

Welcome to today's FDA/CDRH Webinar

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Breakthrough Devices Program

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Agenda

- Background
- Scope and structure of final guidance
- Differences between draft and final version
- Regulatory framework
- Highlights of final guidance
- Questions

Objectives

- Understand the following elements:
 - Purpose and scope of the Breakthrough Devices Program
 - Breakthrough device criteria and what obtaining a breakthrough device designation means for a sponsor and the FDA review teams
 - Administrative process for submitting a breakthrough device designation request and how to engage with the FDA after a designation has been obtained

Definitions & Abbreviations

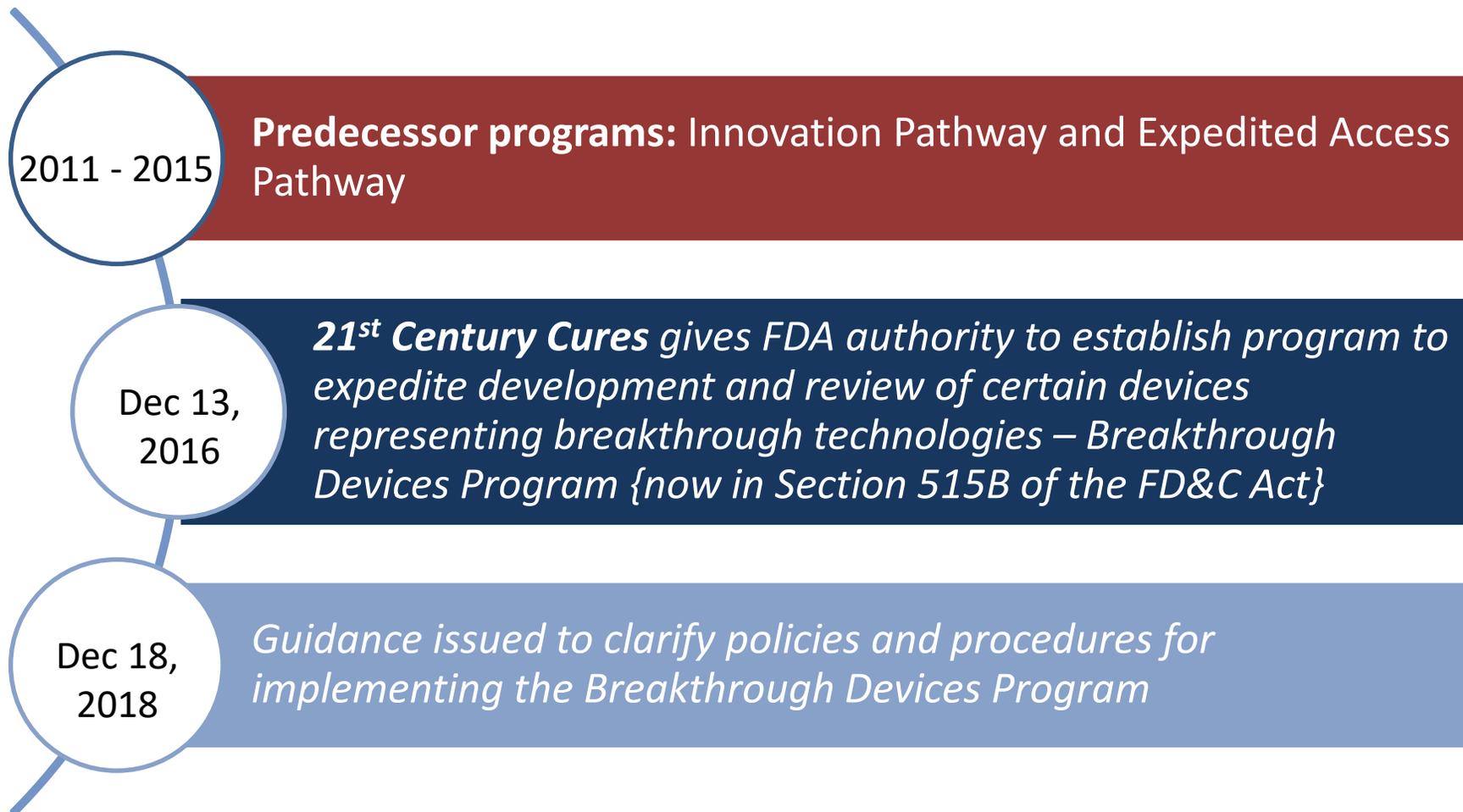
- ***Q-Submission:*** submission mechanism to request different types of interaction with the FDA
 - Requests feedback regarding potential or planned medical device submissions
 - Request certain formal determinations that are not standalone marketing submissions or research authorizations
 - Examples include: Pre-Submissions, Study Risk Determinations
- ***Investigational Device Exemption (IDE):*** mechanism to request approval for a significant risk clinical study of an unapproved device or unapproved use of a device
- ***FD&C Act:*** Federal Food, Drug & Cosmetic Act

Context for Breakthrough Devices Program Guidance

CDRH Vision: Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world

- Early Feasibility Studies
- Patient Engagement
- Real World Evidence
- **Breakthrough Devices Program**
- Case for Quality

Context for Breakthrough Devices Program Guidance





Breakthrough Program Purpose

- Help patients have more timely access to devices
- Expedite device development and review for certain medical devices
- Work with sponsors to define a roadmap from early stages of device development to FDA marketing authorization
 - Breakdown perceived barriers
 - Collaboration & interaction



Program Definition

The Breakthrough Devices Program is a **voluntary program** for certain **medical devices and device-led combination products** that provide for **more effective treatment or diagnosis of life-threatening or irreversibly debilitating** diseases or conditions. This program is intended to help patients have more timely access to these medical devices by **expediting their development, assessment, and review, while preserving the statutory standards** for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the Agency's mission to protect and promote public health.

Program Overview



- For granted breakthrough devices,
 - Designation tracks with the device for subsequent submissions
 - Prioritized review and other benefits
- If denied, traditional pathways still available for obtaining the FDA's feedback (for example, Pre-Submissions) and marketing submission

Scope of Guidance



- Summarizes the policies under which the FDA's Breakthrough Devices Program operates
- Clarifies the administrative processes used to facilitate review of breakthrough devices designation requests
- Provides an overview of options for obtaining the FDA's feedback to support device development



Differences Between Draft and Final Guidance

- Revised structure of guidance to be consistent with the chronology of how sponsors enter the program and use its features
- Clarified medical products that may be eligible for the program
- Clarified policies and procedures for obtaining the FDA's feedback following breakthrough designation

Structure of Guidance

- Introduction and background for Breakthrough Devices Program
- Program principles
- Components of a designation request, including a description of the statutory criteria
- Subsequent regulatory mechanisms for obtaining feedback on granted breakthrough devices



Eligibility for Breakthrough Devices Program



Eligibility Considerations

- Medical devices and device-led combination products are eligible
- Subject to marketing authorization via Premarket Approval (PMA), De Novo, or 510(k)
- Meets the breakthrough criteria specified in Section 515B(b) of the Federal Food, Drug & Cosmetic Act



Breakthrough Device Criteria

- **Criterion 1:** “provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; **AND**

Breakthrough Device Criteria

Meets **one** of the following sub-parts in **Criterion 2**:

- 2A: that represent breakthrough technologies; or
- 2B: for which no approved or cleared alternatives exist; or
- 2C: that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or
- 2D: the availability of which is in the best interest of patients.”

A Closer Look at Criterion 1

- **Criterion 1: Provides for more effective treatment or diagnosis of life threatening or irreversibly debilitating disease or condition**
 - Is the condition life-threatening or irreversibly debilitating?
 - Consider if there is reasonable expectation that the device could provide for more effective treatment or diagnosis relative to current standard of care in the U.S.
 - Consider non-clinical data (bench, animal study), literature, scientific rationale
 - Clinical data not required but can be helpful

A Closer Look at Criterion 2

- **Criterion 2A: represents a breakthrough technology**
 - Consider technological advances or new use of an existing technology
 - Consider potential to lead to clinical improvement
- **Criterion 2B: no approved or cleared alternatives exist**
 - Consider whether there is an approved drug, biologic, or device for the same indication that is consistent with standard of care

A Closer Look at Criterion 2

- **Criterion 2C: significant advantages over existing approved/cleared alternatives**
 - Consider whether the device may “reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients’ ability to manage their own care (such as through self-directed personal assistance) or establish long-term clinical efficiencies”

- **Criterion 2D: Availability of device is in the best interest of patients**
 - Consider other types of specific public health benefits
 - For example, potential for the device to address a known failure mode or has a benefit for patients who are unable to tolerate available therapies

Policies and Procedures for Breakthrough Devices Program

Program Principles

- Derived from provisions in Section 515B Food, Drug & Cosmetic Act
 - Interactive and timely communication
 - Review team support
 - Senior management involvement
 - Engaging external experts during review
 - Prioritized review of subsequent submissions (for example, Q-Submissions, Investigational Device Exemptions (IDE), marketing submission)

Program Principles

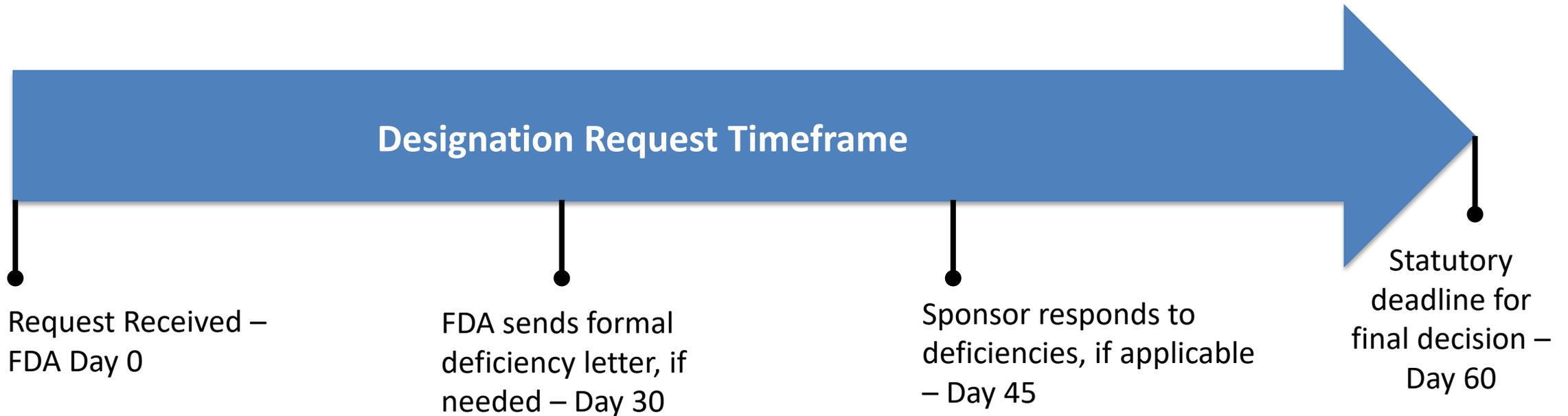
- Opportunities for the following as scientifically appropriate
 - Premarket and postmarket balance of data collection
 - Application of flexible and efficient clinical study design
 - Expedited manufacturing and quality systems compliance review for breakthrough devices subject to premarket approval application

What to Include in a Designation Request



- Submitted as a “***Designation Request for Breakthrough Device***” Q-Submission
 - A standalone submission distinct from other requests for feedback
 - Includes the following elements (Appendix 1):
 - Device description including principles of operation, properties relevant to clinical function, images or engineering schematics
 - Proposed Indication for Use
 - Justification for how the device meets the designation criteria
 - Planned marketing application
- More information available in Appendix 1 of the guidance

Breakthrough Device Designation Request Process



Program Features

- Various options available for feedback on device development after a breakthrough device designation has been granted
 - ***“Interaction for Designated Breakthrough Device”*** Q-Sub:
 - Data Development Plan
 - Breakthrough device “sprint” discussion
 - Clinical protocol agreement
 - Pre-Submissions
- Regular status updates

Data Development Plan (DDP)

- High-level optional document intended to help ensure predictable and transparent review by outlining data collection expectations for the entire product lifecycle
 - Addresses non-clinical and clinical evaluations
 - Describes any proposed use of balancing premarket and postmarket data collection
- Often the first submission following a granted breakthrough designation
- Review timeframe
 - Target of 45-day review period for providing formal feedback
 - Face-to-face meeting or teleconference can be held

DDP Example Formats

Non-clinical Test	Reference Standard, Method, Acceptance Criteria, Objective, etc.	Timeline
Test name/type. Examples: Electromagnetic compatibility, biocompatibility, animal study	Relevant standard, description of method, acceptance criteria, objective, etc. to describe testing expectations. Examples: IEC 60601-1-2; sensitization and irritation testing per ISO 10993; acute animal study to assess functionality	When test results should be provided to FDA. Examples: In feasibility study IDE, in pivotal study IDE, in marketing application, in post-approval study.

Clinical Study (include type of clinical study; for example, feasibility study/pivotal study)		
Purpose of Study		
Study Design		
Study Population including: <ul style="list-style-type: none"> • Population description • Inclusion criteria • Exclusion criteria 	Safety & Effectiveness Endpoints <ul style="list-style-type: none"> • List each separately and include any references to clinically recognized scales, statistical analyses as needed 	Follow-up Schedule <ul style="list-style-type: none"> • Include relevant timepoints and assessments

More information available in Appendix 2 of the guidance

Sprint Discussion

- For sponsors needing timely resolution of issues for device development progress
- Highly interactive with ability for sponsor to provide additional information and proposals during the review
 - Please be ready to engage and respond to the FDA's feedback
- Goal of reaching mutual agreement
- **Single topic** with refined goals
 - For example, animal study protocol
- Example timeline provided in guidance
 - Intended to occur over a relatively short timeframe
- Sprint discussion ends with summary of final feedback and extent of agreement sent to sponsor



Clinical Protocol Agreement

- Mechanism for obtaining written agreement on a clinical protocol
- Considered binding on both the FDA and sponsor
- Documented agreement in a letter

Subsequent Regulatory Submissions

- Breakthrough device sponsors may use other regulatory mechanisms for feedback
 - More traditional Pre-Submission topics that are tracked as an **Interaction for Designated Breakthrough Device Q-Submission** to facilitate prioritized review
 - Other types of Q-Submissions (for example, Study Risk Determinations, Submission Issue Meetings)
- Priority review for Investigational Device Exemptions (IDE) and marketing submissions

Status Updates

- Brief email or teleconference updates between sponsor and lead reviewer on progress of device development
- In between formal submissions
- No data or feedback in the discussions
- Suggested intervals of every other month, or as agreed to by both parties

Conclusion

- Breakthrough Devices Program is a voluntary program intended to expedite development and review of certain medical devices to treat or diagnose life-threatening or irreversibly debilitating diseases or conditions
- A formal designation process where sponsors provide evidence and/or justification for how their device meets the statutory criteria
- Provides sponsor with various mechanisms to engage FDA early to expedite development and review of device
- Program success depends on commitment and engagement of both FDA and sponsors

Resources

- Breakthrough Devices Program webpage:
<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm441467.htm>
- Breakthrough Devices Program Final Guidance:
<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664.pdf>

Questions?

For questions regarding the Breakthrough Devices Program (for example, appropriate use and review process), please contact:

BreakthroughDevicesProgram@fda.hhs.gov

For general questions, please contact the 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 the heading: “How to Study and Market Your Device” and subheading: “IDE”