility/first-in-human IDE studies submitted to each premarket Division

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Early Feasibility Study (EFS) Program

- **Intent - To facilitate US EFS under the IDE regulations**
- **Scope - Elements that define an early feasibility study:**
  - Small number of subjects
  - Device that may be early in development, typically before the device design has been finalized
  - Does not necessarily involve the first clinical use of a device

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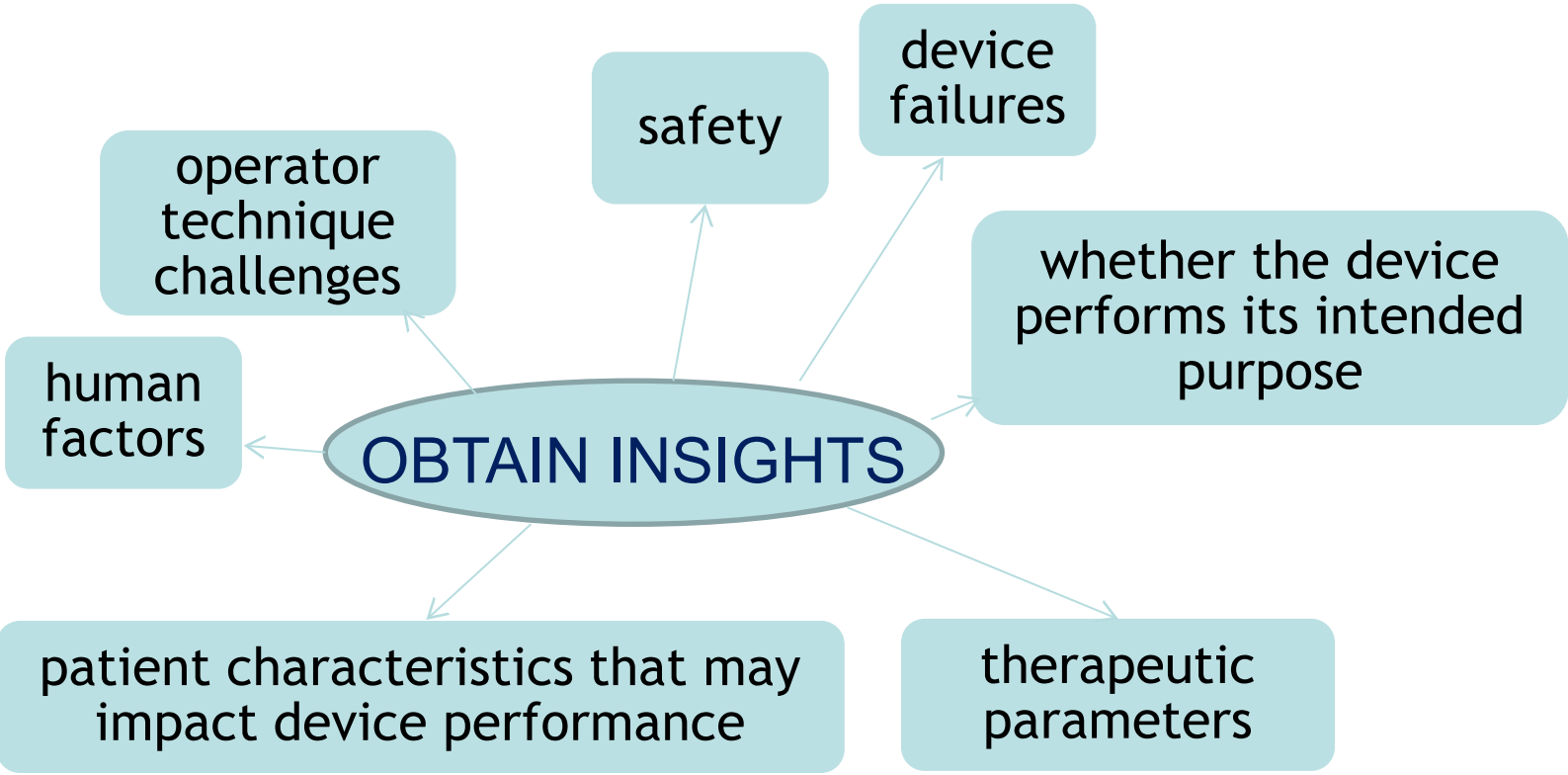
Purpose of Early Feasibility Studies



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Why focus on EFS?

- EFS is often a critical step in device innovation and development
- When EFS are conducted in the US, important new technologies may become available to US patients sooner.

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What is CDRH doing to support EFS in US?

- Issued Guidance to outline FDA's thinking on EFS and how FDA can be more flexible
- Established and trained EFS experts in each ODE review division to assist sponsors and review teams
- Currently developing "CDRH-learn" module focused on EFS

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EFS Guidance

- **Key Guidance Principle - Approval of an early feasibility study IDE may be based on less nonclinical data than would be needed to support the initiation of a larger clinical study of a more final device design**
- **Guidance Provisions - A regulatory toolkit that enables sponsors and regulators to think in new ways about device development**
  - Justifying the appropriate evidence needed to move from bench to clinical study
  - Allowing timely device and clinical protocol modifications

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The Right Testing at the Right Time

- Comprehensive testing during early phases of device development may add cost without significant return
- It may be acceptable to defer some nonclinical testing until the device design has been finalized
- An early feasibility study incorporates enhanced risk mitigation strategies and patient protection measures as compared to a pivotal study

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EFS Process

- **Sponsors contact EFS coordinators and interact informally to:**
  - Discuss the EFS guidance policies and principles
  - Help with understanding the device evaluation strategy (DES) concept and developing the DES table
  - Prepare for initial interactions with the review team
- **Submit the initial Pre-Sub**
  - Reach agreement on the information needed in the Report of Prior Investigations to support study initiation
  - Supplement Pre-Sub as needed
- **Submit the original IDE and continue interacting with CDRH throughout the conduct of the EFS**

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EFS Team

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Clinical Trials Program: Future Plans

- Continued monitoring of performance for IDEs in general and EFS IDEs
- Draft Benefit-Risk Guidance for IDEs
- Development of additional clinical trials training for CDRH review staff and external stakeholders
- Submission quality improvements

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Submission Quality

- Meeting our FY15 goals will require work by both FDA and IDE sponsors
- Many IDE submissions fail to "tell the sponsor's story"
- Many others fail to provide basic information needed to support FDA's IDE review
- Interaction with sponsor during IDE review can help resolve minor issues, but improvements in submission quality are a critical component as well

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Some major nonclinical reasons for IDE Deficiencies

- Device description
- Mechanical testing
- Biocompatibility
- Animal testing

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Types of questions that relate to submission quality

- Describe device components and materials
- Describe principle of operation and key characteristics
- Clarify version of device tested compared to version for clinical study
- Clarify what testing was done with rationale
- Provide adequate description of test conditions, success criteria, and results

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Conclusions

- Strengthening the Clinical Trial Enterprise is a high priority for CDRH.
- We have made major progress in the past year.
- However, much work remains and future progress will be a joint effort between FDA and our external stakeholders.

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Important Guidance Documents

- FDA Decisions for IDE Clinical Investigations
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM279107.pdf
- IDEs for Early Feasibility Medical Device Clinical Studies
  - http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm279103.pdf
- Design Considerations for Pivotal Clinical Investigations for Medical Devices
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM373766.pdf
- Evaluation of sex-specific data in medical device clinical studies
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM283707.pdf

Questions?

Division of Industry and Consumer Education:
DICE@fda.hhs.gov

Slide Presentation, Transcript and Webinar Recording will be available at:

http://www.fda.gov/training/cdrhlearn

Under Heading: How to Market Your Device

How can CDRH best meet your needs for clinical trials training and communication?

Please fill out our short survey so that we may better understand your needs for education related to FDA requirements for clinical device trials.

Link: https://www.research.net/s/fdamdct