

> Making Technology Work
at the Investigator Site

+ *Electronic Data Capture (EDC) systems have been employed at clinical investigator sites (Sites) for over 10 years now. System usage dates back even further than that if we consider systems that called for onsite data entry but shipment of data diskettes to the sponsor. Yet most discussions and conference topics today center around how pharmaceutical companies use these systems, while talks about the Site's perspective on EDC are few and far between.*

Sites should not feel neglected, as every EDC vendor and sponsor company using EDC will readily point out that if data collection isn't working at the point of entry, EDC is doomed to failure. This paper discusses the use of EDC at the Site.

First and foremost, the Site participating in clinical trials has an obligation to the health and wellbeing of every subject/patient. Unless the Site is strictly a clinical research center, they will also have patients who are not clinical trial participants. Many Sites are, as a rule, very busy operations, contending with all of the routine sidebars of the day – appointment changes and cancellations, insurance claims, paperwork, pharmacy interactions, lab samples, patient phone calls, and more.

Just as the medical credo is to 'do no harm,' the credo of the EDC vendor should be 'add no pain.' Systems used at Sites for clinical trials cannot become an imposition for the staff and cannot disrupt workflow.

While progress in technology has resulted in improved systems at the Site, the burden has increased in some regards. How can this be? Initially, there were only a few EDC providers and few EDC studies. Participating Sites were likely to have only a single EDC study ongoing at any point in time, or perhaps had several related protocols running on the same EDC system. So they didn't have many systems to learn and didn't have a countertop full of EDC laptops. Additionally, early EDC systems were not online systems. Most required a dial-up to 'send' data, or perhaps had an automated daily dial-up. Because the programs were running on a local computer and not reliant on communications networks for performance, speed of page turns and saving forms was extremely fast, and rarely a disruption to workflow.

Production or Disruption – the Internet

As EDC became more popular, new vendors cropped up, and the burden to the Site increased. Sites were conducting more EDC trials, hence the need for multiple computers supported by multiple vendors.

As the promise of the Internet found its way into EDC, the burden increased yet again. Sites now had to contend with the earlier 'offline' laptops and the new online systems that offered a significant deterioration in expected system performance compared to the locally-run applications. Horror stories of 1-2 minute page turns were widely circulated.

Of course, the argument can be made that EDC systems have continued to improve and that Sites are much better off than they were with the early systems. Sites using Merge eClinical etrials' EDC software typically experience five second or better page turn times. But while it is true for Merge eClinical, there is still room for further improvement across vendors. EDC systems will continue to add faster and better functionality, become more refined, and will be widely accepted as the standard.

So, what has changed for the Sites and how is the burden being reduced? Certainly the Internet is a major contributor to improvements in the overall EDC process. The (near total) elimination of store-and-forward data transport and synchronization of multiple databases is a huge advance both for the sponsor and the Site. EDC systems that used synchronization always posed problems for the Site, causing them to spend far too much time with the vendor's Help Desk. Now sponsors are able to store/place a study on a central server and give end-users access via a URL, user name and password. No longer is software installed locally and gone are the headaches of troubleshooting when the program or modem connections did not work as planned.

These advances have eased the burden in a significant way.

The shift from locally stored data to a central repository has other benefits for the Sites, as well. The fear of potentially mixing data from other sponsor trials has been removed

(i.e., if more than one trial was conducted on the same computer). And any security issues related to sponsors or other personnel seeing their data during a site visit have been eliminated. The ability to use a single computer, usually a computer that is already at the Site, for multiple web-based studies is gradually clearing those cluttered countertops, although you may still find a few EDC systems that are deployed on dedicated laptops for a variety of reasons. A bit further down the road, expect to see fewer systems that require hardware deployment.

Workflow Matters

If we can assume that most existing Site computers can be used for EDC, and if we assume that our global communications infrastructure now supports relatively good connection speeds, then we can examine other workflow issues.

A system that works well from a technology perspective doesn't necessarily work well from a business or end-user perspective. Indeed, it is easy to develop a web data collection tool, yet it is a far more difficult task to develop a full-functioned application that accommodates the typical and atypical clinical trial process. While some veteran solution providers continue to improve the experience for the Site, others, less experienced in the business rules, deliver products that hinder the user's routine. The EDC system cannot be viewed by the Site as an annoyance, an obstacle, an interruption, or an impingement on an otherwise efficient process. The system must be viewed as an asset, a benefit, an enabler, and an advantage over outdated, paper-laden processes. It is up to the EDC provider, and to some degree the sponsor organization, to impart this attitude to the Sites. And it is only achieved when systems are delivered that produce the "wow" factor and leave Sites wanting to do more trials this way.

Sites often complain that the sponsor is passing what was an in-house data entry task down to them and that it requires more work. One shouldn't argue with those Sites that feel this way, because it can certainly be true. But the question is *Why?* It is not the concept of EDC that is problematic, but rather it is that certain systems are not meeting Site needs. Therefore, they really do result in additional work. It doesn't mean that it takes more time to enter data into the system, although that may be the case. It could be other factors, such as software problems or support calls, that are contributing to the burden and the Site's overall dissatisfaction.

Keep it Simple

Without a doubt, the user interface and navigation through EDC systems can also be a source of frustration, particularly when a Site is using software from multiple vendors. While paper CRFs usually have their own sponsor-specific or protocol-specific nuances for completion, paper is still paper. But think how challenging it can become for the Site Coordinator who is using three or four different EDC systems and has to remember each little trick or subtlety of each system! This is often hard for the vendor to put into perspective because the vendor knows his or her own system and can work through it nimbly. And, of course, each vendor believes its system is the best and the easiest to use. But how would the vendor react if asked to demonstrate, after one hour of training, three competing products along with their own product? How many times would he pause? How many times would he simply forget how to perform a particular function?

Benefits for Sites

As systems continue to improve, Sites will readily recognize the benefits. With the right system, the increased workload argument goes away. In a paper trial, there is usually a source document.

Sometimes it's a worksheet that mimics the formal CRF from which data is transcribed into the formal CRF. Replacing this formal paper CRF with an efficient EDC system will not add to the workload and it eliminates the need to hunt through shelves of binders. Sites should see a reduction in the number of onsite monitoring visits since much of the data review is done offsite by the CRA. With EDC, Sites now have access to reports, which they often did not have in paper trials. And some systems help facilitate the grant payment process by providing instant notification to the sponsor on completed procedures or visits, thereby reducing the time between visit and payment to the site.

Keys to Success

In order to give Sites a positive EDC experience, reduce their burden and gain their acceptance, even preference, what will it take? As one might suspect, there is no single right answer, but there is a host of factors that, together, must be considered by the EDC provider.

- **Service.** Sites have health care professionals committed to the well-being of their patients. They don't want extra tasks and they don't want to call the Help Desk. Their lives don't revolve around the EDC system! When interacting with the Site, the vendor has to empathize with them,

display unwavering courtesy and professionalism, and demonstrate a desire to help.

- The EDC application – the core application. The core application itself, not the specific clinical trial protocol, must take advantage of technologies that can improve usability and, once again, reduce the burden on the user. For example, minimize the requirements for specific platforms, browsers or connectivity such that they don't require a DSL or cable in order to achieve acceptable performance. Or don't require a dedicated computer. Also critical in this category is ease of use. You can't escape any EDC article or conference without hearing 'user-friendly' at least a hundred times. But you do see how important this becomes when you consider that one Site may be using many systems. The interface has to be intuitive. The EDC vendor's goal should be to offer a system that requires 'zero' training – a user could walk their way through it alone. The closer we come to achieving this goal, the more satisfied and less confused the Sites will be.
- The EDC application – the specific clinical study. This really goes hand in hand with service. The system provider must demonstrate their system knowledge and expertise by guiding sponsors as the clinical trial is being developed. By understanding the capabilities and limitations of their system, the vendor should make recommendations on the study design that will have a positive impact on the Site.
- Technology. Fortunately, general technology developments and infrastructure improvements are on our side. The technology issues that hindered EDC in the past, such as 9600-baud rate, etc., will only get better and better, and we will all benefit from these advancements.

In summary, the best EDC system is one that addresses the needs of a range of users with differing responsibilities and expectations. The system must be viewed as a help, not a

hindrance, and providers must deliver a high level of professional service in order to gain Site acceptance and become the method of choice.

The good news is that the outlook has, without a doubt, improved and is steadily rising. With the strong play of technology and infrastructure advances working in our favor, EDC systems will be able to satisfy the Site and offer a compelling solution that simplifies their important work in clinical trials.

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.

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