Introduction to the Breakthrough Devices and Safer Technologies Programs

FDA Small Business Regulatory Education for Industry (REdI)

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Ouided Rouabhi

Assistant Director

Policy and Operations Team 1

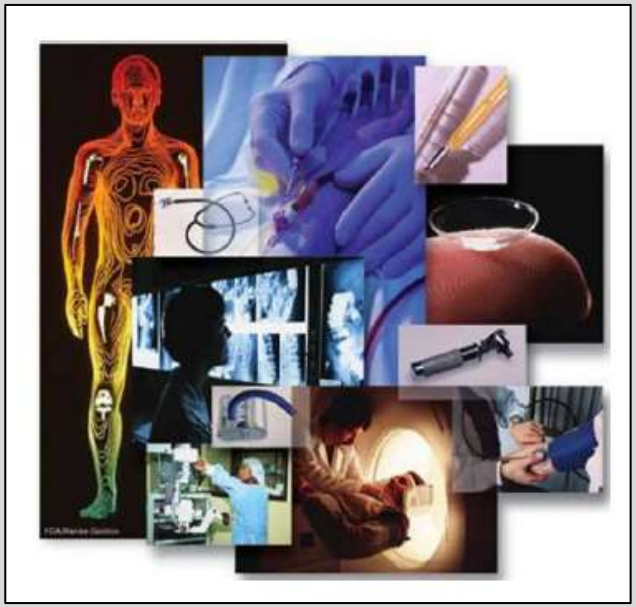
Division of Clinical Policy and Quality

Office of Clinical Evidence and Analysis

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

U.S. Food and Drug Administration



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

– CDRH Vision Statement

Learning Objectives

For the Breakthrough Devices and Safer Technologies Programs:

- Provide an overview of the program
- Identify program features
- Review the process for requesting entrance
- Share our experience with the program

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

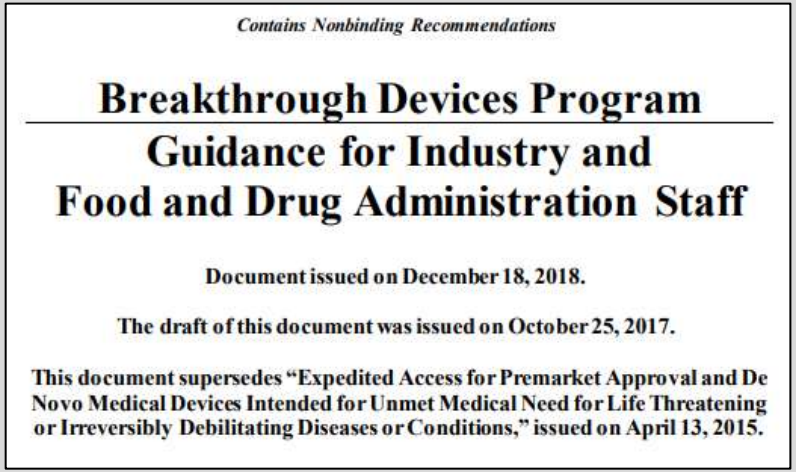
Breakthrough Devices Program Guidance:
www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program

Principles and Benefits

- Interactive and timely communication
- Prioritized review of marketing application
- Enhanced opportunity for pre/post-market balance
- Efficient and flexible clinical study design
- Expedited review of preapproval manufacturing and quality systems compliance
- Preserves statutory standard for marketing authorization

Regulatory Context

- Program is statutorily mandated under Section 515B of the FD&C Act
- Guidance describes implementation
- Sponsors may voluntarily participate



Contains Nonbinding Recommendations

Breakthrough Devices Program

Guidance for Industry and Food and Drug Administration Staff

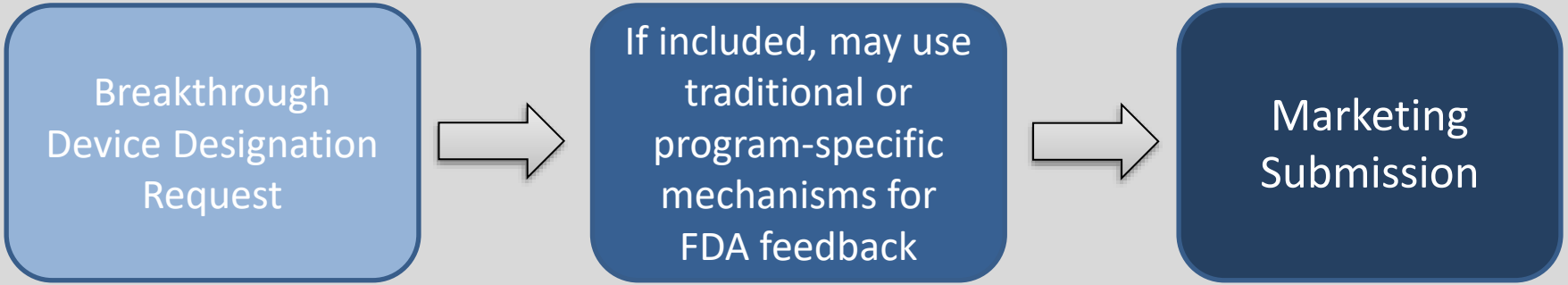
Document issued on December 18, 2018.

The draft of this document was issued on October 25, 2017.

This document supersedes "Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions," issued on April 13, 2015.

Breakthrough Devices Program Guidance:
www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program

Program Overview



For granted Breakthrough Devices:

- Designation tracks with device for subsequent submissions
- Prioritized review and other benefits

Eligibility Considerations

- Medical devices and device-led combination products
- Subject to future marketing authorization through Premarket Approval (PMA), De Novo, or 510(k)
- Meets Breakthrough criteria specified in Section 515B(b) of the FD&C Act
  - Must fully meet Breakthrough Device Criterion 1 AND one of the sub-parts of Breakthrough Device Criterion 2

Breakthrough Device Criterion #1

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

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

Considerations for “more effective”

- Sponsor should demonstrate *reasonable expectation* that device could provide for more effective treatment or diagnosis of disease or condition identified in proposed indications for use
  - Technical success: the device could function as intended
  - Clinical Success: a functioning device could more effectively treat or diagnose the identified disease or condition

- Mechanisms for demonstrating a reasonable expectation of technical and clinical success could include literature or preliminary data (bench, animal, or clinical)

Breakthrough Devices Program Guidance:
www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program

Considerations for disease/condition

- Life-threatening: a disease or condition for which the likelihood of death is high unless the course of the disease is interrupted in a population or subpopulation
  - Examples: acute stroke, myocardial infarction, cancer

- Irreversibly Debilitating: impact on such factors as survival, day-to-day functioning, and the likelihood that the disease or condition, if left untreated, will progress to a more serious disease or condition
  - Examples: amyotrophic lateral sclerosis (ALS)

Breakthrough Devices Program Guidance:
www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program

Breakthrough Device Criterion #2

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,…; or
- 2D: the availability of which is in the best interest of patients.

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

Knowledge Check

Eligible devices for the Breakthrough Devices Program must meet which of the following criteria?

A. Provide for more effective treatment or diagnosis

B. Target a life-threatening or irreversibly debilitating disease or condition

C. Plan to pursue a PMA, De Novo, or 510(k) marketing pathway

D. All of the above

Breakthrough Devices Program Features

Breakthrough Devices Program Features

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

Breakthrough Device Designation Request

Designation Request Process

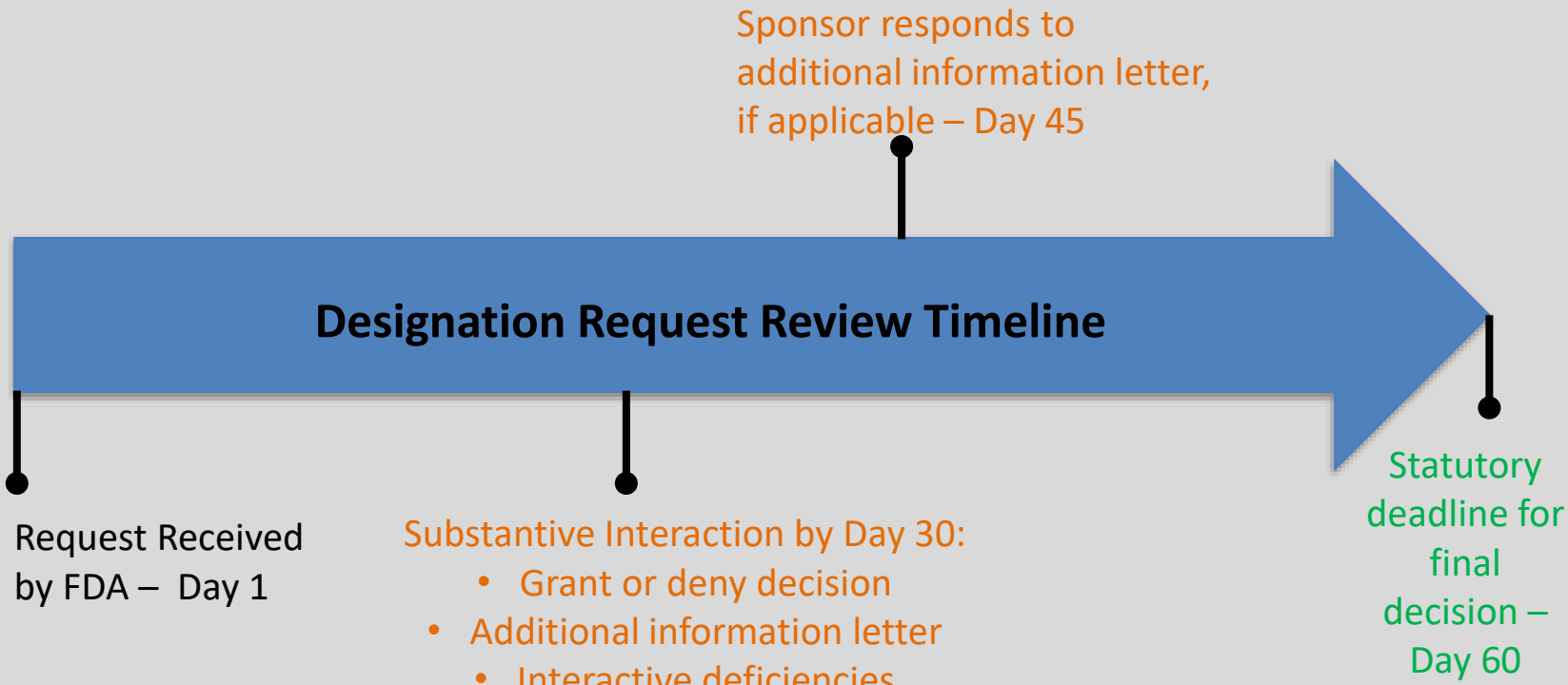
- No standard designation request template
- Submitted through a Q-submission
- Clearly indicate “Breakthrough Device Designation Request” in your cover letter
- Appendix 1 of Breakthrough guidance provides a helpful outline

Breakthrough Device Designation Request: Example 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:
www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program

Breakthrough Device Designation Request Process

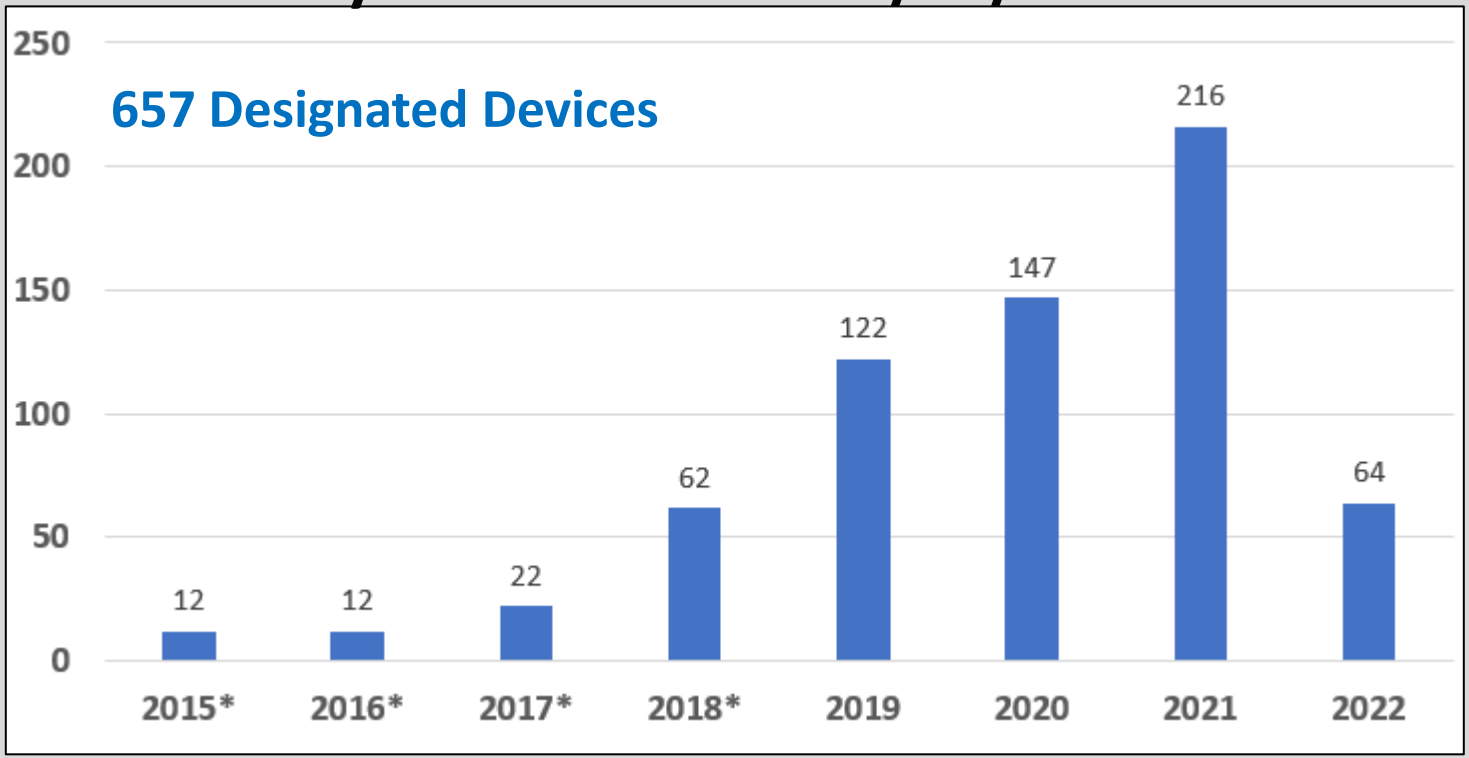


Experience with Breakthrough Devices Program

Breakthrough Devices Program: Webpage Updated

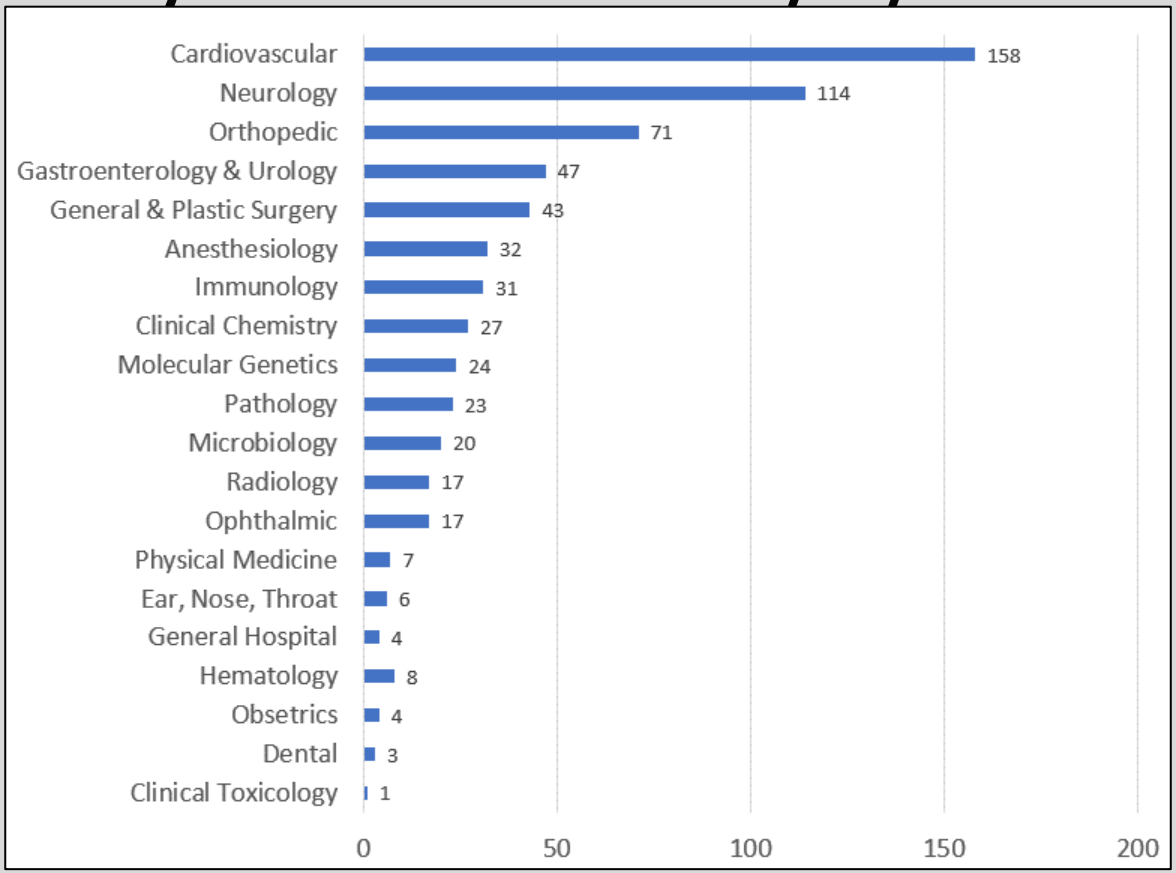
www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program

Number of Granted Breakthrough Device Designations by Fiscal Year as of 3/31/2022



CDRH has granted 652 Breakthrough Device designations and CBER has granted 5.
**Data includes devices that were designated under the precursor Expedited Access Pathway (EAP).*

Number of Granted Breakthrough Device Designations by Clinical Panel as of 3/31/2022



Breakthrough Device Marketing Authorizations as of 3/31/2022

44 Marketing Authorizations:

- 19 PMAs
- 14 De Novos
- 11 510(k)s

CDRH and CBER Breakthrough Device Marketing Authorizations

Below is a list of CDRH and CBER Breakthrough Devices that have obtained marketing authorization.

CDRH and CBER Breakthrough Device Marketing Authorizations

Data as of March 31, 2022

Total of 44 Marketing Authorizations, including 42 CDRH devices and 2 CBER devices

Search: Show entries

Manufacturer	Trade Name	Marketing Submission Number	Marketing Submission Decision Date
CARTIHEAL, LTD.	AGILI-C	P210034	03/29/2022
SPECTRANETICS, INC.	CAVACLEAR LASER SHEATH	DEN210024	12/21/2021
KOIOS MEDICAL, INC.	KOIOS DS	K212616	12/16/2021
APPLIEDVR, INC.	EASEVRX	DEN210014	11/16/2021
SYNCTHINK, INC.	EYE-SYNC	K202927	10/02/2021
PAIGE.AI	PAIGE PROSTATE	DEN200080	09/21/2021
CANARY MEDICAL, INC.	CANARY TIBIAL EXTENSION WITH CANARY HEALTH IMPLANTED REPORTING PROCESSOR (CHIRP) SYSTEM	DEN200064	08/27/2021
MICROTRANSPONDER, INC.	VIVISTIM PAIRED VNS SYSTEM	P210007	08/27/2021

Safer Technologies Program

Safer Technologies Program (STeP)

Intended to help patients have more timely access to certain medical devices and device-led combination products that **are reasonably expected to significantly improve the safety** of currently available treatments or diagnostics that target an underlying disease or condition associated with **morbidities and mortalities less serious than those eligible for the Breakthrough Devices Program** by expediting their development, assessment, and review

Safer Technologies Program for Medical Devices Guidance:
www.fda.gov/regulatory-information/search-fda-guidance-documents/safer-technologies-program-medical-devices

Breakthrough Devices Program

- More effective treatment or diagnosis
- Life-threatening or irreversibly debilitating diseases/conditions

STeP

- Significant safety improvement
- Diseases/conditions less serious than those eligible for the Breakthrough Devices Program
- Not life-threatening or reversibly debilitating

Regulatory Context

- Motivated by FDA's Medical Device Safety Action Plan
- Guidance describes implementation
- Modeled after Breakthrough Devices Program
- Sponsors may participate voluntarily

Safer Technologies Program for Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on January 6, 2021.

The draft of this document was issued on September 19, 2019.

Safer Technologies Program for Medical Devices Guidance:
www.fda.gov/regulatory-information/search-fda-guidance-documents/safer-technologies-program-medical-devices

General Eligibility Considerations

- Medical devices and device-led combination products

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

STeP Specific Eligibility Factor #1

Factor 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**

STeP Specific Eligibility Factor #2

Meets **one** of the following sub-parts in **Factor 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.

Knowledge Check

The specific eligibility factors for entrance into STeP are the same as those for the Breakthrough Devices Program.

A. True

B. False

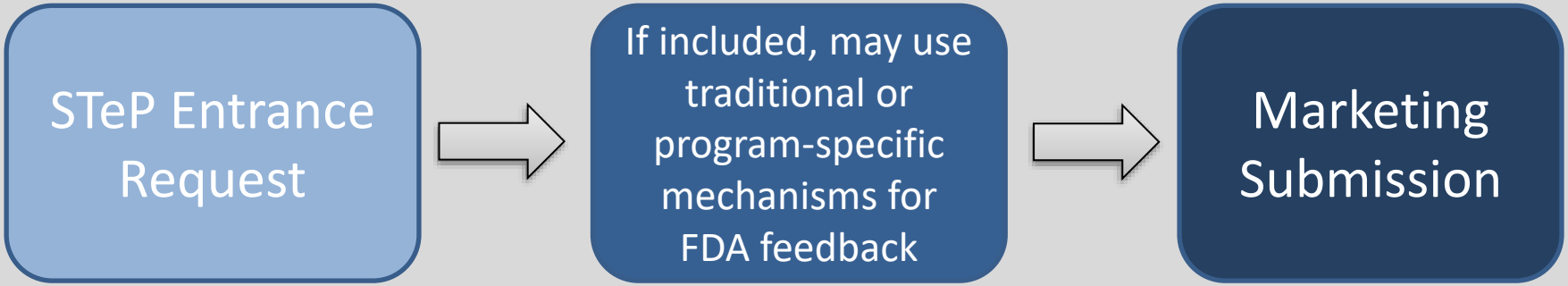
STeP Principles and Benefits

- Modeled after 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

Safer Technologies Program Features

STeP Program Features

- Data Development Plan
- Sprint discussion
- Traditional pre-submission
- Regular status updates



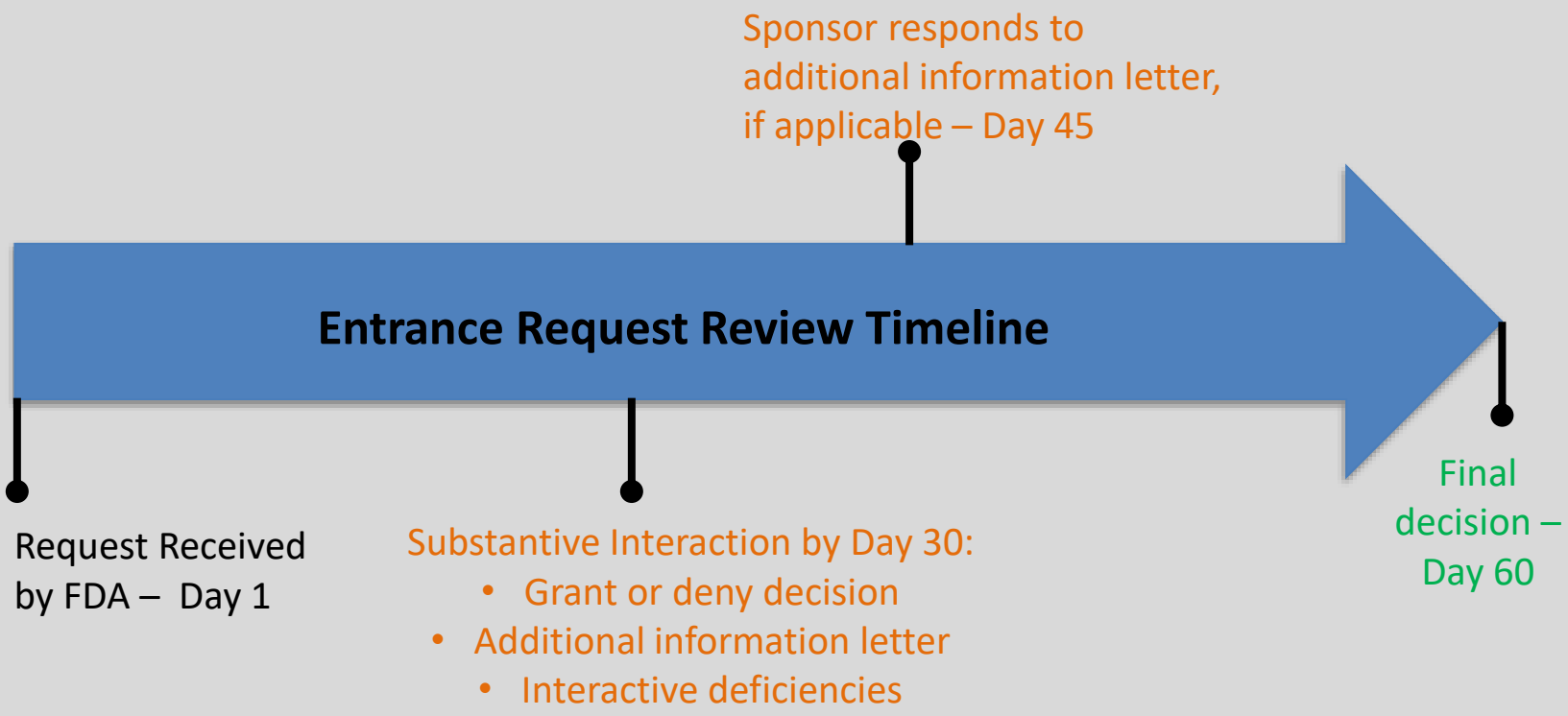
Safer Technologies Program Entrance Request

STeP Entrance Request: Example Content

- **Background**
  - Device Description
  - Expected Safety Improvement
  - Indications for use
  - Regulatory History
- **Planned Marketing Submission**
- **Eligibility Factors**
  - Factor 1
    - Discussion of how eligibility factor is met for proposed device and indications.
  - Factor 2
    - Discussion of which component(s) of eligibility factor 2 are met for proposed device and indications.
    - Only one component of 2A-2D must be met; however, recommend to address all components in submission.

Source: Appendix 1 of STeP Guidance:
www.fda.gov/regulatory-information/search-fda-guidance-documents/safer-technologies-program-medical-devices

STeP Entrance Request Process



Early Experience with Safer Technologies Program

Early Experience with STeP

- Final Guidance Issued – January 2021
- Program open to submissions – March 2021
- As of April 30, 2022, nine (9) devices granted entrance into STeP in multiple clinical panels
  - Similar to early Breakthrough Devices experience

Clinical Panels

- Gastroenterology and Urology
- Neurology
- Obstetrics
- Clinical Chemistry
- General and Plastic Surgery
- Orthopedic

Early Experience - Program Eligibility

Key Reminders:

- Device should not be eligible for Breakthrough Devices Program **due to less serious nature of the disease or condition** treated, diagnosed, or prevented by the device
- Device should be reasonably expected to significantly improve the benefit-risk profile of a treatment or diagnostic **through substantial safety innovations**

Resources

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

BreakthroughDevicesProgram@fda.hhs.gov

SaferTechnologiesProgram@fda.hhs.gov

- **Breakthrough Devices Program Guidance:**

www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program

- **Safer Technologies Program for Medical Devices Guidance:**

www.fda.gov/regulatory-information/search-fda-guidance-documents/safer-technologies-program-medical-devices

Summary

- Breakthrough Devices and Safer Technologies Programs are intended to provide patients and health care providers with timely access to innovative devices
- These programs expedite the development, assessment, and review of certain devices that meet the program eligibility criteria
- Eligible sponsors may request entrance through a Q-submission, following instructions in the guidance

Program Comparison Summary

	Breakthrough Devices Program	Safer Technologies Program
Statutory Program	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
Program features	Sprint discussion Data Development Plan Traditional Pre-Subs Status updates Clinical Protocol Agreement	Sprint discussion Data Development Plan Traditional Pre-Subs Status updates

Questions