Understanding the Breakthrough Devices Program

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Center for Devices & 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.

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

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

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
- Preserve the statutory standards

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

Considerations for "more effective"

- Sponsor should demonstrate a *reasonable expectation* that the device could provide for more effective treatment or diagnosis of the disease or condition identified in the 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)

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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)

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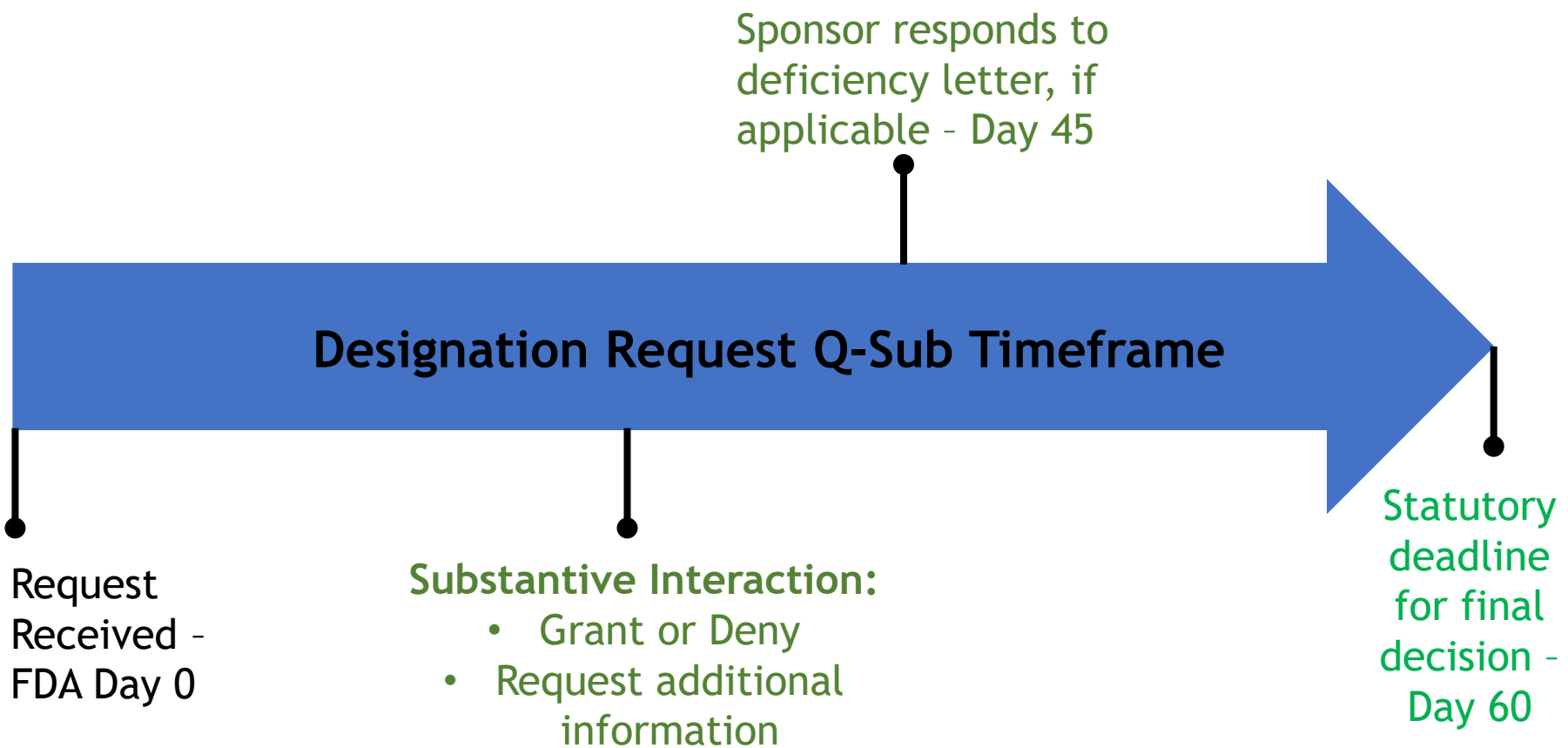
Breakthrough Device Criteria

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

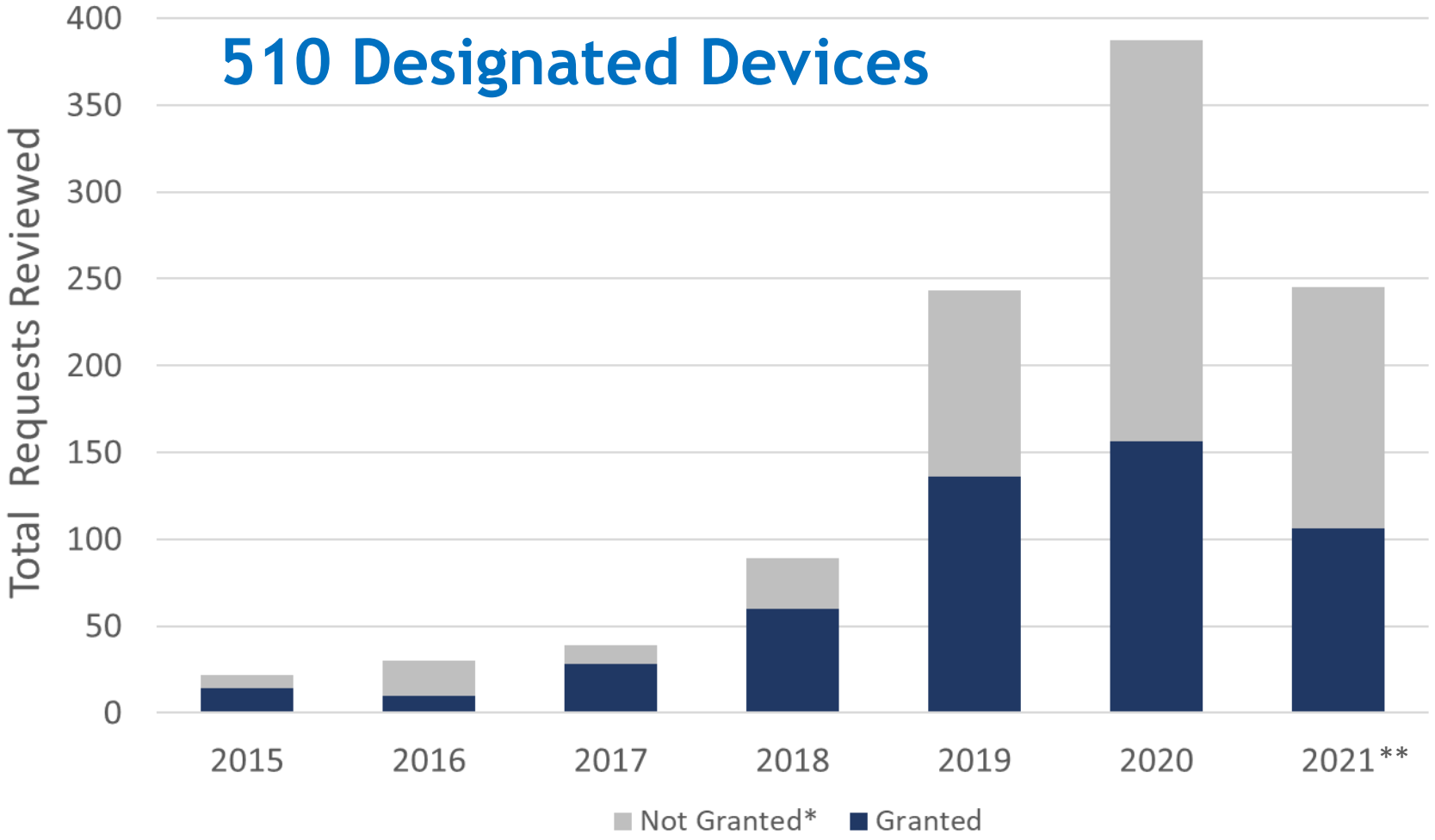
Breakthrough Device Designation Request Process



Breakthrough Devices Program Features

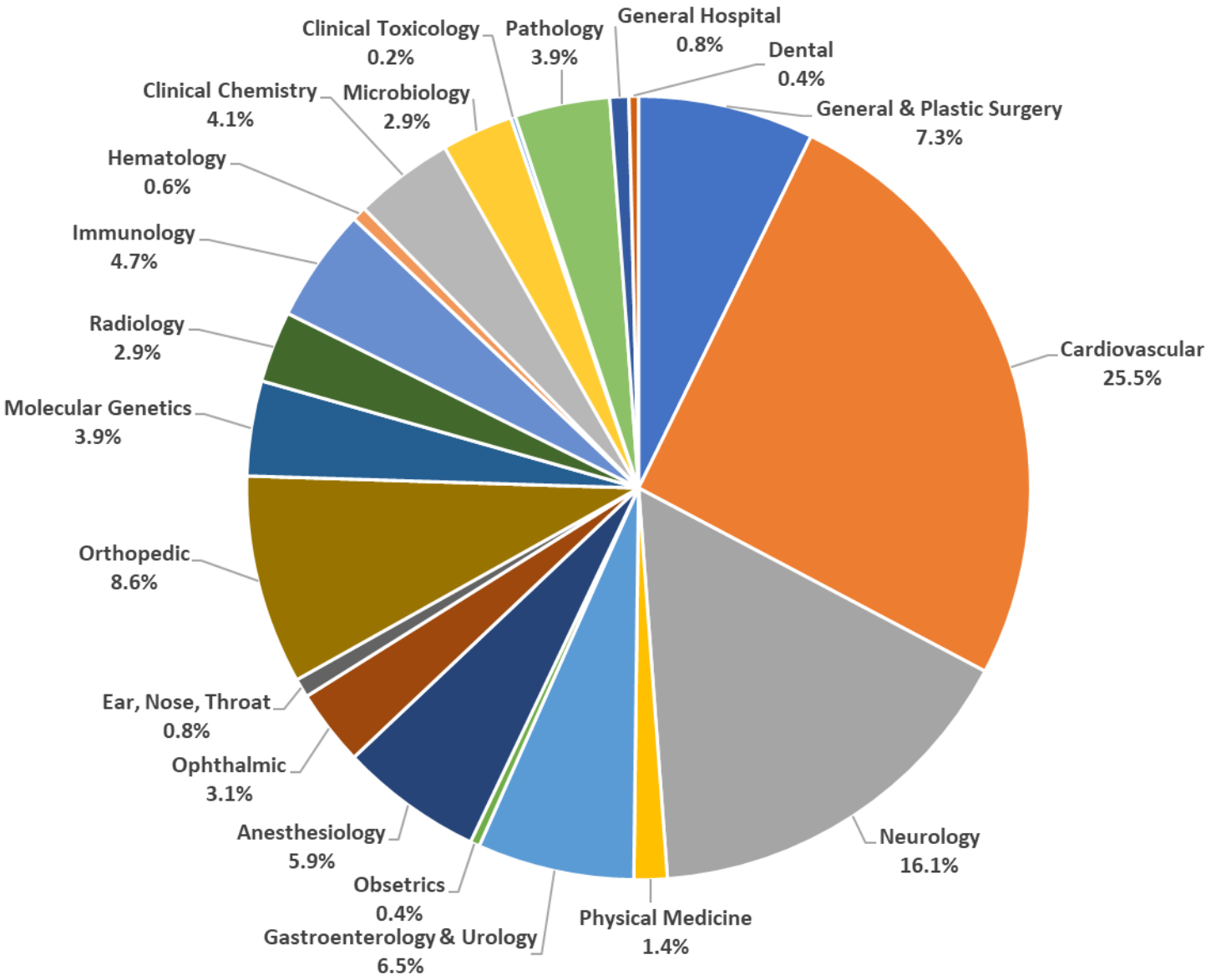
- Data Development Plan
  - Optional map of development process from entry into program until marketing submission & post-market activities as necessary
- Sprint Discussion
  - Highly interactive process to facilitate reaching rapid agreement on a single development issue (e.g., animal study protocol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

Breakthrough Device Designation Requests



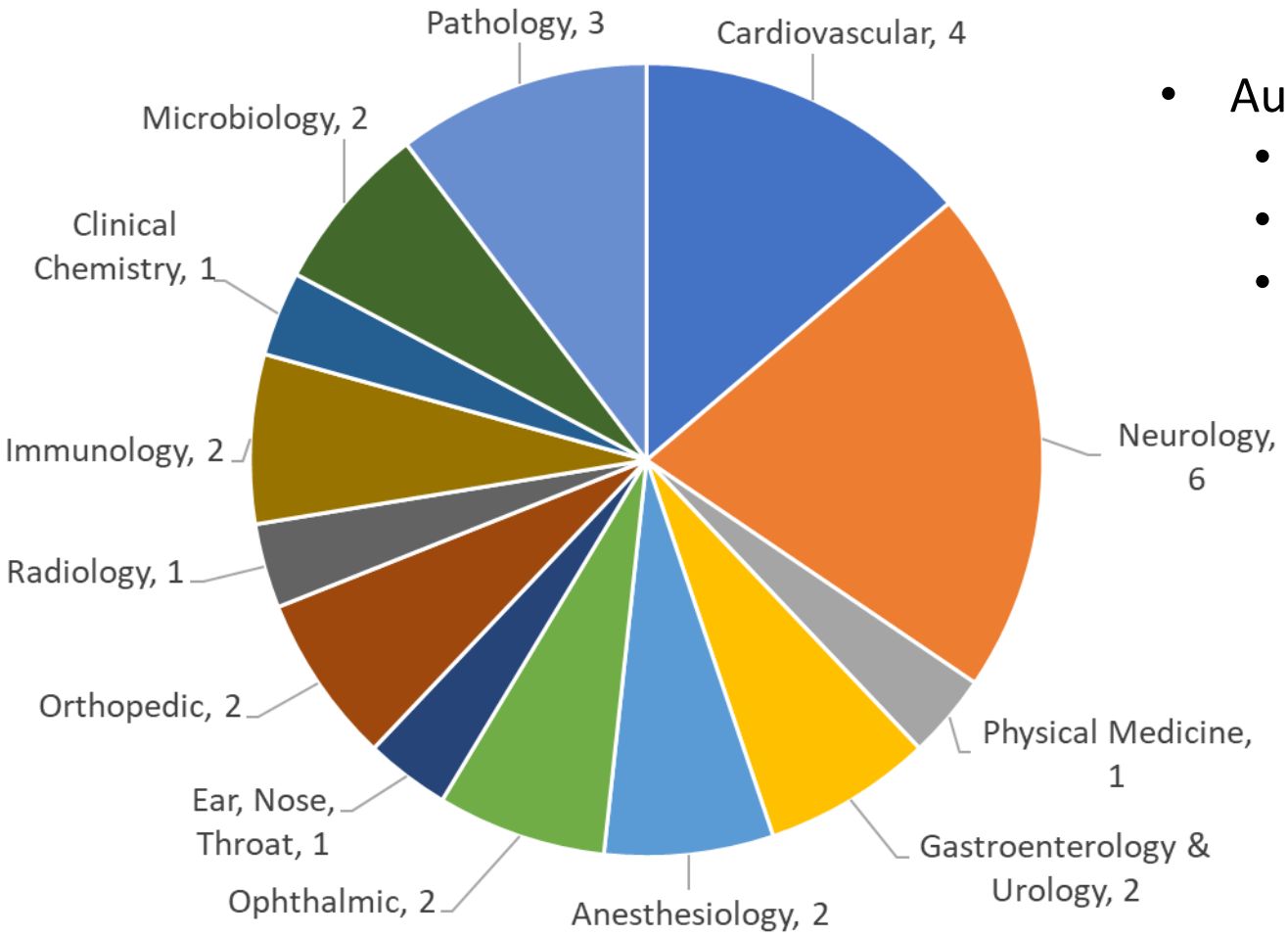
** Not granted reflects denials and withdrawn requests*
***Data for CY21 is through June 30*

Granted Designations by Clinical Panel



As of June 30, 2021

Breakthrough Device Marketing Authorizations



- Authorizations include
  - 12 PMAs
  - 9 De Novos
  - 8 510(k)s

As of June 30, 2021

Safer Technologies Program

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 (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

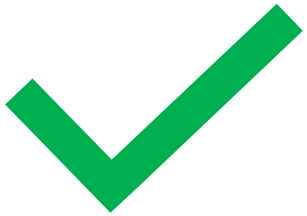
- Voluntary program
- Not statutorily mandated

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

STeP Implementation

- Guidance finalized January 2021
- Program launched March 2021
- Modeled after Breakthrough Devices Program
- Intended for devices that improve the benefit-risk profile of a treatment or diagnostic through substantial safety innovations

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

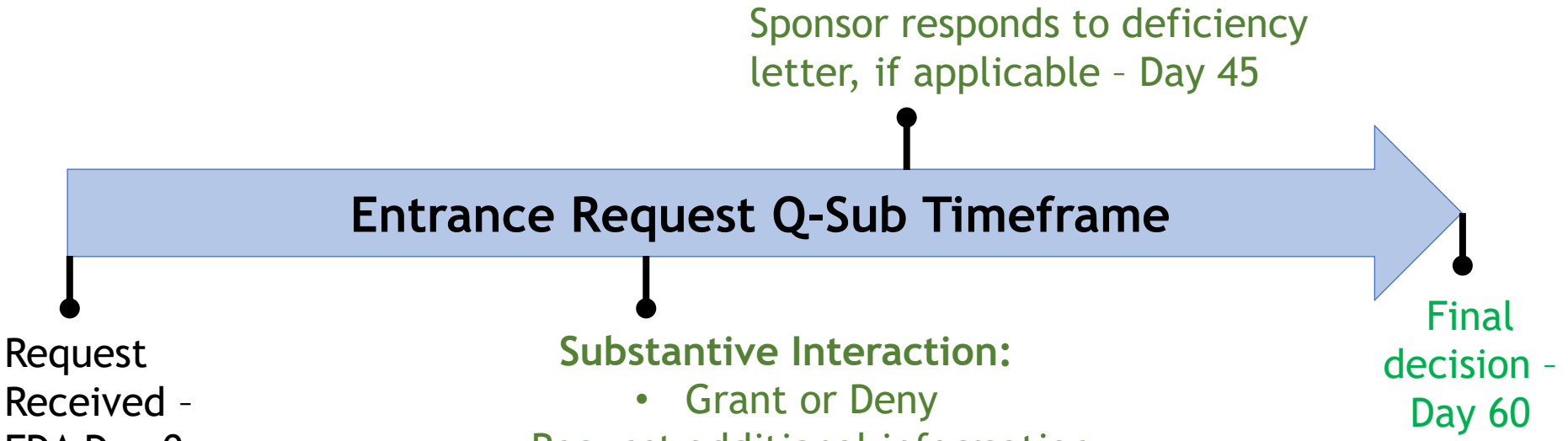
2. Device should be reasonably expected to significantly improve the benefit-risk profile of a treatment or diagnostic through substantial safety innovations that provide for one or more of the following:
    a) a reduction in the occurrence of a known serious adverse event,
    b) a reduction in the 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.

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 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



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 Guidance:

https://www.fda.gov/media/108135/download

Safer Technologies Program Guidance:

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