

> Gaining Meaningful Outsourcing  
Efficiencies When Using Electronic  
Data Collection

**+** *In the '90s, there were many Fortune 1000 companies that were resistant to the type of change that electronic commerce technology was promising. Electronic commerce had been talked about for many years and reams of paper had been used printing research that claimed online buying would change the way businesses worked. Still, businesses were reluctant to change because the way they operated was working. They were still making decent profits so why rock the boat?*

*But at some point, as it always does, efficiency overtook the resistance to change.*

Disintermediation, the process of removing the middleman from the purchasing cycle, became the norm as people started buying their own airline tickets instead of going through a travel agent, bought their computers from the manufacturer rather than from a reseller, and sold their antiques in a global electronic yard sale rather than taking them to an antique or consignment store.

Competitive pressures and stock prices made change not an option or a luxury, but a necessity. Compaq and IBM dismantled huge reseller organizations to adopt a Dell-like direct sales model. Travel agencies folded. Commerce changed forever.

Say what you will about the dot-com bombs, the fact is, in just a few short years, technology changed forever the way many businesses are run and those that survived did so because they were able to embrace the technologies. Today, there are few businesses that don't use the Internet in some form or fashion. MBA schools are stocked with case studies of businesses that failed to quickly adopt the transforming technologies around them. From Kodak and the impact of digital photography to the record business and the impact of digital music – we see examples everyday of businesses that resist the inevitability of technological progress and falter or die.

A similar type of resistance can be seen in the life sciences outsourcing community. Those responsible to shareholders don't want to rock the boat. Paper works. They are making a profit on paper trials, so why bother introducing technology that can improve efficiency? But this argument, like the argument used at Compaq, Kodak and your local travel agency, will only last as long as it takes for a competitor to beat them by using technology. And that time is not far off.

The advantages of using Electronic Data Capture have been highly publicized and, in many cases, hyped to suggest an

over-reaching range of benefits to the clinical process. Some industry experts have criticized the claims, suggesting that it is unfair to publish only the upside of technology adoption—while Merge eClinical has repeatedly said that technology alone can create as many problems as it can solve and that only by combining technology with process change can companies really impact the bottom line.

Outsourcing providers have offered that there are no, or very few, efficiencies to be gained – that for every dollar saved for the lack of double data entry and streamlined resolution of edit checks/queries there is an increase in staff to support all of the perceived issues with EDC (purchase computers for all of the sites, numerous help desk calls and assistance, the need for high-speed connection, the need of a paper process for all of the sites who refuse to use EDC, etc.). In Merge eClinical's experience, the team has identified many areas of impact that can assist sponsors in realizing cost reductions of 20-35% off of the paper process and an ability to close databases in weeks versus months.

The most obvious of areas impacted through the use of EDC is Data Management. The removal of paper from the process and the use of direct entry by site personnel, reduces the need for courier shipments, and eliminates the costly and time-consuming double data entry process.

Does the Data Manager's function change? Yes, it becomes less administrative and more analytic. Rather than chasing paper, data managers will now have the time to study the data for trends and to use the data instead of just collecting it. EDC also provides fields that are limited to entries that suit the question, whether numeric, dates, drop-down menus, check boxes, and text memo fields – this eliminates the many transcription errors that occur in the paper process. There is also a drastic reduction in the number of manual queries initiated by Data Managers, since the

majority of queries for blank fields, ranges, and complex cross-panel checks are programmed into the system and fire in real time, so sites make immediate corrections. In one recent presentation, the Global Head of R&D at a major pharma presented some metrics that indicated their internal query rate for paper had been 33 per 1,000 pages processed versus 4 per 1,000 for EDC. These results are typical when transferring from a paper-based trial to an electronic trial.

Another area for drastic cost reduction and greater quality is in the area of Clinical Monitoring.

Currently, monitoring needs are recognized on a cycle basis, where CRAs establish a visit schedule on a frequency of 4-6 weeks, even though sites may not have the activity to require such visits. At an average of \$2,500 per one-day visit, the costs can add up very quickly. When using EDC, monitors have the ability to review eCRF pages from a remote location, such as a home or office, and work with site personnel on issues or questions without making a physical visit. If proactive, monitors can identify whether sites require additional training, need further education on the items to collect, and assist them very early in the process. This method stands in stark opposition to the traditional approach of waiting for a visit to identify sites that have been completing the Case Report Forms incorrectly or not capturing data required by the protocol.

The benefit of EDC is that monitors or internal data reviewers can handle most of the questions and issues from a remote location and visit the sites when the workload dictates a full day onsite.

Now, in lieu of estimating the monitoring activity based on cycles (4-6 weeks), the estimate can now be based on pages completed and workload (site visit when they reach 150 completed pages). The goal is that a monitor will review source documents and address serious issues only – no longer will they arrive at a site to determine that the site has not yet completed any CRF pages. Merge eClinical has identified that a 30% reduction in monitoring can be realized using EDC for field visits, with a third of this time savings being added back for in-house review.

Costs can be further reduced in the area of printing and courier shipments, since CRFs will no longer be sent overnight and processed, and there will be no additional forms printed for mid study changes.

Policing by the CRA is eliminated for mid-study changes since the eCRFs are deployed directly to the server and sponsors can be assured that the paper version of the protocol is in use. The site personnel access these forms upon entry into the system, ensuring that the proper questions/forms are being used.

The costs for reprinting, and reprinting, and reprinting are eliminated, as well as daily shipments of these forms by sites using expensive couriers.

EDC also provides a greater level of efficiency for Project Managers. The PMs are generally tasked with generating reports for weekly teleconferences and meetings to discuss the status of the trial. Metrics, such as enrollment, adverse events, queries, demographics, etc., are gathered by PMs through phone contact with sites and reports from Data Management. In many cases, this data could be weeks old at best and not provide a very accurate picture of the trial status for rapid decision-making.

By using an EDC tool, sponsors, CROs, and sites can view the exact same data during the calls and know that they have the most current data available. The immediate access to data leads to rapid decision-making on sites, CRA effectiveness, and the overall status of the trial. With the Web-based reporting tools available for the study teams, PMs can now focus on managing the study by replacing non-performing sites and focus on the general conduct of the trial. The expense charged for generating reports and contacting the parties involved for information is virtually eliminated. Merge eClinical has demonstrated that databases can be closed much faster, recognizing weeks versus months of savings in time and cost.

A recent discussion with a large pharmaceutical company led to a determination by CROs that start-up processes for paper-based trials would be 4 months and the close out period would be 6 months for a large international program running for 4 years. A similar trial run by a sponsor working with Merge eClinical recognized a start-up of 2 months and a closeout of 3-1/2 weeks for a 300 site, 6,000 patient trials conducted internationally. The overall impact of being able to close and lock a database faster in this particular case would have realized a 5-6 month savings in costs and time – essential for trials being conducted in Phase IIIb or IV where they are looking for additional claims or benefits of their drug. How does this time saving translate into sales dollars when an additional 6 months are gained for a patentprotected drug?

Lastly, through the use of integrating much of the clinical data that surrounds the process, such as Central Laboratory data, information can be reviewed on a more proactive basis to allow for very few outstanding issues at the end of the study. Since the data is collected into one central repository at Merge eClinical, a transfer request by a sponsor for interim review is painless and provides a more comprehensive collection of data.

The cost benefits of EDC can be tremendous and should be considered when drafting study budgets that include other outsourced vendors to ensure there isn't duplication of effort. This is also key in ensuring that non-essential services are not added if they can be reduced through the use of technology. These cost savings have been recognized on smaller, country-based studies, but can offer even greater impact for studies that collect a large volume of data. What is the value for a sponsor when they can achieve a 30% reduction in the overall cost of a trial and produce cleaner results in weeks versus months? There is no doubt that subsequent process change will lead to a better use of EDC, but results like these are real and are being delivered now.

## About Merge Healthcare

Merge Healthcare is the leading provider of enterprise imaging and interoperability solutions. Merge solutions facilitate the sharing of images to create a more effective and efficient electronic healthcare experience for patients and physicians. Merge provides enterprise imaging solutions for radiology, cardiology and orthopaedics; a suite of products for clinical trials; software for financial and pre-surgical management, and applications that fuel the largest modality vendors in the world. Merge's products have been used by healthcare providers, vendors and researchers worldwide to improve patient care for more than 20 years. Additional information can be found at [www.merge.com](http://www.merge.com).

Merge Healthcare  
4000 Aerial Center Parkway  
Morrisville, NC 27560-8508  
919.653.3400  
[www.merge.com/eclinical](http://www.merge.com/eclinical)

