

# ELECTRONIC DATA CAPTURE TURNS THE CORNER... **At Last!**

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New systems **THAT MAKE TRIAL  
PARTICIPATION EASIER FOR  
INVESTIGATION SITES** spur adoption.



**Today, setting up an EDC system at an investigative site requires only a standard PC** with a Web browser and an Internet connection.

**W**ith the average cost of developing a new drug exceeding \$1 billion and the process often spanning more than a decade, pharmaceutical manufacturers continually seek ways to improve efficiencies at all stages of the development continuum, allowing them to bring safe products to market faster and at a lower cost.

The clinical phase of drug development — which averages \$361 million per drug candidate — tops the list as a target for improvement. While there are many factors that contribute to rising clinical trial costs, such as growing complexities in identifying and recruiting candidates worldwide, many pharmaceutical manufacturers and contract research organizations (CROs) are taking aim at accelerating the collection and availability of data. Electronic data capture (EDC) systems are increasingly at the forefront of such initiatives.

There is general agreement from trial sponsors that EDC offers real potential to improve data quality, accelerate data collection, and reduce costs. Studies, for example, show that organizations have been able to reduce case report form (CRF) cycle times from 45 days to nine days with EDC. By reducing the time spent rectifying transcription errors and inaccurate data values, trial sponsors can focus on

more important tasks, including regulatory compliance and source document verification. Further, the near real-time analysis of results enabled by EDC helps to improve decision making in terms of expanding or discontinuing a study. A 2006 study of 29 pharmaceutical companies by the Tufts Center for the Study of Drug Development found that the 10 companies fastest to deliver drugs to market used more electronic data management technologies than the companies that were slower to introduce new products.

While a growing number of pharmaceutical manufacturers and CROs are realizing the benefits of EDC, widespread adoption has remained elusive. Recent indicators, however, signal that adoption may be reaching a critical tipping point. In late 2006, Health Industry Insights, an IT analyst research firm, projected that EDC use in new clinical trials would reach 40% by the end of that calendar year, up from 32% in 2005.

While several factors have converged to accelerate EDC adoption, the introduction of next-generation systems designed to meet the unique needs of investigative teams and patients is among the most important drivers.

## IT'S ALL ABOUT ME

Over the years, trial sponsors have cited

many reasons for not adopting EDC for widespread use, including prolonged setup time at the front end of clinical trials, high training costs, and lack of integration with back-end systems. One of the most frequently cited challenges, however, has been resistance from investigation sites.

While EDC systems can reduce a sponsor's data collection and management costs, these very same systems can introduce confusion and inefficiencies for clinical personnel at the investigation site. Early EDC systems were, without question, designed with the trial sponsor in mind. Their primary goal was to streamline the compilation and analysis of data as well as improve data quality and integrity.

Convenience and usability for investigative site personnel was of little consideration. For example, trial sponsors often developed their own proprietary EDC systems, which brought with them hefty training requirements and a steep learning curve for trial investigators. In the earliest days of EDC, investigation sites also had to ensure that they had space for a separate EDC-dedicated PC and assume management of that IT resource. Sites involved in multiple trials had to learn how to operate and manage several different EDC systems, a complexity for which busy healthcare providers have little time or patience.

## THE TIDE IS TURNING

The rise of the Internet and Web-based applications offered new potential for IT simplicity and led to the emergence of Internet-based trials and a host of new tools, such as e-diaries and next-generation EDC systems. Today, setting up an EDC system at an investigative site requires only a standard PC with a Web browser and an Internet connection.

These same developments also enabled IT vendors to design EDC systems that focus on making life easier for trial investigators and patients — helping to overcome trial sponsor reluctance and spur widespread adoption. User-centric EDC systems, tailored to the needs of investigation personnel, empower site personnel with expanded functionality, allowing them to enter information quickly and accurately. This ultimately leads to improved database lock times for sponsor organizations.

## SPEED AND AGILITY

Tasked with rapidly and accurately collecting data while managing other patient care responsibilities, clinical-trial researchers must

**GOAL-ORIENTED EDC**

**UBIQUITOUS ADOPTION OF THE WEB HAS ENABLED VENDORS TO FOCUS EFFORTS ON DEVELOPING EDC SYSTEMS THAT ADDRESS FOUR CRITICAL GOALS OF TRIAL SPONSORS:**

1. Enabling global clinical trials
2. Reducing investigator training time
3. Increasing staff efficiency
4. Improving the quality of data entry and analysis.

Functionality that makes trial participation easier for investigation sites and healthcare professionals is steadily helping to break down pharma and CRO resistance to widespread EDC deployment.

be able to quickly locate and enter patient CRF data. Time wasted searching through records or waiting for downloads keeps site personnel away from their primary task — patient care.

New EDC systems are designed with this requirement in mind. Many offer interfaces that enable simple navigation to CRFs for data display and/or update. At the patient level, systems now often represent CRFs — and their status — as familiar icons, allowing site personnel to quickly perform a visual inspection of the form to determine if additional information is needed before closing out the file. Advances such as these save time and improve productivity.

Some systems also perform online and instantaneous edit checks in the data entry environment, invoking a discrepancy management tool to automatically capture, route, and resolve data discrepancies in the CRF when necessary. For example, a system may send an alert if a CRF contains vital sign or blood chemistry data that fall outside of expected ranges, allowing investigators to validate or correct the data immediately. As important, many newer EDC systems enable electronic messaging between users, such as coordinators, investigators, monitors, and data managers, to accelerate patient data verification and approval.

These capabilities and other user-friendly features make it easier for investigators to enter data rapidly and accurately, and quickly navigate CRF pages using visual cues to make sure all required data are included. As important, these time-saving capabilities make it

more likely that a site will stay with a trial until its completion — an outcome welcomed by trial sponsors.

**MANAGING THE UNEXPECTED**

Clinical sites are inherently unpredictable. Patients often come in for unplanned visits, which require on-the-spot data collection. Newer EDC systems enable site personnel to add planned or unplanned CRF pages and patient visits, helping them to manage unpredictability and retain trial participants. Further, in instances in which a CRF requires verification before approval, researchers can make the verification in the CRF document itself, saving time and adding convenience. Trial personnel can then validate CRF approvals with electronic signatures that comply with the FDA's 21 CFR Part 11 guidance.

In addition, over the course of a clinical trial, sites are consolidated and patients move or decide that another site location works better for them. Trial sponsors, eager to maintain patient participation, need the flexibility to quickly accommodate patients at new sites.

Many systems can now accommodate these changes by displaying patient data collected at previous sites as well as their reassigned sites. This capability facilitates a seamless transition for the patient and the investigator.

**FASTER SETUP; STREAMLINED MAINTENANCE**

The use of Internet-based EDC systems has significantly accelerated site set-up time. The most advanced of these systems leverage the full power of the Internet at sites around the globe.

These systems require no software downloads or configuration of local computer hardware, simplifying deployment.

Web-based electronic data capture systems also offer patient-centric navigation for rapid data entry and updates. Investigative personnel at clinical sites require tools that allow them to quickly locate patients and their visits, as well as associated CRFs.

Time wasted searching through records or waiting for downloads takes away from the primary task of site users.

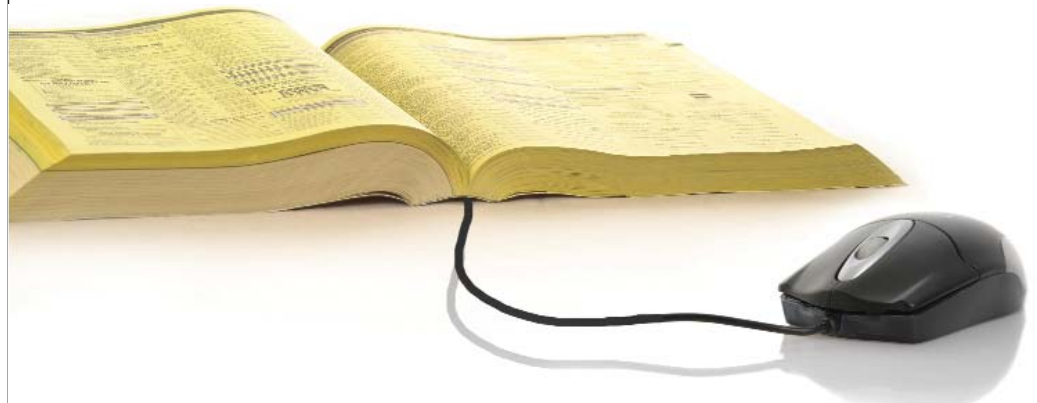
At long last, EDC appears on the cusp of realizing its potential for helping pharmaceutical manufacturers bring safe and effective drugs to market faster and more cost effectively.

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