Contributed by Gil Kampfner

ELECTRONIC DATA CAPTURE
FROM A PAPER PAST TO AN ELECTRONIC FUTURE

Study Coordinator A is an early adopter of technology on the cutting edge of the next-generation processes who is always eager to try something new. Study Coordinator B is a risk-averse, technological laggard who subscribes to the "if it isn't broken, don't fix it" mantra. Herein lies one of the fundamental reasons clinical trials — and, more broadly, the life-sciences industry — have been slow to adopt new technologies. Life-sciences industry experts agree that clinical trials are the largest bottleneck in the new drug development process. Technologies exist to relieve many of these bottlenecks, and yet broad, industrywide adoption of these technologies is still slow. One such technology is electronic data capture (EDC), the computerized collection of clinical study data. Although EDC has promised to be a silver bullet for improving trials for more than 20 years, industry acceptance has been sluggish. That is all changing.

EDC ON THE RISE

According to Industry Health Insights, from 2006 to 2011 spending on EDC is predicted to surpass $3.1 billion, with almost half of all new Phase I to Phase III studies being conducted using EDC systems. Compare this with 2003, when a mere 4% of studies were conducted with EDC systems. And the applications have matured, too, from pilot studies to globally deployed enterprise studies.

One reason for the anticipated increase in EDC adoption is that it provides a more efficient and effective method for managing clinical study data. Long dependent on antiquated, paper-intensive processes, clinical trials across the industry create more than a quarter of a billion pages of case report forms (CRFs), the sheer volume of which makes clinical-trial conduct even more challenging. As a result, searching, retrieving, and reworking information can take up to one-quarter of the study team's time. With improved data quality, near real-time trial information, enhanced patient safety, and improved operational efficiency, EDC systems promise to alleviate this problem.

EVOLUTION OF STANDARDS

The evolution of data standards has given EDC a shot in the arm. The Study Data Tabulation Model (SDTM) standard developed by the Clinical Data Interchange Standards Consortium (CDISC) has shown life-sciences organizations the direction the FDA is going, which in turn leaves little ambiguity about the direction of the industry. It is exactly the kind of assurance these organizations need.

TECHNOLOGY ACCEPTANCE

While the industry is headed in the right direction, there is still one hurdle to overcome: the aforementioned technology acceptance challenge. Like many technologies that fail to be quickly accepted, the slow adoption of the EDC solution can be attributed to the time and cost associated with a new business process. Often referred to as a "hard shift," the adoption of EDC does not allow for a transition phase to acclimate technicians to the new system. It requires operating procedures to be rewritten and job responsibilities to be changed.

New methods for creating electronic CRFs have to be adopted, and edit check or data validation requires new resources. Companies adopting an EDC solution must also incur system costs for in-house applications and integration of the EDC system with other systems. And what about Study Coordinator A versus Study Coordinator B? How can life-sciences organizations address these dramatically different styles?

One solution — the hybrid EDC system — aims to alleviate the challenges posed by a hard shift, while at the same time accommodating the realities of managing CRFs via paper. The hybrid approach allows users to access both paper-based and electronic CRFs through the same system. In short, a hybrid model provides the efficiency and accuracy of EDC systems without major organizational headaches involved in shifting directly to EDC. With a hybrid approach, clinical development teams can adjust to electronic data processing at their speed. Technologically savvy clinicians can dive into electronic processing, while more set-in-their-ways clinical teams can continue to use the paper systems with which they're comfortable. More importantly, the company can adopt a hybrid approach without totally revamping its existing standard operating procedure (SOP) documents.

A hybrid approach also enables companies to retain the quick response of an EDC system. With paper-electronic hybrids, clinical studies can be conducted without the difficulty and challenge of integrating data from disparate databases. Patient data from both paper entry and EDC can be captured and managed in one system. The data also are directed to a bookmarked PDF that meets regulatory standards. With a hybrid data approach, management of queries can be accomplished quickly, facilitating the data resolution process.

Although the adoption of EDC all but guarantees a reduction in clinical development timetables, many companies have not yet made the decision to get on board. That is why the time has come to ease the transition to EDC. The hybrid approach unifies and simplifies the paper and electronic data capture processes and provides flexibility to accommodate investigator needs. An EDC hybrid solution is a viable way to reshape the industry in the coming years until full, industrywide adoption of EDC becomes a reality.

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