FDA seeks comment on proposed guidelines for high-quality clinical studies

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FDA seeks comment on proposed guidelines for high-quality clinical studies

The FDA today issued draft guidance to help researchers and manufacturers design better quality clinical studies in support of premarket approval (PMA) applications for medical devices.

Manufacturers submit PMA applications for high-risk (class III) medical devices. These applications undergo the most stringent type of FDA device review. PMA submissions include data from pivotal clinical studies which the FDA uses, along with other information, in determining approval.

The proposed guidance outlines agency expectations for clinical trial design issues such as minimizing data bias and variability, setting appropriate study objectives, selecting the appropriate type of study, and choosing study sites and study participants.

It is one of 25 action items listed in the FDA's Plan of Action for Implementation of 510(k) and Science Recommendations announced earlier this year to enhance predictability and transparency of regulatory pathways and to strengthen the 510(k) process.

"We want to help manufacturers and researchers take the least burdensome approach to getting safe and effective products to market, said Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health. "This guidance will help manufacturers and researchers better understand the FDA's basic expectations for clinical trials. We encourage researchers to contact the FDA to discuss the most practical approach to studying their device."

The evidence needed to support a PMA application varies depending on the medical device. But today's draft guidance can help manufacturers and researchers design a pivotal study that is a practical investment of time, effort, and resources and has a high likelihood of demonstrating safety and effectiveness.

Although this guidance is developed primarily for clinical studies used to support

PMAs, the recommendations of this guidance may also be used in designing clinical studies used to support 510(k) submissions.

For more information:

CDRH Plan of Action for 510(k) and Science
[2]

Draft Guidance for Industry, Clinical Investigators, and Food and Drug Administration Staff: Design Considerations for Pivotal Clinical Investigations for Medical Devices [3]

FDA: Medical Devices
[4]

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