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Researchers Call For More FDA Credit In Device Studies

by Elizabeth Orr

A paper recently published in *JAMA Cardiology* argues that acknowledging US FDA in published device research could serve as an assurance of study quality and provide important context to physicians.

The role of US FDA in designing pivotal trials of new medical devices too often goes unacknowledged, two researchers said in a paper recently published in the *Journal of the American Medical Association* (JAMA) *Cardiology.*

The *Viewpoint column* argues that the Center for Devices and Radiological Health plays a key role in shaping device pivotal trials via the investigational device exemption (IDE) process. To ensure data collected during the pivotal trial can support device approval, FDA normally guides sponsors toward a study protocol that includes "appropriate" design, trial end points and duration, and is adequately statistically powered for agency purposes.

And study sponsors conducting research for an FDA approval usually follow recommendations requiring a sophisticated trial infrastructure, including monitoring, audits, core laboratory review, patient safety monitoring and statistical analysis. As a result, the column states, they're often more complex in design than other device studies.

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Harvard's Ariel Stern says.

“Pivotal studies are supported by highly trained staff members from within the sponsor company and from contract research organizations,” authors Aaron Kaplan and Ariel Stern wrote. “Device studies that are performed outside the context of FDA/CDRH approval typically lack many of these features.”

But FDA’s role is rarely acknowledged in published trial data, Kaplan and Stern say. They think more researchers should explain how FDA contributed for several reasons, including consistency with standard scientific practices around attribution; highlighting that a trial met regulatory standards; and giving readers a more nuanced understanding of the context of the research.

Aaron Kaplan, director of clinical research at the Geisel School of Medicine at Dartmouth University, told *Medtech Insight* that the paper grew out of his dual roles as a research cardiologist and a medical device developer. He often saw products reach the market when he believed the trial had been highly influenced by FDA.

“But you go to these studies, and you often can’t find that FDA was even a part of it,” he said. “The premise of the paper was, how can that be?”

Additionally, he believes that more acknowledgement of FDA would build public understanding of FDA’s process. “There’s a big dialogue going on whether FDA standards are appropriate or inappropriate, and reminding people that these are trials that were for FDA approval helps with keeping that in people’s consciousness.”

His coauthor, Ariel Stern, is a health economist at Harvard Business School who researches the way the regulatory approval process creates different incentives for different types of products. She says adding discussion of the FDA’s role to published research could serve as a kind of seal of quality.

“One takeaway is that informing consumers about the regulatory science side of this gives understanding that trials that are done in pursuit of FDA approval are done often with extremely high standards that will help practitioners actually interpret the studies that get published,” she said. “So if we see a study that gets published based off a pivotal trial that was done to a standard that would be sufficient for PMA approval, we know that's actually a higher quality trial, perhaps, than one that isn't done in pursuit of meeting the standards that CDRH has set.”

Stern and Kaplan have submitted some data supporting the journal column to a major cardiology conference, and hope to present early in 2018.

From the editors of The Gray Sheet