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FDA Issues Draft Guidance on Determining when Data from Foreign Clinical Studies Can Support Device Submissions

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It is becoming increasingly common for medical device companies to conduct clinical studies outside the United States and then seek to use data from these foreign studies in regulatory submissions to FDA. In a draft guidance issued on April 22, 2015, FDA lays out the factors it considers when confronted with data from foreign studies in premarket device submissions.

FDA has long accepted foreign studies in device submissions, but this draft guidance provides greater clarity for sponsors seeking to rely on foreign data. This guidance furthers the goals that Congress expressed in 2012 with the Food and Drug Administration Safety and Innovation Act (FDASIA), which added section 569B to the Federal Food, Drug, and Cosmetic Act. In particular, section 569B, which is codified at 21 USC 360bbb-8b, requires FDA to accept data from foreign studies and to notify sponsors of its reasoning if it finds such data inadequate to support device approval or clearance.

This draft guidance also clarifies that FDA will accept foreign data for not only premarket approval applications and premarket notifications (510(k)s) but also investigation device exemption applications (IDEs), de novo petitions, and humanitarian device exemptions.

The bulk of the draft guidance discusses how FDA analyzes foreign data. As with data from US clinical trials, FDA must determine whether data from a foreign study constitute "valid scientific evidence" under 21 CFR 860.7. As FDA explains in the guidance, however, "certain challenges exist in using data derived from foreign studies of devices." When confronted with foreign data, FDA considers not only general features of good study design under 21 CFR 860.7 but also "special considerations." FDA identifies three main "special considerations" that apply to the analysis of foreign studies:

1. Differences in study populations. Any differences in the race, ethnicity, age, gender, and sex of a foreign study population and US patient population could affect the applicability of the foreign data to a US regulatory authorization. Foreign and US populations may also differ in the prevalence of confounding factors—including smoking, diabetes, and obesity—that can affect the risks of an intervention as well as clinical response. FDA expects that sponsors mitigate any differences between the foreign study population and US patient population or explain why the differences do not affect safety or efficacy.

2. Differences in clinical conditions. Other countries may have different standards of care, clinical facilities, or levels of clinical skill, which can affect the analysis of the benefits and risks of the studied device relative to standard practice in the United States. FDA will want to understand how clinical practices in the region where the study was conducted compare to practices in the United States.
3. Differences in regulatory requirements. When studies are initiated to satisfy the requirements of foreign countries rather than FDA, the study may not be designed to address the questions necessary to satisfy FDA requirements. For example, studies designed to demonstrate safety and performance may not be sufficient to address FDA requirements of safety and efficacy.

The draft guidance walks through seven concrete examples to explain FDA's thinking when confronted with foreign clinical data.

In addition to explaining FDA's approach to foreign data, the draft guidance encourages sponsors to seek FDA's input early—before initiating foreign studies or relying upon already completed foreign studies. When sponsors engage with FDA before finalizing their foreign study protocols, they may be able to design foreign studies that better support not only foreign regulatory submissions but also submissions to FDA.

FDA is accepting public comments on the draft guidance through July 20, 2015.

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