

**FDA Webinar: Safer Technologies Program: Draft Guidance**

**Moderator: Irene Aihie  
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Coordinator: Welcome and thank you for standing by. Your lines are in listen-only mode until today's question and answer session. At that time if you would like to ask a question, you may do so by pressing Star and then 1.

Today's conference is being recorded. If you have any objection, you may disconnect at this time.

I would now like to turn the call over to Irene Aihie. You may begin.

Irene Aihie: Hello, and welcome to today's FDA webinar. I'm Irene Aihie of CDRH's Office of Communication and Education. On September 19, 2019, the FDA issued the draft guidance titled Safer Technology's Program for Medical Devices. The draft guidance outlines the agency's vision for the safer technology program for medical devices.

Once the guidance is finalized, the program will be a voluntary pathway for certain medical devices that are expected to significantly improve the safety profile of currently available treatments or diagnostic that address less serious diseases or conditions than those eligible for the breakthrough devices

program. But the use of which may be associated with serious or life-threatening risk.

Today Joshua Chetta, biomedical engineer in the Office of Clinical Evidence and Analysis here in CDRH will present an overview of the draft guidance document. Following the presentation, we will open the lines for your questions related to the information provided during the presentation. Additionally, there are other sensor subject matter experts here with us today to assist with the Q&A portion of our webinar.

Now I give you Joshua.

Joshua Chetta: Thank you, Irene. Good afternoon, everybody. Today, we'll be providing an overview of the recently released draft guidance document that introduces FDA's proposed Safer Technologies Program.

My goal for this presentation is to give everyone an understanding of the purpose and scope of the draft guidance document for the Safer Technologies Program which I'll sometimes refer to by its acronym, STeP. Additionally, I'll go over the proposed eligibility factors for acceptance into the program and describe some of the programmatic principles and features. It's important to highlight upfront that STeP is a proposed program and not yet for implementation.

We will address each of those learning objectives by walking through the following topics. First I'll provide some background information, go over the scope and structure of the draft guidance document, and in the third part of the presentation will get into more detail on some of the important highlights of the proposed program. I will close with a summary of what we talked about, provide resources and then take questions.

First, background information. The Safer Technologies Program is proposed as a voluntary program for product that are expected to offer significant safety improvements compared to currently available medical options through innovative technological features. The focus of this program is on ensuring timely patient access to these medical devices while preserving FDA's statutory standard for marketing authorization. To capitalize on our growing experience with the Breakthrough Devices Program, STeP is based on some features and approaches from Breakthrough.

The idea for STeP was first introduced in the medical device safety action plan released in April 2018. The medical device safety action plan outlines a vision for how FDA can continue to enhance programs and processes to ensure the safety of medical devices. It covers five key areas, one of which is spurring innovation towards safer medical devices. To meet this goal, FDA outlined steps it intends to take to advance policies that encourage innovation and facilitate timely patient access to safe and effective medical devices.

Specifically, we propose leveraging policies and program features from the Breakthrough Devices Program to incentivize the development of technology that can make devices and their use safer. It's worth spending a few minutes, then, talking about the Breakthrough Devices Program to understand how that approach might be applied to this goal.

The Breakthrough Devices program is a voluntary program for devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Once the device is granted breakthrough designation, future submissions may be subject to expedited review and there may be a more interactive approach to the review of those submissions with additional input from senior management.

Those key principles motivated our proposal for STP and additional information is available at the link at the bottom of this page for the Breakthrough Devices Program.

We've seen significant growth and the use of the Breakthrough Devices Program over the past few years. Having seen some of those benefits in programmatic features for addressing that medical device regulatory challenge, we feel that a similar approach may be beneficial for incentivizing safety innovation. In particular, devices can be associated with serious and life-threatening adverse event even if those devices themselves are intended to treat or diagnose less serious conditions. Incentivizing safety innovation for these types of devices represent an opportunity for significant public health benefit and the Safer Technologies Program underscores FDA's goal for expediting development of these safety improvements.

Hopefully that provided some context for why the FDA has published this draft guidance document. I'm going to move on and talk briefly about the scope and contents of that document before getting into the details of the proposed program in the third part of this presentation.

As mentioned previously, STeP is currently a proposal issued in draft guidance. Our goal right now is to elicit feedback from the community on this proposed program. We encourage everyone to submit comments by November 18. Would like to note that our intent to implement the program after finalization, after issuance of the final guidance document, we anticipate that we may need up to 60 days to operationalize the program.

The draft guidance document itself includes background information. It discusses the motivation for the proposed program as well as the discussion of

the programmatic principles that we intend to apply. It also includes an in-depth discussion of the proposed eligibility factors for acceptance into the program. And finally, it describes different mechanism for feedback and interaction available for devices that have been accepted into STeP.

And that same structure here is what we will go over in the next section of this presentation. First will cover program principle and spend a little bit of time on eligibility factors and finish up with discussion of the types of feedback available in the program.

The central goal of STeP is to expedite development and review for devices accepted into the program. To help facilitate this, when appropriate and as resources permit, FDA intends to apply the following concepts to devices in the program: interactive and timely communication, review team support and senior management engagement, timely postmark of data collection, efficient and flexible clinical study design, expedited review of manufacture and quality systems compliance for devices with preapproval inspection requirements. Each of these concepts is discussed more fully in the draft guidance document and together they form a comprehensive approach drawn from our experience with breakthrough devices and other prioritized review programs.

It's worth mentioning that if necessary FDA plans to prioritize resources for the Breakthrough Devices Program over STeP because the Breakthrough Devices Program is statutorily mandated.

FDA intends to prioritize review of regulatory submission for devices in STP as appropriate and as resources permit. Similarly, along with FDA's intention to facilitate expeditious submission review, we expect that sponsors of devices in this program will work interactively with the FDA and act in a timely

manner to do all of the following; respond to FDA's request, collect premarket and post-market data, and market their device, if authorized.

FDA feels that the principles outlined in this document represent a shared recognition on the part of the Agency and device sponsors of the public health importance of medical device safety.

Let's get into program mechanics a little bit more. FDA envisions STeP as being comprised of two phases. In the first, a sponsor will submit a request for acceptance into the program through a Q-submission and if the device is accepted, then in the second phase, additional programmatic features and mechanisms for feedback may be available.

I'm not going to cover the actual submission process in this presentation, but the draft guidance document does include a discussion of that process in Appendix 1 of the document. It also includes an example of the format and recommended information to be included in submission, requesting inclusion into the program.

Once request for acceptance into STP is received, FDA is proposing a 60-day timeline for decision on that request to either accept it into the program or deny the request. The decision on whether or not to accept a device into the program will be based on whether the device meets the eligibility factors for the program.

The draft guidance document lays out the eligibility factors and includes in-depth discussions about FDA's considerations for those factors. And we'll send a few minutes going through the factors here as well. The first is a general eligibility factor focused on the marketing pathway for the device.

The general eligibility factor says that the device should be subject to marketing authorization via the PMA, de novo request or 510K pathways.

In addition, the device requesting acceptance into the program also needs to meet the two specific eligibility factors. The first specific eligibility factor addresses the severity of the disease or condition treated or diagnosed by the device. And the second eligibility factor addresses the significance of the safety improvement and the type of improvement that is realized through innovation.

The specific eligibility factors are, one, the 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 two, the 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.

There's a bit of information here and it's worth covering each of these eligibility factors in more detail. First, we'll look at the first factor related to the disease or condition severity. This eligibility factor says that the device should treat, diagnose or prevent a disease or condition that is less serious than those eligible for the Breakthrough Devices Program. The draft document provides a discussion of our considerations for meeting this factor and includes some examples as well.

Such diseases or conditions may be non life-threatening or reasonably reversible. Their impact on the patient may be only for a short timeframe. And might not impact daily function or progress to a more serious disease. It's important to point out again that this factor covers the intent of the device but as I mentioned previously, devices that treat or diagnose less serious diseases or conditions can still result in serious adverse events and negative health consequences.

And the second part of the specific eligibility factors, covers how those negative outcomes are addressed by the safety innovation with a focus on the significance of the safety improvement as well as the specific type of improvement realized through the innovation. We'll break up the second eligibility factor into a few slides. We'll start by looking at just the first part.

The first part of the second factor states that to be eligible for the program, the device should be expected to make a significant improvement to the benefit risk profile of the treatment or diagnostic through substantial safety innovation. The document lays out our proposed considerations for meeting this factor which includes some of the following.

The device should address a known safety concern. You'll also note that we focus on the impact of the benefit risk profile in this factor and it's important that the safety improvement should generally not compromise the device's effectiveness. Similarly in addressing a known adverse event or safety concern, the device should not increase the chance or severity of another adverse event. And finally we expect the safety innovation to be significant and to stem from innovation, either new technological feature or new use of technology.

The first part of this second eligibility factor outlines the expectations for the significance of the safety improvement. And the second part of this factor goes on to provide four specific outcomes at least one of which should be realized by the technological innovation for the device to be considered eligible for the program. We'll discuss what the draft guidance document says about each of these subparts to the second specific eligibility factor in more detail in the next few slides.

The first subpart, says that the safety innovation for the device should provide for reduction in the occurrence of a known serious adverse event. For the purpose of meeting the eligibility factor, the document notes that the reduction should be reasonably expected and significant. FDA will consider both acute and longer-term serious adverse event that are reasonably attributed to the device. And the draft guidance document does include some examples of ways the device might meet this subpart.

In the second subpart of specific eligibility Factor 2, it says that the safety innovation for the device should provide for a reduction in the occurrence of a known device failure mode. For the purpose of meeting this eligibility factor, the failure mode should be associated with serious health consequences for the patient and should be something known to occur and not simply a risk of something that might occur.

The third subpart in the eligibility factor says that the safety innovation for the device should provide for reduction in the occurrence of a known use -related hazard or use error. The draft guidance document notes that these terms are defined in the FDA guidance document “Applying Human Factors and Usability Engineering to Medical Devices.” For the purpose of meeting the eligibility factor, FDA will consider safety issues that impact patients as well as users of the device such as physicians, nurses, or caretakers.

Additionally, this program intended to focus on addressing issues with device design or operational features rather than those use hazards or use errors associated with inadequate or unclear labeling.

The fourth and final subpart of this specific eligibility factor says that the safety innovation for the device should provide for an improvement of the safety of another device for intervention. For the purpose of meeting this eligibility factor the device requesting inclusion should be expected to offer a specific type of improved safety benefit for another medical device or intervention. Additionally, the device under consideration for acceptance into the program may or may not be a formal medical device accessory as defined in the guidance that can be found at the link at the bottom of the page but the device requesting acceptance should be a finished medical device.

With that, we'll move on from the consideration of program eligibility factors and there are three other important considerations that the draft guidance document mentions about the acceptance review process that are worth mentioning here. The first is that a decision on whether to accept the device into STeP or not does not constitute a formal decision on any other regulatory question including the regulatory path, device classification or whether the device is an accessory.

Second, our expectation is that requests for acceptance into the program will be submitted prior to a marketing submission that we may consider requests admitted in parallel. Please note the that for these cases, some of the optional features and mechanisms for feedback in the program will likely not be as beneficial. Finally, the draft guidance states that FDA may accept multiple devices into the program that intend to address the same safety issue or improvement.

And to close out this section I'll briefly cover the additional mechanisms for feedback available for devices accepted into STP. These additional mechanisms are optional, and sponsors may choose to request one of these through a Q-submission. These are similar to some of the options available under the Breakthrough Devices Program. First devices accepted into STeP have the option of requesting Sprint discussions with the goal of reaching mutual agreement on a specific topic within a set time period.

Second, sponsors may request to review of the data in the development plan. This is a high-level document intended to help ensure predictable, efficient, transparent and timely device assessment and review by outlining data collection expectations for the entire product lifecycle. Sponsors may also request traditional presubmissions for those questions or requests that don't fit into the other mechanisms for feedback. And finally sponsors may choose to schedule regular status updates with FDA. As mentioned early in the presentation, FDA intends to expedite the review of these requests as resources permit.

And with that, I'll wrap up with a quick summary of this presentation, a list of resources for more information and then take questions. The Medical Device Safety Action Plan laid out a vision to apply the lessons learned and programmatic principle from the Breakthrough Devices Program to spur innovation towards safer medical devices. The Safer Technologies Program is fulfilling that vision by incentivizing safety innovation for those devices that address - that fall outside the scope of the Breakthrough Devices Program's eligibility.

We laid out our proposal for STP in this draft guidance and are seeking comments and input. The draft guidance document is available at this link and

the webpage on this page also includes instructions and resources for submitting comments on the document. Comments are requested by November 18.

I'll end the presentation there and we'll open the line out for questions. You can also submit question to the Division of Industry and Consumer Education or DICE at any time. You can find a copy of this presentation online at the link on this slide. Thank you for your time.

Irene Aihie: Operator, we'll now take questions.

Coordinator: If you would like to ask a question on the phone lines, you may do so by pressing Star and then 1. You will be prompted to record your name which is used to introduce your question. Again that is start and then 1 if you would like to ask a question. One moment for our first question.

Joshua Chetta: While we're waiting for the questions to get queued up, a few quick reminders. We've gotten this question a few times since we've issued the draft guidance. It's not necessary for all subcriteria in specific eligibility Factor 2 to be met. So we talked about four different subparts of that second specific eligibility factor. I want to highlight that it's only necessary to meet one of those subparts.

You need to meet the general eligibility factor for inclusion in the program, the first specific eligibility factor and one of the subparts of the second specific eligibility factor.

Coordinator: Our first question on the phone line is from (Katherine Becker). Your line is open.

(Katherine Becker): Hi, good afternoon and thank you for the helpful overview of the draft guidance. My question is whether the agency intends to allow sponsors to apply for this designation and request with other related Pre-sub issues. Or does it have to be a presub request in and of itself? Thank you.

Joshua Chetta: That's a great question. Thank you very much. We expect these requests for acceptance into the program to be their own Q-submissions. Other questions that might be related should be submitted in a separate Q- submission as appropriate.

(Katherine Becker): And I actually have a related follow-up question to that if possible. Could you then submit perhaps sequentially the request for designation and then a follow up Q-subsay the same day or next day separately to be tracked just in case? I'm thinking about the timelines here and usually it's about 70 days for a presub response. You're talking about 60 days here. So it seems like a lot of time could be wasted by not doing those at the same time. Thank you.

Joshua Chetta: It's an interesting question. You know, keep in mind that the same reviewers will be responsible for probably addressing the questions in both of those separate Q-submissions. You know, the other thing to keep in mind is that once the - if a device is accepted into the program, we envision that the additional Q-submission type such as a sprint discussion would allow for kind of address that lag time that you might get. So the hope is that those sprint discussions would be more interactive with a little bit shorter timeline that we would expect for that feedback to be provided in.

(Katherine Becker): All right, thank you.

Coordinator: Our next question is from (Andrea Mushinborn). Your line is open.

(Andrea Mushinborn): Hi, thank you for the great information. Can you comment on whether this program will have an impact on reimbursement?

Joshua Chetta: That's unfortunately outside the scope of this program and kind of what FDA is responsible for.

(Andrea Mushinborn): Understood, thank you.

Coordinator: As a reminder, you may press Star 1 if you wish to ask a question. The next question is from (Brandon Sievers). Your line is open.

(Brandon Sievers): Thanks for the presentation. My question is in regard to the distinction between devices eligible for the breakthrough program compared to the STeP program. So with the breakthrough program, my understanding is that the device needs to treat or diagnose a life-threatening disease and be more effective. Whereas the STeP program doesn't have that effectiveness requirement. So my question is, if there was a device diagnose a life-threatening disease that has a significant safety advantage but isn't necessarily more effective in terms of the therapeutic outcome, but maybe it has more effective procedural advantage in terms of the efficiency of the procedure and the number of devices used, would the STeP program be applicable? Or the breakthrough program?

Joshua Chetta: It's a great question. Appreciate the really getting into the details here which is great and really engaging with us. You know, when you're getting into kind of some specifics like that I do think it's probably helpful to speak with the review team that would likely be responsible for evaluating that. So that's the type of thing that a presubmission might be helpful for. I will say that, you know, well let me - I'm going to turn it over to Dr. (Maureen Drea) who's here

in the room with me. She's been, kind of, overseeing the Breakthrough Devices Program for quite a while and may have a little more insight on this.

Dr. (Maureen Drea): Great, thanks Josh. And thank you for that question. One of the things that we really are trying to use to distinguish the two programs is the underlying disease or condition being treated and its severity. So with breakthrough, I think that's kind of the first cut that you could possibly make in making a decision on which program the device may be applicable for and eligible for. And it's really looking at whether or not the disease is treating or diagnosing a life-threatening or irreversibly debilitating condition. And really based on the answer to that question that might guide you into one program versus the other.

Again, like as Joshua mentioned, it's a good idea to also consult with the premarket review team responsible for this device area and the diseases area and try to work with them also to see if they have recommendations for you regarding more based on the type of benefits that you believe your device will be exhibiting for patients.

(Brandon Sievers): Okay, thank you.

Coordinator: Once again, you may press Star 1 if you would like to ask a question. Our next question is from (Michelle Rubioni). Your line is open.

(Michelle Rubioni): Hello, thank you so much for the webinar. My question is the STeP program really focuses on the device offering significant improvement, the safety profile. Is that the plan in a future final guidance to define or delineate more what they mean by significant? Or is that more the sponsor to determine and present in their submission?

Joshua Chetta: Again, this is a great question. You know, our - one intention that we have with this program is to really focus our efforts and resources on addressing those, you know, highly impactful public health concerns. And so those kind of - one of the intentions behind putting that work significant in there, we do expect these to be, you know, substantive improvements to the safety profile. And we do expect, you know, our hope is that they would be leveraged to address those kind of big public health safety concerns.

It's a great point about putting a little more clarity around what we mean by those types of, you know, defining those terms maybe a little more clearly in the final guidance document. That's the type of comment that, you know, just put a plug in for this. That's the type of comment that is very helpful to, you know, to be added to the public docket while the comment period is open because that's something that we can take and kind of dial into any revisions that we might make as we're finalizing this.

(Michelle Rubioni): Thank you very much. I appreciate it.

Coordinator: Thank you and we have no more questions. Irene, you may proceed.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH webpage at [www.fda.gov/training/cdrhlearn](http://www.fda.gov/training/cdrhlearn) by Thursday, November 14. If you have additional questions about today's presentation, please use the contact information provided at the end of the slide presentation. As always, we appreciate your feedback.

Following the conclusion of today's webinar, please complete a short 13-question survey about your FDA CDRH webinar experience. The survey can

be found at [www.fda.gov/cdrhwebinar](http://www.fda.gov/cdrhwebinar) immediately following the conclusion of today's live webinar.

Again, thank you for participating. This concluded today's webinar.

Coordinator: This concludes today's conference. Thank you for your attendance. You may disconnect at this time.

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