What’s New in GCP? FDA Issues Guidance to Aid Patient Engagement in Device Trial Development

The FDA released draft guidance Sept. 24 to aid sponsors in gaining patient perspectives and experience in the design and conduct of device clinical studies.

The “FDA believes medical device clinical investigations prospectively designed with input from patient advisors may help to address common challenges faced in these clinical investigations,” the agency said. This approach could result in:

- faster study/research participant recruitment, enrollment and study completion;
- greater study/research participant commitment, resulting in decreased loss to follow-up;
- greater study/research participant compliance resulting in fewer protocol deviations/violations;
- fewer protocol revisions;
- streamlined data collection resulting in better quality data;
- and more relevant data on outcomes that matter to patients.

The draft guidance is intended to help sponsors understand how they can use patient engagement to elicit experience, perspectives and other information to improve the design and conduct of medical device clinical investigations. In addition, it highlights the benefits of engaging with patient advisors early in the medical device development process and illustrates which patient engagement activities are generally not considered by the FDA to constitute research or an activity subject to FDA’s regulations, including regulations regarding institutional review boards. It also addresses common questions and misconceptions about collecting and submitting to the FDA patient engagement information regarding the design and conduct of a medical device clinical investigation.

The guidance defines patient engagement as “intentional, meaningful interactions with patients that provide opportunities for mutual learning, and effective collaborations. In the context of planning for a clinical investigation, engaging with patient advisors creates an opportunity to share patient experiences, perspectives, needs, and priorities during the design and conduct of a clinical investigation. Importantly, FDA views this type of patient engagement differently from interactions that sponsors or clinical researchers may have with individuals who participate in a specific clinical investigation as study/research participants,” the guidance said.

The guidance notes that “patient advisors refers to individuals who have experience living with a disease or condition and can serve in an advisory or consultative capacity to improve clinical investigation design and conduct, but who are not study/research participants themselves. Patient advisors may include, but are not limited to, individuals who have participated in previous clinical investigations of the same disease/condition or similar device type, individuals who were screened for but ultimately did not qualify for or did not elect to participate in a similar clinical investigation, representatives from a disease-specific or cross cutting patient organization, healthy individuals who may be potential non-therapeutic (e.g., diagnostic) device users, or caregivers (also known as care partners) of patients who may have experience with the disease/condition/device.”
Clearly Define Patient Advisors’ Role

The guidance recommends sponsors identify patient advisors and clearly define the patient advisors’ role early in the clinical investigation planning process. “We encourage sponsors to be clear in their clinical investigation plan about which activities are part of the research plan (i.e., for study/research participants) versus those that are non-research patient engagement efforts (i.e., for patient advisors) that may improve the design and conduct of the clinical investigation,” the guidance said.

“Patient advisors who are educated about clinical investigations, the various approaches to managing the disease/condition of interest, and how a device may work may be better equipped and feel more empowered to voice their perspective in engagement activities. We encourage sponsors to consider using existing educational materials and/or partner with organizations that provide training for patient advisors to help them most effectively contribute,” the guidance said. The FDA said that some patient engagement activities that may enhance the design and conduct of clinical investigations include, but are not limited to:

- Working with patient advisors to improve the informed consent document to ensure patients understand the information presented for the clinical investigation;
- Obtaining input from patient advisors on flexible options for follow-up visits and data collection techniques to reduce unnecessary burden on study/research participants who may have challenges fulfilling the follow-up schedule. Such techniques may include allowing weekend hours, permitting the study/research participants’ primary healthcare provider to perform some follow-up assessments, allowing phone or home visits by clinical researchers, or using mobile or online technologies to enable virtual or remote follow-up;
- Discussing with patient advisors their views on which potential endpoints are clinically meaningful in the treatment of the specific disease/condition;
- Working with patient advisors to inform the concepts that should be captured by patient reported outcome (PRO) measures in the clinical investigation to better reflect outcomes that are important to patients; and
- Working with patient advisors to inform the design of a patient preference study to help understand the benefit-risk tradeoffs among patients for the proposed treatment or multiple treatment options used for the disease/condition.

In addition, “sponsors should consider involving patient advisors during the early planning phases of the clinical investigation so that their input can be incorporated while the protocol is being developed,” the guidance said.

“Especially in innovative areas or new target patient segments, we encourage sponsors to confer with patient advisors when designing or planning the clinical investigation,” the guidance said. “In more established areas, patient advisor input on draft protocols may translate into time and cost-saving improvements that also make the design more patient-centric. Such input should generally be incorporated before the final protocol and informed consent documents are submitted to the IRB for review.”

The guidance noted that for clinical investigations that require submission of an investigational device exemption (IDE) application, “this information should be included in the final protocols and informed consent documents submitted to the FDA for review as part of the IDE application.”

For ongoing studies that “face significant challenges with study/research participant recruitment and/or retention, sponsors may want to consider involving patient advisors along with the research coordinator to troubleshoot and propose potential solutions,” the guidance said.
IRB Requirements Do Not Apply

“Because patient engagement activities with patient advisors primarily involve interaction in a consultative or advisory capacity, FDA does not generally consider these types of activities to constitute research or an activity subject to FDA’s regulations on their own,” the guidance said. “Therefore, FDA’s research regulations, including IRB requirements, generally would not apply.”

The guidance noted that “because there are a variety of research contexts in which sponsors may engage with patients to obtain information on their experiences and perspectives, a full discussion of which laws may apply to such activities is beyond the scope of this draft guidance. FDA recommends that sponsors work with IRBs and Health Insurance Portability and Accountability Act (HIPAA) Privacy Boards to determine what laws may apply for a specific research activity.”

However, if a sponsor is considering incorporating input from patient advisors in the design or conduct of a medical device clinical investigation, they “are encouraged to engage in early interactions with FDA and to obtain feedback from the relevant FDA office/division on appropriate design and any applicable regulatory requirements.”


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