# Experience with the Breakthrough Devices & Safer Technologies Programs

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# Disclaimer

The presenter has no financial relationships to disclose.

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# Center for Devices and Radiological Health Vision Statement

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

**Examples of Actions to Realize this Vision**

- Early Feasibility Study Program
- Streamlining the Clinical Trial Enterprise
- Patient Science & Engagement
- Real World Evidence
- **Breakthrough Devices Program**
- **Safer Technologies Program (STeP)**
- Digital Health Center of Excellence

# Breakthrough Devices Program

# Breakthrough Devices Program

Intended to help patients have more timely access to 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** by expediting their development and prioritizing their review

- Voluntary program
- Statutorily mandated under Section 515B of the FD&C Act
- Preserve the statutory standards of marketing authorization.

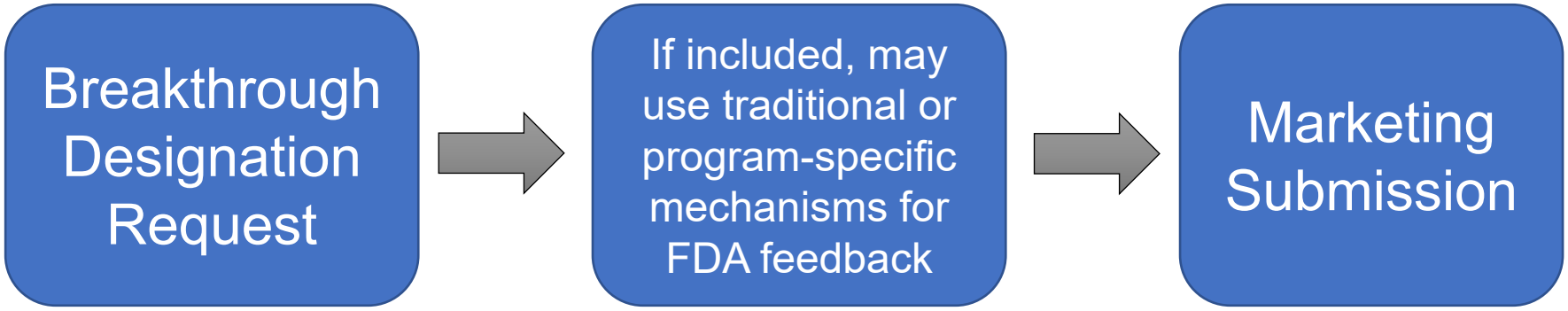
Breakthrough Devices Program Guidance: https://www.fda.gov/media/108135/download

# Breakthrough Devices Program History

- Expedited Access Pathway (EAP)
  - EAP Final Guidance-April 2015
  - FDA considered EAP designated devices to be under Breakthrough
- 21st Century Cures Act- December 2016
  - Established statutory framework for Breakthrough Devices Program
- Breakthrough Devices Program
  - Final Guidance-December 2018

# Principles & Benefits

- Expedited feedback/interaction
- Prioritized review of marketing application
- Potential acceptance of greater uncertainty
- Enhanced opportunity for pre/post-market balance
- Efficient and flexible clinical study design



# Eligibility Considerations

- Medical devices and device-led combination products
- Subject to future marketing authorization via Premarket Approval (PMA), De Novo, or 510(k)
- Meets the Breakthrough criteria specified in Section 515B(b) of the FD&C Act

# Breakthrough Device Criteria

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

*Reference: Section 515B(b)(1) of Food, Drug and Cosmetic Act*

# 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."

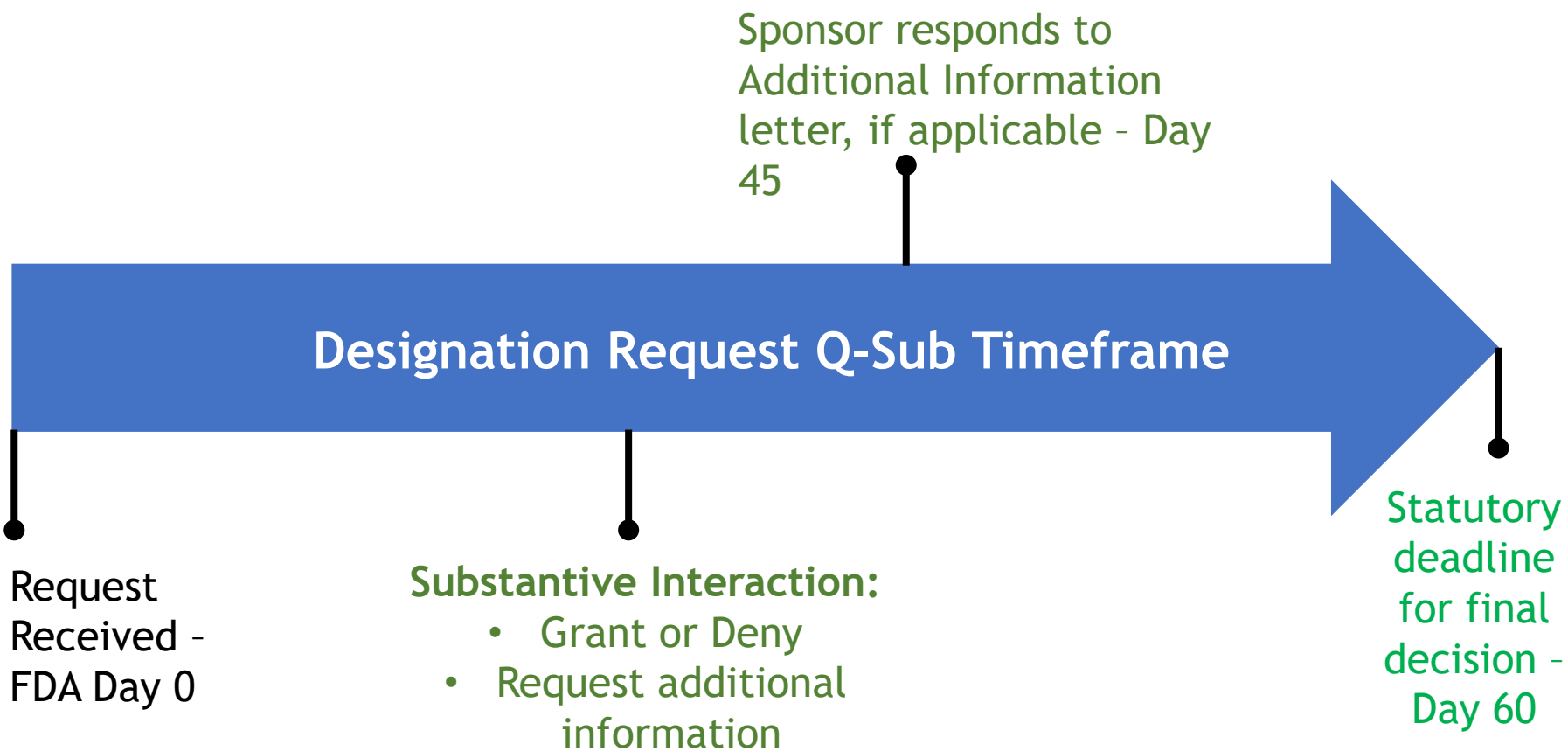
***Reference: Section 515B (b)(2) of Food, Drug and Cosmetic Act***

# Example Breakthrough Device Designation Request Content

- Background
  - Device Description
  - Indications for use
  - Regulatory History
- Designation Criteria
  - Criterion 1
    - A discussion of how the criterion is met for the proposed device and indications.
  - Criterion 2
    - A discussion of which component(s) of criterion 2 are met for the proposed device and indications.
    - Only one component of 2A-2D must be met; however, it is recommended to address all components in your submission.
- Planned Marketing Submission

Source: Appendix 1 of Breakthrough Guidance https://www.fda.gov/media/108135/download

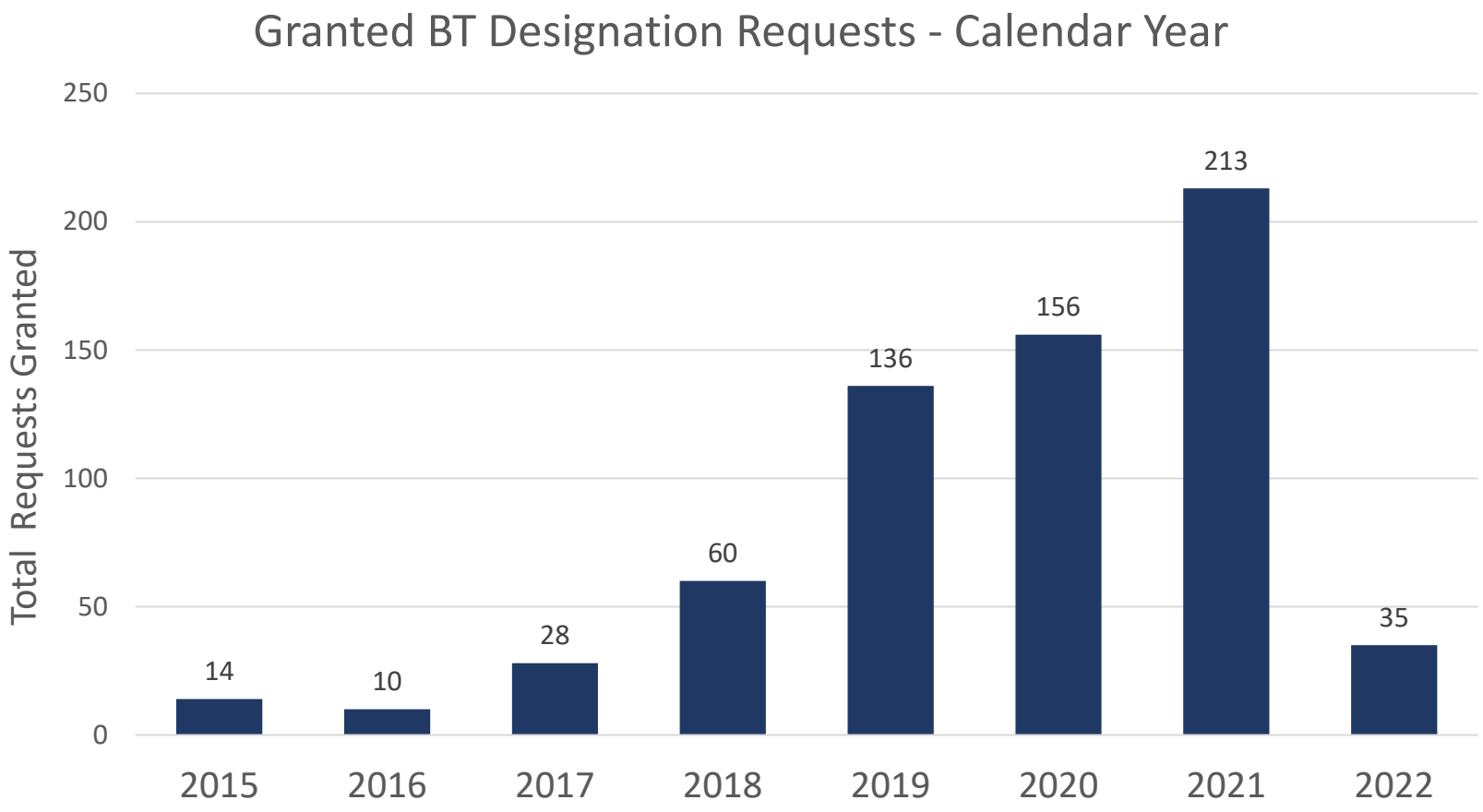
# Breakthrough Device Designation Request Process



# Breakthrough Devices Program Features

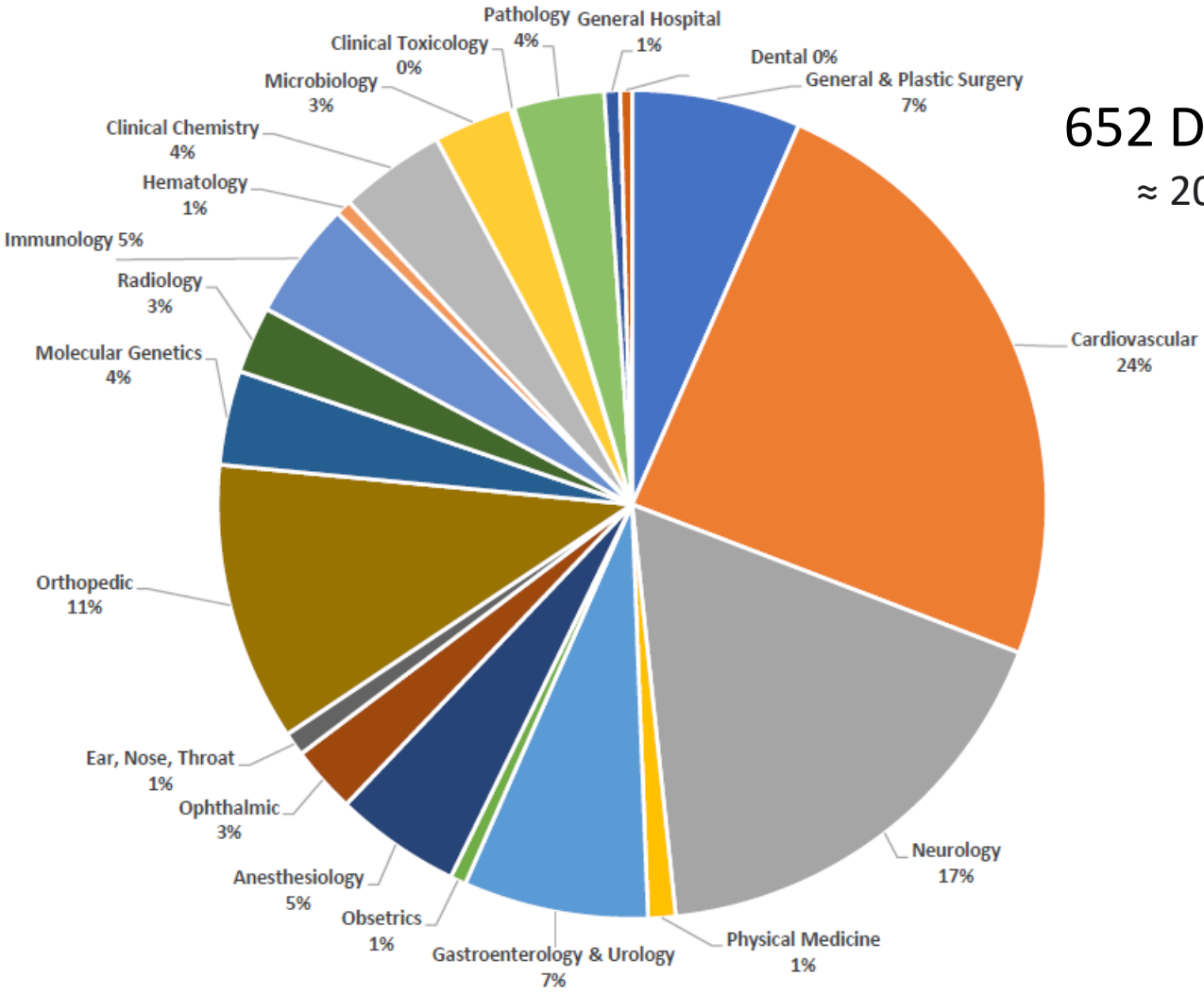
- Data Development Plan
  - Optional map of development process from entry into program until marketing submission & post-market activities as necessary
- Sprint Discussion
  - Highly interactive process to facilitate reaching rapid agreement on a single development issue (e.g., animal study protocol review)
- Clinical Protocol Agreement
  - Binding agreement  on clinical study design/protocol
- Regular Status Updates
  - In between submissions, no feedback expectations
  - Useful for planning purposes

# Granted Breakthrough Device Designation Requests




*As of March 31, 2022*

# Granted Breakthrough Device Designation Requests (Cont.)

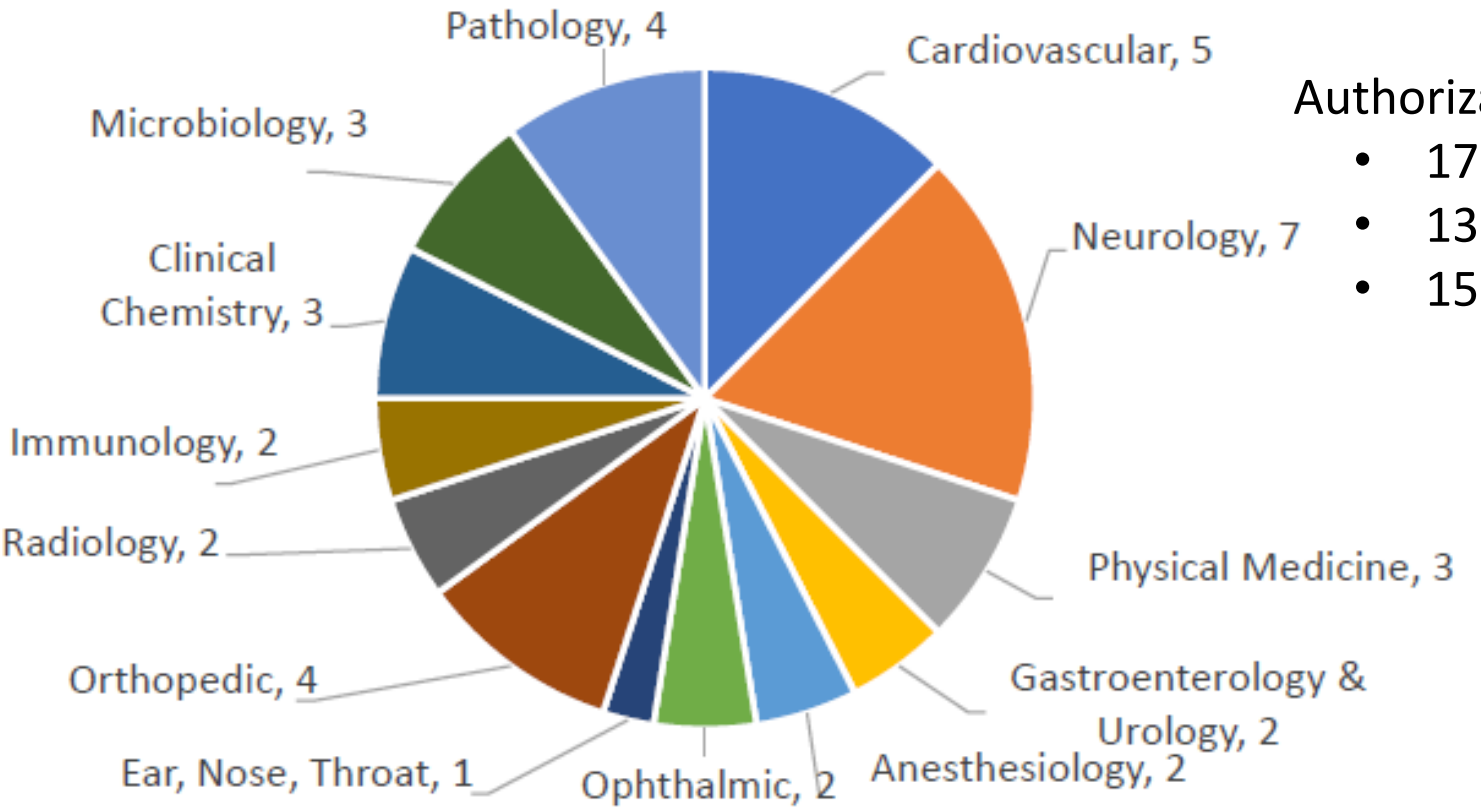



652 Designated Devices

≈ 20% (129/652) are IVD

*As of March 31, 2022*

# Breakthrough Device Marketing Authorizations




Authorizations include

- 17 PMAs
- 13 De Novos
- 15 510(k)s

*As of March 31, 2022*

# Safer Technologies Program (STeP)

# Medical Device Safety Action Plan

- Outlines vision for how the FDA can continue to enhance programs and processes to assure the safety of medical devices
- Safer Technologies Program (STeP) motivated by the FDA's Medical Device Safety Action Plan[1]


[1] Medical Device Safety Action Plan
https://www.fda.gov/media/112497/download

# Safer Technologies Program

- A voluntary program for certain types of medical devices and device-led combination products that are **reasonably expected to significantly improve the safety of currently available medical treatments and diagnostics through innovative technological features**
- Focused on increasing timeliness of patient access to these medical devices
- Preserves the statutory standards for marketing authorization
- STeP is modeled on some principles and features of the Breakthrough Devices Program, but is for devices that target underlying diseases or conditions associated with morbidities **less serious** than those eligible for breakthrough designation

STeP Guidance: https://www.fda.gov/media/130815/download

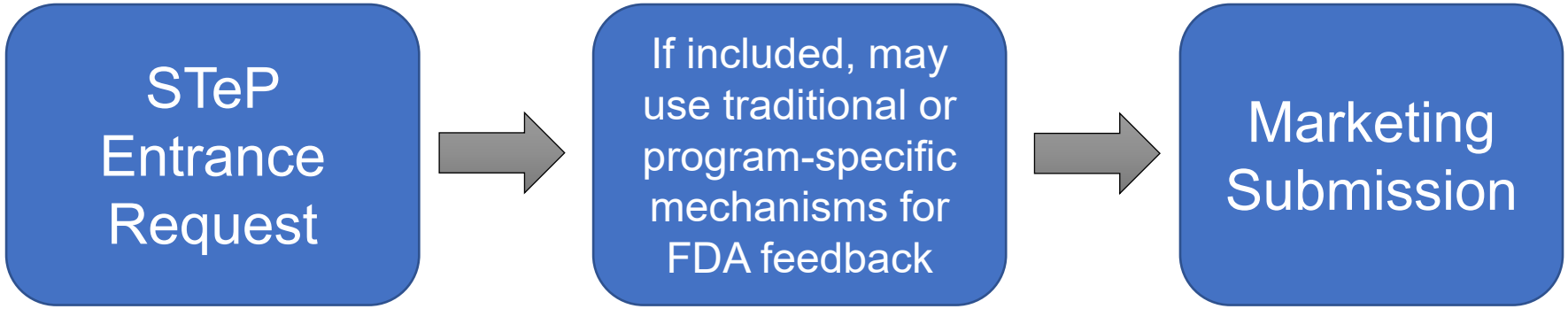
# STeP Principles & Benefits

Modeled after the Breakthrough Devices Program

- Interactive and timely communication
- Review team support and senior management engagement
- Timely post-market data collection
- Efficient and flexible clinical study design
- Expedited review of manufacturing and quality systems compliance for devices with preapproval inspection requirements

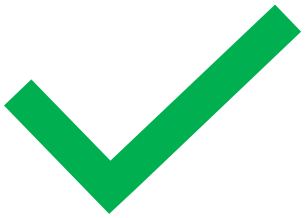
# STeP Implementation & Overview

- Guidance finalized January 2021
- Program launched March 2021
- STeP Overview



# General Eligibility Factors

- Medical devices and device-led combination products



- Subject to future marketing authorization via Premarket Approval (PMA), De Novo, or 510(k)

# Specific Eligibility Factors

1. Device should not be eligible for the Breakthrough Devices Program due to the less serious nature of the disease or condition treated, diagnosed, or prevented by the device;

*and*

2. Device should be reasonably expected to significantly improve the benefit-risk profile of a treatment or diagnostic through substantial safety innovations that provide for one or more of the following:
    a) a reduction in the occurrence of a known serious adverse event,
    b) a reduction in the occurrence of a known device failure mode,
    c) a reduction in the occurrence of a known use-related hazard or use error, or
    d) an improvement in the safety of another device or intervention.

# Example STeP Entrance Request Content

- Background
  - Device Description
  - Expected Safety Improvement
  - Indications for use
  - Regulatory History

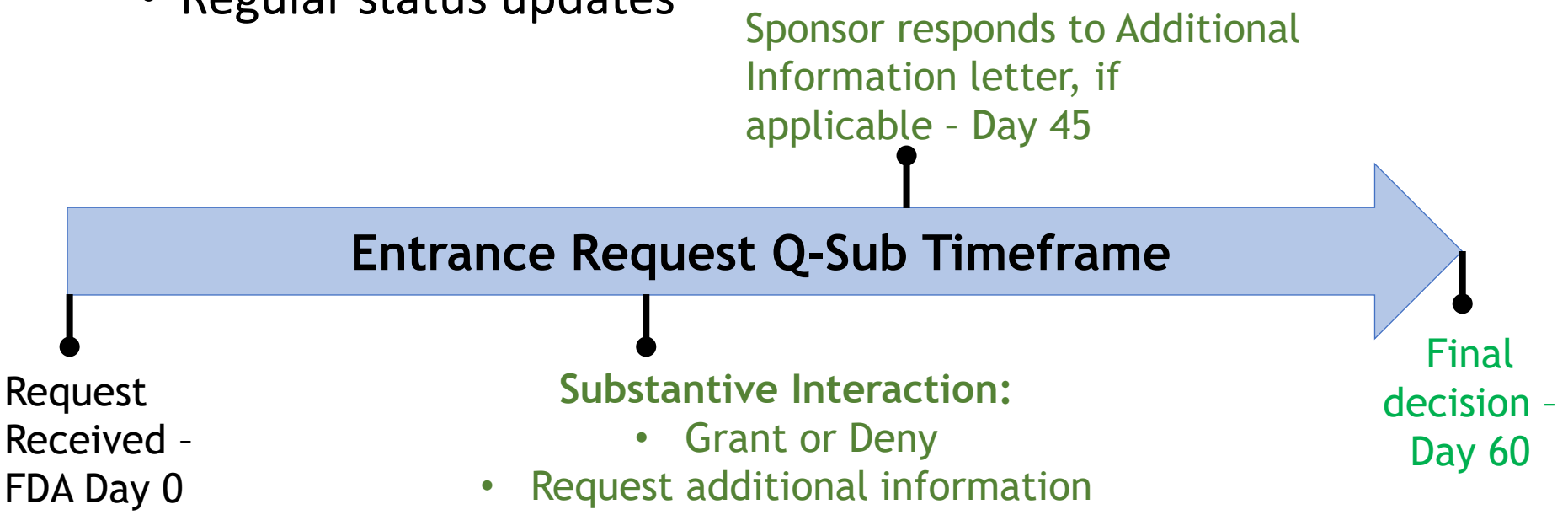
- Planned Marketing Submission

- Eligibility Factors
  - Factor 1
    - A discussion of how the eligibility factor is met for the proposed device and indications.
  - Factor 2
    - A discussion of which component(s) of eligibility factor 2 are met for the proposed device and indications.
    - Only one component of 2A-2D must be met; however, it is recommended to address all components in your submission.

Source: Appendix 1 of STeP Guidance: https://www.fda.gov/media/130815/download

# STeP Entrance & Program Features

- Entrance request for inclusion in STeP
- STeP features:
  - Sprint discussion
  - Review of a Data Development Plan (DDP)
  - Pre-submission
  - Regular status updates



# Program Comparison Table

| | Breakthrough Devices Program | STeP |
|---|---|---|
| **Statutorily mandated** | Yes | No |
| **Diseases/Conditions** | Life-threatening and/or irreversibly debilitating | Not life-threatening and/or reversibly debilitating |
| **Devices that provide** | More effective treatment or diagnosis | Significant safety improvement |
| **Formal request to participate in program** | Yes | Yes |
| **Program features** | Sprint discussion<br>Review of Data Development Plan<br>Traditional Pre-Subs<br>Status updates<br>Clinical Protocol Agreement | Sprint discussion<br>Review of Data Development Plan<br>Traditional Pre-Subs<br>Status updates |

# Summary

The Breakthrough Devices & Safer Technologies Programs will help patients have more **timely access to innovative technologies** helping to support CDRH's vision for U.S. patients to have access to high-quality, safe, and effective medical devices of public health importance first in the world.

# Resources

For questions regarding the Breakthrough Devices or Safer Technologies Programs, please contact:

BreakthroughDevicesProgram@fda.hhs.gov

SaferTechnologiesProgram@fda.hhs.gov

Breakthrough Devices Program Website: https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program

Breakthrough Devices Program Guidance: https://www.fda.gov/media/108135/download

Safer Technologies Program Website: https://www.fda.gov/medical-devices/how-study-and-market-your-device/safer-technologies-program-step-medical-devices

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