Three ways to work with the FDA for better patient-focused trials

Putting patients at the center of drug development allows us to design more efficient clinical trials that yield better data about a product's risks and benefits. Companies that collaborate with the FDA can get direct feedback on their methodology and help build consensus on patient-relevant outcomes that might be accepted as proof of efficacy and safety.

Here are three useful practices for getting the most out of your collaboration:

1 Engage in public-private forums

Access FDA expertise and make new proposals for patient-focused approaches by participating in FDA public-private partnerships. For example, the agency's Oncology Center of Excellence collaborates with companies, patients, and caregivers through Project Patient Voice to make patient-reported symptom data from completed clinical trials publicly available.

The FDA's Clinical Outcome Assessment (COA) Qualification Program allows drug developers to work directly with the FDA to obtain regulatory acknowledgment that a clinical outcome tool is a reliable measure of how a patient feels or functions. Qualified COAs are made public and can be used by drug developers in clinical studies without the need for the FDA's reconfirmation of suitability. To date, at least seven COAs have been qualified under this process.

2 Seek input from demographically diverse patients

The FDA strongly encourages companies to enroll diverse clinical trial participants to adequately represent the target patient population. Likewise, companies should seek input from a diverse patient group because multiple factors affect patients' experience of the same disease. As a result, patients differ on which clinical and quality of life outcomes are most important to them.

Patient advocacy groups (PAGs) with diverse memberships and populations typically underrepresented in clinical trials can be excellent sources of information. The U.S. Department of Health and Human Services' Office of Minority Health lists organizations and PAGs that companies can contact and partner with to identify diverse ethnic and cultural patient populations.

3 Engage early with regulators on patient experience data

The FDA has conducted numerous workshops and issued guidance on patient-focused drug development and patient-reported outcome measures. To accelerate progress in these areas, the agency encourages companies to develop methodologies and instruments that better assess patient experience and maximize participation in clinical trials. But they also expect companies to use sound methodologies.

Taking advantage of the FDA's willingness to collaborate can benefit companies and patients alike. For example, the FDA's Center for Devices and Radiologic Health (CDRH) has considered patient-preference information (PPI) when evaluating a weight loss treatment, ear tubes to prevent infections, and home dialysis devices. Unlike patient-reported outcomes collected as part of a trial, PPI is patient survey information about which features are most important to patients and which risks patients are willing to take to use them.

Choosing the right partner

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