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Medical Devices

FDA Rule to Standardize Data Adds Paperwork for Device Makers

By Jeannie Baumann

Device companies that opt to test their products in foreign countries will have to gather more information and documents before applying for approval in the U.S.

A final rule requires all data collected to support device applications—whether it's one to authorize clinical trials or to prove that an experimental device is similar to one that's already on the market—must comply with standards known as Good Clinical Practice (GCP). A spokeswoman for the Food and Drug Administration said the agency is updating its standards for accepting clinical data from studies conducted outside the U.S. "to reflect the increasing globalization of clinical trials and the evolution of clinical trial standards for protecting human subjects."

Snapshot

- FDA issues final rule on accepting clinical data for medical devices
- Effective date is Feb. 19, 2019

"Such requirements for the acceptance of clinical data provide greater assurance of human subject protections and of the quality and integrity of clinical data submitted in device applications and submissions. The rule also provides greater consistency in the requirements for acceptance of data from clinical studies for different device applications and submissions," FDA spokeswoman Deborah Kotz told Bloomberg Law in a Feb. 20 email.

The changes require a statement that the studies conducted outside the U.S. complied with the same standards for domestic studies, including ones for human subject protection, institutional review boards, and investigational device exemptions (IDEs). Device makers need IDEs to conduct clinical trials for unapproved devices.

This requirement seems reasonable, Carol Pratt, an FDA regulatory attorney based in Portland, Ore., with Lee & Hayes PLLC, told Bloomberg Law. It also allows the FDA to include those compliance statements as records that must be maintained. "I think this will help ensure compliance in studies of [non-significant risk] devices and/or studies sponsors believe are exempt."

"The rule is intended to update the standards for FDA acceptance of data from clinical investigations and to help ensure the quality and integrity of data obtained from these studies and the protection of human subjects—no matter where the research is conducted (inside the U.S. or OUS) and regardless of the type of application or submission the research is used to support," Kotz said. OUS is an FDA term for outside the U.S.

This rule is effective Feb. 21, 2019.

More Documentation

Suzan Onel, an FDA regulatory attorney with Kleinfeld, Kaplan & Becker, LLP in Washington, told Bloomberg Law the final rule won't substantially change what's required what happens in the U.S. for nonsignificant risk devices, a classification that triggers different FDA regulations that must be followed based on risk level.

Practically speaking, IRBs--U.S. ethics boards charged with protecting human subjects--have been upping the documentary evidence needed to support clinical investigations and the rationale for considering an investigation to be classified as nonsignificant risk, she said.

For clinical investigations conducted outside the U.S., the final rule "clearly increases the documentary demands on companies and sponsors," Onel said in a Feb. 20 email. "However, I think the final rule provides useful clarity as to when clinical data will be accepted in support of a US premarket submission and includes additional provisions to try to build in necessary flexibility. For example, the final rule builds in reference to foreign international ethics committees (IECs) and provides some leniency with respect to foreign determinations of significant risk and non-significant risk device investigations."

Beth Luoma, a Minneapolis-based associate attorney at DuVal & Associates, P.A., said it's unclear what real effect the final rule will have on whether a medical device application is approved or cleared. "What is certain, is that

this will require device makers to provide significantly more information in submissions relying on OUS clinical data."

"Clearly, FDA is reluctant to rely only on device makers' statements that their OUS clinical studies were conducted in accordance with GCP," Luoma told Bloomberg Law in a Feb. 20 email. "Instead, FDA intends to perform a role akin to the IEC, and will require information so that it can be assured of data integrity and the protection of human subjects," she said. DuVal & Associates counsels companies in FDA-regulated industries.

Many companies try to get their devices cleared through the European Union before getting FDA approval or clearance because it is generally believed to be faster and cheaper, Pratt said. This final rule will have a big impact, especially for low-to-moderate risk devices. "This could be particularly important for [in vitro diagnostics] because the US and the EU have different regulatory frameworks/definitions," she said in a Feb. 20 email.

The FDA for years has been moving to replace its regulatory language on the Declaration of Helsinki, a 1964 document that lays the groundwork for ethical standards in human subject protection, with GCP standards. Onel noted the final rule also removes the reference to conformance with the Declaration of Helsinki "and continues to leave the door open for FDA to decide to accept data from a clinical investigation that does not meet GCP."

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For More Information

The final rule is available at http://src.bna.com/wvQ.

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