

FDA announces new expedited program for devices expected to significantly improve the safety of existing technologies

23 September 2019

On 19 September 2019 the U.S. Food and Drug Administration (FDA or the agency) released the draft guidance document entitled "[Safer Technologies Program for Medical Devices](#)" (STeP), effectively following through on the agency's intention to spur innovation toward safer medical devices, as described in its [2018 Medical Device Safety Action Plan](#).

STeP is designed to be a voluntary program for medical devices and device-led combination products that offer a significant safety advantage compared to commercially available products. FDA envisions STeP as a complement to the [Breakthrough Devices Program](#). Products that offer significant safety advantages, but otherwise do not meet the criteria for breakthrough status could be eligible for similar benefits through the STeP program.

STeP overview

STeP will allow the agency to expedite the development and review of devices that have the potential to significantly improve safety. Modeled on the Breakthrough Devices Program, STeP provides for early interactions between FDA and sponsors in device development, incorporating features such as interactive and timely communications, early engagement on Data Development Plans, prioritized review, and senior management engagement. Resources permitting, the agency plans to leverage the Breakthrough Devices Program features to maximize the impact of STeP; however, when necessary, the Breakthrough Devices Program will be prioritized because it is statutorily mandated.

STeP will accept submissions for devices or device-led combination products that are subject to review under a premarket approval application (PMA), De Novo classification request, or premarket notification (510(k)). Statutory standards for premarket review and substantial equivalence will continue to apply to devices accepted into STeP, although FDA will use postmarket data collection as deemed appropriate for expedited development. Acceptance into STeP is not intended to constitute a formal decision on the applicable regulatory pathway or device classification; rather, it indicates the agency expects one of the above marketing authorization submissions will be necessary.

Eligibility

Devices and device-led combination products are eligible for STeP if they target diseases or conditions that are less serious than those eligible for the Breakthrough Devices Program. Inclusion in STeP also requires that the device "is 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. reduction in the occurrence of a known serious adverse event,
- b. reduction in the occurrence of a known device failure mode,
- c. reduction in the occurrence of a known use-related hazard or use error, or
- d. improvement in the safety of another device or intervention.

Notably, the draft indicates that FDA will consider devices for inclusion in STeP that have the potential for significant safety improvements over the current standard of care, including FDA-approved drugs, biologics, or "other technologies."

As with the Breakthrough Devices Program, requests for inclusion in STeP should be submitted through the Q-submission process.

Conclusion

Our in-depth experience with breakthrough designated products has indicated that breakthrough status can be quite valuable for companies as they navigate the premarket review process, particularly for more novel products. Thus, the STeP program may well prove to be a meaningful option for companies that would not be breakthrough eligible, but would benefit from more frequent FDA interaction and expedited review. In our experience, companies tend to have greater benefit from the interactive and expedited review associated with these programs when they engage with FDA during the development and evaluation phases of the device.

However, it remains to be seen whether the agency's resources will be able to meet the full promise of the program. We have observed that the proliferation of new initiatives to expedite product review can dilute overall impact. FDA makes explicit in the draft guidance that the Breakthrough Devices Program will take precedence for resources over STeP. As we track the development of this new program, we will be watching how the agency's response and prioritization in the context of competing expedited review programs affect review times for all medical device pathways.

* * *

Comments submitted to [FDA-2019-D-4048](#) by 18 November 2019 will be considered in the agency's work on the final guidance. FDA will begin accepting submissions to STeP 60 days after the guidance is finalized.

On 6 November 2019 FDA will host [a webinar on the Safer Technologies Program](#).

Contacts



Randy J. Prebula
Partner, Washington, D.C.
T +1 202 637 6548
randy.prebula@hoganlovells.com



Jennifer Agraz Henderson
Partner, Washington, D.C.
T +1 202 637 5783
jennifer.henderson@hoganlovells.com



Yarmela Pavlovic
Partner, San Francisco
T +1 415 374 2336
yarmela.pavlovic@hoganlovells.com



Lina R. Kontos
Counsel, Washington, D.C.
T +1 202 637 5713
lina.kontos@hoganlovells.com

www.hoganlovells.com

"Hogan Lovells" or the "firm" is an international legal practice that includes Hogan Lovells International LLP, Hogan Lovells US LLP and their affiliated businesses. The word "partner" is used to describe a partner or member of Hogan Lovells International LLP, Hogan Lovells US LLP or any of their affiliated entities or any employee or consultant with equivalent standing. Certain individuals, who are designated as partners, but who are not members of Hogan Lovells International LLP, do not hold qualifications equivalent to members. For more information about Hogan Lovells, the partners and their qualifications, see www.hoganlovells.com.

Where case studies are included, results achieved do not guarantee similar outcomes for other clients. Attorney advertising. Images of people may feature current or former lawyers and employees at Hogan Lovells or models not connected with the firm.

© Hogan Lovells 2019. All rights reserved.