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Medical Device Regulatory Affairs

Safer Technologies Program

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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

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.

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

STeP Program Features

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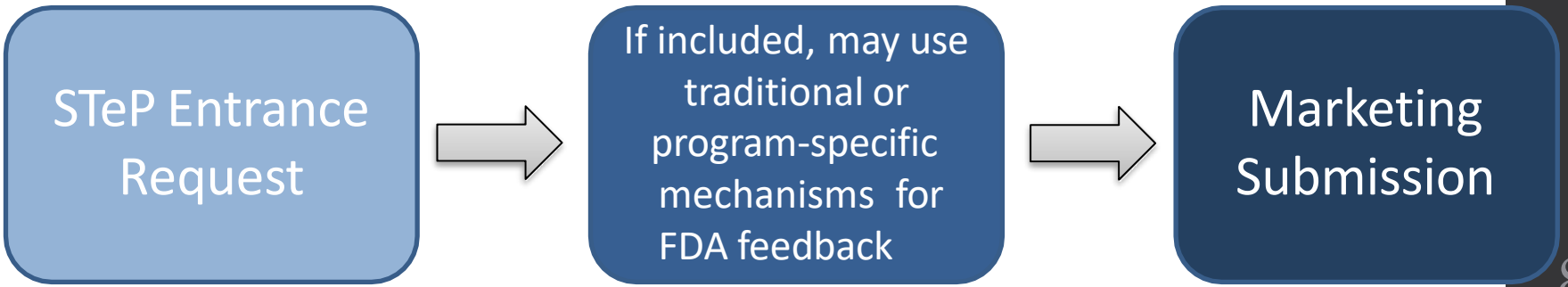
- Data Development Plan
- Sprint discussion
- Traditional pre-submission
- Regular status updates



STeP Request: Example Content

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- **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 Request Process

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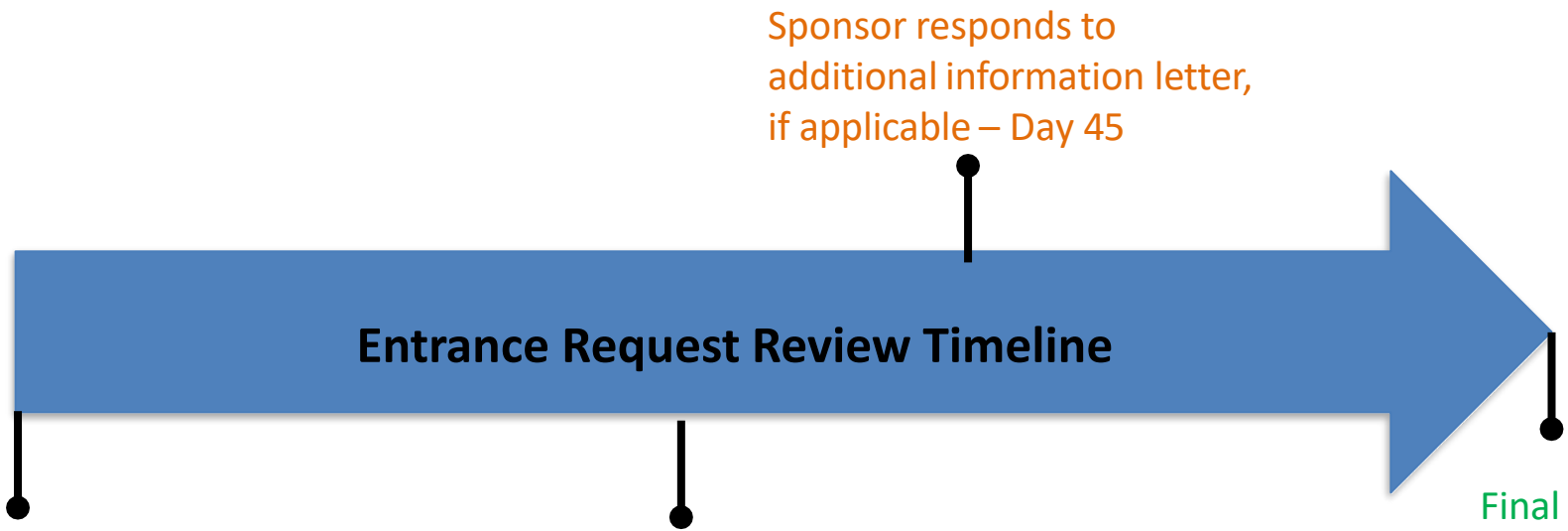

Early Experience with STeP

- 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**

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

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	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

Resources

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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