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# Safer Technologies Program (STeP) for Medical Devices Final Guidance

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February 1, 2021

# Objectives

Understand the following:

- Purpose and scope of the new, voluntary Safer Technologies Program (STeP)
- Eligibility factors for inclusion in STeP
- Programmatic principles and features of STeP

# Agenda

- Background
- Overview of the guidance
- Highlights of STeP
  - Program Principles
  - Eligibility Factors
  - Mechanisms for Feedback
- Summary, Resources, and Questions

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# Safer Technologies Program

- A new, 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 Timeline



Guidance drafted



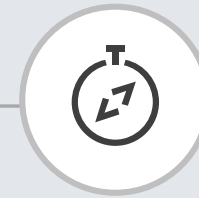
Draft published  
September 19, 2019



Public comments  
received, incorporated  
into final guidance



Final guidance issued  
January 6, 2021



STeP  
Guidance  
Webinar



Anticipated  
program  
implementation  
March 8, 2021

Medical Device Safety  
Action Plan  
April 12, 2018

# 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<sup>1</sup>



<sup>1</sup> Medical Device Safety Action Plan <https://www.fda.gov/media/112497/download>



# Medical Device Safety Action Plan

One goal discussed in the plan is to spur innovation towards safer medical devices. The FDA intends to:

- Advance policies that encourage innovation and facilitate timely patient access to safe and effective medical devices
- Explore actions and regulatory incentives to encourage the development of technologies that make devices and their use safer
  - Leverage policies and program features similar to those available under the FDA's Breakthrough Devices Program

# Breakthrough Devices Program



- Voluntary program for medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions
- Unlike STeP, the Breakthrough Devices Program is statutorily mandated
- Key Program Principles:
  - Expedite device development and review
  - Opportunities for interaction to efficiently support device development
  - Increased opportunity for senior management involvement

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

Breakthrough Device Program guidance: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program>

# Motivation for STeP

- Breakthrough Devices Program is for devices that treat or diagnose life-threatening or irreversibly debilitating diseases or conditions
- Devices that treat or diagnose less serious conditions than those eligible for Breakthrough Devices Program can still result in complications and/or serious adverse events

# Motivation for STeP

- Breakthrough Devices Program is for devices that treat or diagnose life-threatening or irreversibly debilitating diseases or conditions
- Devices that treat or diagnose less serious conditions than those eligible for Breakthrough Devices Program can still result in complications and/or serious adverse events
- Efforts to improve safety are directly related to improving overall clinical benefits → Public health benefit
- The FDA recognizes the need to expedite development and review of devices that may make significant safety improvements → STeP

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# Overview of the Guidance

Document includes:

- Introduction and Background
- Program Principles
- Eligibility Factors for STeP Entrance and Review Process
- Mechanisms for Feedback on Devices Included in STeP

# Changes from Draft to Final Guidance

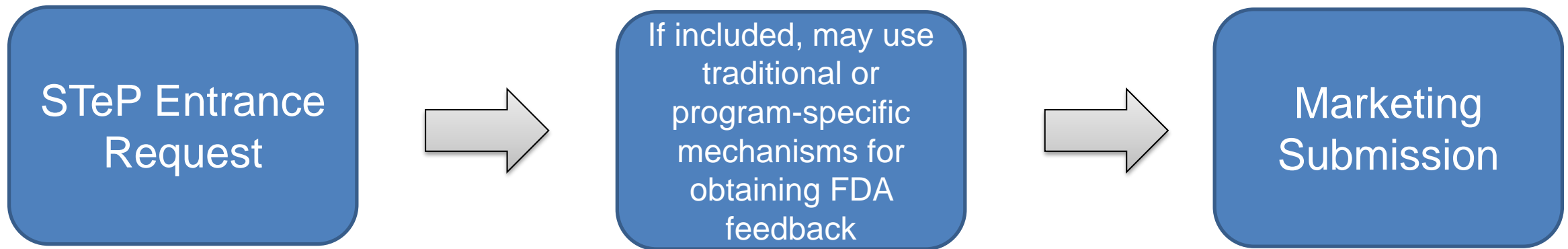
- Final guidance issued on January 6, 2021
- The FDA revised the final guidance in response to stakeholder comments:
  - Further explanation of program scope
  - Clarification of the review timelines
  - Emphasized that participation in STeP does not impact the statutory requirements for marketing authorization nor does it affect the application of least burdensome policies and approaches.

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# STeP Overview



- If included in STeP, subsequent submissions receive programmatic benefits
- If denied inclusion in STeP, traditional pathways still available for obtaining FDA feedback (e.g., pre-Submissions) and marketing pathways remain unchanged

# STeP Program Principles

To expedite development and review of devices included in STeP, the FDA intends to apply the following principles, when appropriate and as resources permit:

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

# STeP Program Principles

Sponsors of devices under this program are expected to work interactively with the FDA, and, in a timely manner to:

- Respond to FDA requests
- Collect premarket and postmarket data
- Market their devices, if authorized



# STeP Program Eligibility

- Inclusion in STeP is only at the request of the sponsor and with the FDA's agreement
  - Sponsors should submit STeP entrance requests as a Q-submission
  - The FDA intends to include device in STeP or deny inclusion within 60 calendar days of receipt
- Device should meet both the general and specific program eligibility factors

# General STeP Program Eligibility Factor

## General Eligibility Factor:

Device should be subject to marketing authorization via the PMA, De Novo request, or 510(k) pathways

- For device-led combination products subject to these marketing pathways, the FDA intends to evaluate which constituent part of the product (i.e., device or drug/biologic) is providing the proposed safety improvement, and to only consider including products in STeP if the safety improvements are made to the device constituent part

# STeP Program Eligibility Factors

In addition to the general eligibility factor, device should also meet specific eligibility factors.

## 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.

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# Specific Eligibility Factor 1

## Specific Eligibility 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;

Such diseases or conditions may:

- Be considered non-life-threatening or reasonably reversible
- Affect patient quality of life or be debilitating for short timeframes
- Be associated with health consequences that do not significantly impact daily function, and/or might not progress to a more serious disease or condition



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  - d) an improvement in the safety of another device or intervention.

# Specific Eligibility Factor 2

## Specific Eligibility Factor 2:

Device should be reasonably expected to significantly improve the benefit-risk profile of a treatment or diagnostic through substantial safety innovations...

Some considerations:

- The device should be reasonably expected to make a clinically meaningful improvement in the prevalence and/or severity of the safety issue
- Safety improvements should not compromise the device's effectiveness
- FDA intends to consider whether the safety innovation introduces the potential for new serious adverse events or use-related hazards and their impact to the benefit-risk profile
- A substantial safety innovation is one that incorporates an innovative technological feature or represents an innovative use of a technology to accomplish the significant safety improvement

# STeP Program Eligibility Factors

In addition to the general eligibility factor, the device should also meet specific eligibility factors.

## 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;  
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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:
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  - 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.

# Specific Eligibility Factor Considerations

## Specific Eligibility Factor 2a:

Device should be reasonably expected to significantly improve the benefit-risk profile of a treatment or diagnostic through substantial safety innovations that provide for...

### (a) a reduction in the occurrence of a known serious adverse event

Some considerations:

- The device should be reasonably expected to result in a significant reduction in the occurrence of a known serious adverse event, based on device principles of operation
- The FDA intends to consider serious adverse events that are reasonably attributed to use of a medical product that occur in acute timeframes as well as those that are associated with long term adverse outcomes

# Specific Eligibility Factor Considerations

## Specific Eligibility Factor 2b:

Device should be reasonably expected to significantly improve the benefit-risk profile of a treatment or diagnostic through substantial safety innovations that provide for...

### (b) a reduction in the occurrence of a known device failure mode

Some considerations:

- Device should be reasonably expected to reduce the occurrence of a known failure mode that is likely to result in serious adverse health consequences, including those that are likely to result in death, to be life-threatening, or to involve permanent or long-term injuries to patients
- Device should not be addressing hypothetical device failure modes

# Specific Eligibility Factor Considerations

## Specific Eligibility Factor 2c:

Device should be reasonably expected to significantly improve the benefit-risk profile of a treatment or diagnostic through substantial safety innovations that provide for...

**(c) a reduction in the occurrence of a known use-related hazard or use error**

Some considerations:

- Use-related hazard or use error may result in serious safety issues for patient as well as device user (e.g., clinician, caretaker)
- The device should address errors or hazards associated with device design or operational features rather than those stemming from inadequate or unclear labeling

# Specific Eligibility Factor Considerations

## Specific Eligibility Factor 2d:

Device should be reasonably expected to significantly improve the benefit-risk profile of a treatment or diagnostic through substantial safety innovations that provide for...

**(d) an improvement in the safety of another device or intervention**

Some considerations:

- The device is expected to offer a specific and significant type of improved safety benefit for another medical device or intervention
- Device requesting inclusion in STeP should be the finished device but may or may not be a medical device accessory\*

\*<https://www.fda.gov/medical-devices/classify-your-medical-device/medical-device-accessories>

# STeP Entrance Requests

- Requests for inclusion in STeP are submitted as “**STeP Entrance Request**” Q-submissions
  - Submission should not include other requests for feedback (e.g, Data Development Plan)
- Appendix 1 includes an illustrative example of the type of information that should be included in the request:
  - Device description, including principles of operation, properties relevant to clinical function, images or engineering schematics
  - Expected safety improvement
  - Proposed Indications for Use
  - Regulatory history (if applicable)
  - Justification for how the device meets the general eligibility factors
    - Planned marketing application
  - Justification for how the device meets the specific eligibility factors



# STeP Entrance Requests

- The FDA's review of STeP entrance requests will include assessment of how the device meets general and specific program eligibility factors
- Review timeline
  - The FDA intends to request additional information, if needed, by 30 days after receipt
    - These requests do not stop the review clock
  - Sponsor response to additional information expected by the date stipulated in the additional information request
  - The FDA intends to notify sponsor whether or not the device has been included by day 60
- STeP has a delayed implementation in order to operationalize the program
  - The FDA currently anticipates accepting STeP Entrance Requests for review beginning on March 8, 2021

# Additional Considerations for STeP Entrance Requests

## Regulatory Path

- A device's inclusion or denied inclusion in STeP does not constitute a formal decision regarding the applicable regulatory pathway or device classification.
- Inclusion of a device into STeP does not constitute a decision on whether the device is an accessory or on its risk classification.

## Timeframe for STeP Entrance Request

- Requests for inclusion in STeP should be submitted prior to marketing submission, but the FDA may consider requests submitted in parallel

## Multiple Devices for Same Expected Safety Benefit

- The FDA may include multiple devices in STeP that are intending to address the same safety issue or improvement

# Mechanisms for Feedback on Development of Devices in STeP

FDA intends to offer sponsors of devices included in STeP the following options for early and regular interaction with the FDA, as resources permit:

- 1. Sprint discussion:** Discussions with the goal of reaching mutual agreement on a specific topic within a set time period (e.g., 45 days)
- 2. Review of a Data Development Plan (DDP):** A DDP is an optional, high-level document outlining (non-clinical and/or clinical) data collection expectations, including timing, for the entire product lifecycle
- 3. Pre-submission:** Covers a broader scope of topics in a single-submission
- 4. Regular Status Updates:** routine informational only updates

# Mechanisms for Feedback on Development of Devices in STeP



- Use of these feedback options is not mandatory
- Sponsors submit requests for STeP sprint discussions, DDP reviews, and Pre-submission feedback as Q-Submissions
  - Cover letter should identify the Q-submission as a “**STeP Interaction Request**”
- Regular status updates are informal interactions without separate submissions
- As resources permit, the FDA intends to provide feedback on STeP interaction submissions in less time than would be expected for a traditional pre-submission

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# Summary

- As part of Medical Device Safety Action Plan, FDA is introducing a new, voluntary program to spur innovation towards safer medical devices through an approach similar to the Breakthrough Devices Program.
- The Safer Technologies Program (STeP) intends to apply similar principles and programmatic features to devices with safety innovations that target less serious diseases or conditions than Breakthrough Devices Program.
- We are currently operationalizing the program and at this time anticipate accepting entrance requests **beginning on March 8, 2021.**

# Resources

- Final guidance document available here:  
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safer-technologies-program-medical-devices>
- Safer Technologies Program webpage:  
<https://www.fda.gov/medical-devices/how-study-and-market-your-device/safer-technologies-program-step-medical-devices>
- Program mailbox: [SaferTechnologiesProgram@fda.hhs.gov](mailto:SaferTechnologiesProgram@fda.hhs.gov)

# Questions?

Division of Industry and Consumer Education:

[DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)

Slide Presentation, Transcript and Webinar Recording will  
be available at:

<http://www.fda.gov/training/cdrhlearn>

Under Heading: How to Study and Market Your Device;  
Subsection: Cross-Cutting Premarket Policy

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