Patient-Centric Clinical Trials: FAD, TREND, OR FUTURE?

One of the prominent topics of discussion in biopharmaceutical R&D during the past few years has centered on methods for improving patient management in clinical trials. While clinical trials have always focused on patients, only recently has an entirely new lexicon entered the consciousness of professionals involved in planning and implementing studies. Phrases such as "patient-centric trials," "patient journey," and "patient-focused" are increasingly being used by trial practitioners and the trade press. Clinicians are speaking about levels of "patient satisfaction" and "patient engagement" as being critical to the success of a trial.

Some of this focus on the patient is a natural by-product of the growing importance of incorporating patient-reported outcomes (PROs) into clinical trials and commercialization plans, but that is only part of the story. The whole picture considers trends in society, technology, patient lifestyles, and the realization that trials can be better designed and executed if the needs of patients are more adequately addressed.

The PRO Data Paradigm

Traditionally, clinical trials have been designed with mainly investigators, trial sites, and biopharmaceutical professionals in mind. The patient was a "subject" who acquiesced to the protocol and regime of the trial. Subjects were randomized, tested, treated, and served as a means for collecting clinical data. Impressions of patients were based mainly on observations from physicians, clinical trial professionals, and data gathered by sites and laboratories. The emergence of PROs, however, changed that paradigm by allowing the voice of the patient to become a significant part of the data generated in a trial.

The persistent challenges of patient recruitment have also elevated awareness relating to the important role patients play during trials. Faced with competing for study volunteers on a global scale, biopharmaceutical firms have begun thinking about ways to make it easier for patients to participate in clinical trials. Sponsors are devising ways to better engage patients and keep them on-track during trials, with the end goal being to improve recruitment, retention, and compliance.

Something as simple as providing patients with text message or email reminders to complete certain study tasks (e.g., attending site visits, completing ePRO) is now becoming commonplace as part of larger programs to improve patient management.

A Patient-Focused Approach

Modern technologies are helping usher in the patient-focused era in clinical trials. For example, patients can dial into an IVR system using a mobile phone from any location and complete their ePRO diary. Similarly, certain vital signs such as blood pressure can be gathered using home-based computer technologies, thereby reducing visits to clinical trial sites. This year Pfizer launched REMOTE, the first participatory patient-centered virtual clinical trial that gathers data directly from patients — rather than at sites — mainly through the application of modern technologies, such as mobile phones and the Web. The industry is anxious to hear the results of such trials, as significant savings may be realized by substituting technology for traditional clinical practices and data collection processes at the site level.

The lifestyles of patients are another key factor driving the patient-centric clinical trial. In today's society, patients are connected to the Internet, own mobile phones, and typically have a laptop or personal computer. They are more likely than ever to engage in social media, operate technologies in their homes or automobiles, and manipulate a wide variety of tools to make their lives more productive and manageable. Patients also face the task of balancing the demands of a clinical trial with those of earning a living, raising a family, or engaging in areas of personal growth. In short, the profile of a clinical trial patient is changing; the modern patient is more techno-savvy, more likely to be employed, and less likely to engage in trials — unless the trial process is made easier for them.

The industry has come a long way in terms of efficiency since the paper-based trials of the 1970s, but there is far more to be done in this regard. Biopharmaceutical companies will need to continue improving trial management by designing protocols with patients in mind and incorporating modern technologies to ease the patient's journey through the clinical trial. PV

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