

Adaptive Clinical Trials

Technology is the Driving Force



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Modern medicine is headed down a path of rapid growth and development and increased efficiency. The FDA and the industry as a whole are looking for ways to bring drugs to market faster while at the same time reducing costs. The common theme that runs through both initiatives is technological advancement.

For years, clinical-trial sponsors have recognized that EDC and ePRO technologies in their trials made it possible to capture and manage trial data digitally, thus making analysis faster and easier. Digitizing the data not only improved the quality and integrity (especially versus paper), it also significantly reduced the time window from last patient visit to database lock since trial data can now be collected in near real time.

Now, these same e-clinical technologies are enabling the next wave of trial design: adaptive trials. Knowing they will receive trial data electronically in near real time, sponsors are designing trials that provide flexibility to make changes mid-study if unexpected adverse events occur, or if aspects of the study are proving to be inefficient and/or ineffective. An adaptive trial is designed to be modified without starting over, which could delay the approval process months or years and add millions of dollars to development costs.

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How does it work?

Patients enrolled in clinical studies are assigned treatments, typically in a double-blind fashion, whereupon the effects of treatment on the patient's condition are closely monitored and compared with other enrollees' results. Adverse events data, other patient outcomes, and data that may originate from a variety of disconnected sources can be used as they become available to adjust the protocol or the allocation of future patients — without, of course, invalidating original hypotheses or introducing bias. This allows study organizers to improve expected patient outcomes during the trial, while still being able to reach valid statistical decisions in a timely fashion. Thus, adaptive processes offer significant cost savings over standard fixed procedures.

Who is On Board?

In July 2006, the FDA announced that drug developers will soon be permitted to adjust parameters of a clinical trial mid-study through adaptive clinical trials. Scott Gottlieb, M.D., the FDA's deputy commissioner for medical and scientific affairs, spoke publicly about how the pharmaceutical indus-

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Technology = Speed, Adaptability, and Data Availability

How does technology fit into the big pharma and innovative biotech picture as it relates to adaptive trials? Patient safety is at the core of reporting clinical-trial data, but the cost of development and importance of accurate data to the credibility of the study are not to be dismissed as a major business advantage. The challenge lies in the ability to seamlessly integrate clinical data with external data, such as lab data or EKG data, to be more effective and strategic throughout the trial — and this is where technology comes in.

Electronically integrating clinical data allows sponsors to build information standards into the database from the very beginning of a clinical trial and maintain those standards throughout any subsequent changes. The overall availability, accuracy, and efficiency of technologies such as EDC,

try and the FDA should be more open to adaptive trials and what they can do for the future of therapeutic development.

When technology meets pharmaceuticals, it brings an entirely new dimension to clinical studies and has the potential to catapult drug development to a new level of innovation. The FDA is recognizing that adaptive trials will encourage finely tuned and rapid drug-development processes, which, in turn can facilitate greater efficiency, greater cost savings, and increased safety.

The increasing number of industry conferences, keynote speeches, and media coverage dedicated to discussions about the future of adaptive clinical trials is an obvious measure of the prominence this topic has, and will continue to have. Researchers, patients, and sponsors should follow the adaptive trials proposition closely, since it has the potential to change the future of medicine. ■

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