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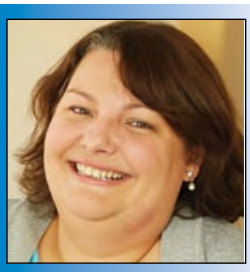
Keeping Pace With Adaptive Design

By Michelle Marlborough, VP of product strategy, Medidata Solutions



Michelle Marlborough, VP of product strategy, Medidata Solutions

Adaptive trials are increasingly used to accelerate studies and reduce the risk of clinical drug development. The Tufts Center for the Study of Drug Development estimated in 2013 that approximately 20 percent of clinical trials already use simple adaptive designs. However, the adoption of complicated adaptive designs such as Bayesian methods may require new technology and working practices.

Adaptive trials require more frequent analysis of study data than traditional clinical trials, yet the frequency and complexity of these analyses vary, depending upon the adaptive trial method. Simple methods may require only a few interim analyses of blinded data with minimal demands on technologies, while complex methods may analyze diverse forms of unblinded data daily. Methods requiring such real-time access to data are only cost-effective when using advanced clinical trial technology.

THE REAL VALUE OF INTEGRATED EDC

Traditionally, electronic data capture (EDC) was a transposition of manual methods of recording data into a webbased media (simply putting the "e" in "eCRF"). However, to support adaptive trials, EDC systems must integrate a wider range of data sources (e.g., clinical assessments, lab data, patient reported outcomes) into a single homogenous data source with minimal manual intervention. Instead of manually combining data once at the end of a study, these technologies integrate the data as it is collected, allowing data to be extracted and analyzed at any point during a trial.

The simplest adaptive design uses an interim analysis to evaluate whether to change a trial's path at some point during the study. In most cases, sponsors will undertake this analysis only after all patient data has been collected and examined by a third-party monitor. But this adds significant time to decision making and restricts the ability to do more complex adaptive trials. Further, the process of verifying every entered data element is increasingly being challenged by the FDA as well as other drug development participants, and research has shown that little data is actually changed post-entry.

Instead, having a single integrated source of all trial data speeds monitoring and verification and eliminates the need for traditional data cleaning prior to analysis. Risk-based data selection enables a targeted verification approach that has proven at least as effective as traditional data monitoring.

REMOVING TRIAL BOTTLENECKS

Having an EDC solution that is part of an interoperable platform also helps when using Bayesian analysis methods, which can add another level of demand on data systems because they include historical data into analyses. After all, aggregating data in a common format for modeling is difficult. (Of course, alignment with CDISC [Clinical Data Interchange Standards Consortium] data format standards will help you receive data in a consistent format regardless of the system used to gather the data.)

Trials like the I-SPY2 trial for breast cancer and the Lung-MAP trial for advanced squamous cell lung cancer (both public-private partnerships led by the Foundation for the National Institutes of Health) show where clinical trials may be headed and how these trials need to be supported by new technology. Both are multi-drug, multi-arm trials that use biomarkers to establish treatment arms. Integrated electronic tools such as EDC and clinical trial management systems, as well as randomization and trial supply management, will ease the operational complexity of these trials as changes are made throughout the study.

The rollout of trials like I-Spy2 and Lung-MAP points to the exciting opportunities that will come when the industry begins to change the way clinical trials are designed based on the data available. But those opportunities are only possible if sponsors are able to tap into real-time flows of data and integrate disparate data sources.