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NEXT GEN EDC **Making EDC Scale**

By **David Stein**

All industries, and all technologies, pass through distinct levels of complexity. The use of the automobile between 1940 and 1970 was transformed by the sheer size and scope of the interstate highway system.

Similarly, in the life sciences industry, the rising prevalence of electronic data capture (EDC) will demand that forward-looking clinical organizations do more than worry about the details of individual trials.

When EDC was in its infancy, its pioneers were busy working out the desired system features, work flow, costs and other issues related to the epoch-defining transition away from paper-based studies.

Now, however, many organizations are using EDC across many therapeutic areas, in larger and larger percentages of trials, all over the world. The operational concerns are multiplying in both number and complexity. It's time to take EDC to the next level.

Beyond Evangelists

Just using EDC on a project-by-project basis is valuable; it familiarizes an organization with the technology's potential. But one-time usage is not the same thing as rolling out EDC broadly throughout a company. Contract research organizations (CROs) obliged to use multiple EDC systems understand this all too well. But for sponsors, the greatest efficiencies will only be achieved by organizations that make EDC "scale," or broadly used around the world.

The first challenge in making EDC scale is the least surprising: expertise. Few biopharmaceutical companies have a large number of in-house experts on EDC. Most have a few champions with deep EDC experience, which has been invaluable to the early phase of EDC implementation. But most companies also have many employees with highly limited exposure to the EDC environment.

This leads to misconceptions. Despite years of grand language heralding "paradigm shifts" and "process re-engineering," many in the industry still believe that the EDC work flow is almost identical to the paper-based process. Sorry. Such misconceptions lead some organizations to think that EDC implementation is simple. Wrong again.

Administering Users

Another challenge is more mundane. How are the user access rights and privileges administered in EDC systems? In the early days of EDC, user administration was simple. Most studies dealt with a small number of sites. Today a sponsor may be dealing with thousands of sites and users. Different systems are needed.

It is a huge task to add new users, cut off those who have left, deal with site turnover and ensure that all training is up-to-date. While there are some support applications to help manage these activities, there is no magic bullet. Time and resources to address user administration should be allocated.

Global Training

Training is affected by using EDC on a broad scale. In the technology's infancy, it was easy to send someone to each site to teach users how to access and use an EDC system. It was also simple to maintain good training records for each person accessing the system. Because the personal touch does not scale, a variety of other techniques—computer-based lessons or recorded web sessions—must now be explored more intensively.

Opinions vary on how much training is required. The most important items are to ensure that anyone accessing the system is trained to use it as intended for their role. Needless to say, training and documentation must be compliant with regulations.

Offshore Issues

The growing number of EDC studies places a burden on the study design teams at a sponsor. To augment their staff, many have begun offshoring, especially to India. While this solves many problems, offshoring also introduces new challenges. India has a wealth of people who are technologically savvy. At the same time, experience in clinical trials is not

as prevalent. This puts the onus on sponsors to train the offshore staff to enable them to build applications that are well-suited for the clinical environment. In the beginning, such training requires significant investment that negates some of the anticipated savings from going abroad in the first place.

Anticipating Churn

What's more, the incredible growth of offshoring to India has led to high staff turnover. Once an employee gains a reasonable amount of clinical expertise, his or her skills are sought by competitors. So significant attrition rates must be anticipated.

Despite offshoring challenges, many sponsors and vendors are having success in supplementing their staff in this way. The point is not to avoid offshoring, but to anticipate likely issues and not be surprised by them.

Data Integration

EDC is never used in a vacuum. It is always used with other systems. To name just a few data streams: lab work, adverse events, randomization and drug supply information, and patient reported outcomes are routinely imported to and exported from EDC systems.

Historically, data from other systems was either keyed into the EDC system, batch loaded or merged in a clinical data management system (CDMS). Now data is increasingly shared via real-time (or near-real-time) integrations.

Integrating systems can make life easier for users. For example, if a site enters demographic information and randomizes a patient, whether by phone or web, why should the same data be laboriously re-entered into the EDC system? Do you really want your overworked site personnel to repeat that chore over and over again? It is more efficient to have the demographic data auto-populate the eCRF (electronic case report form).

Enter Data Once

The benefits of integration also apply to sponsor and CRO data managers. Each time the same information is keyed into different systems, there is an opportunity for a data entry error that would create disparities between systems.

Data managers typically query and reconcile data disparities. Doing so may delay the database lock.

Since properly integrated systems use the same data, such data discrepancies are eliminated and reconciliation between systems is a less vexing issue.

Many companies are moving to a middleware model for integration. At ClinPhone, we call this our Clinical Technology Interchange Platform (CTIP). In this approach, each application connects directly to the CTIP which, in turn, handles all data transfers and mapping. The need to create multiple point-to-point applications is eliminated.

Immortal Paper

Paper-based clinical trials are still with us. Even studies that use EDC may use written forms. Additionally, some sites in remote regions may lack the infrastructure to conduct trials over the web. For this reason, some vendors have added modules to their systems to include paper data management facilities.

If an EDC system is being used to handle paper CRFs and queries, or data clarification forms (DCF), several key features are essential. Such systems must have double data entry and conflict resolution capabilities. They should also provide the ability to print DCFs to route to sites that are not online.

Also, since paper-based data entry is a heads-down activity, the system should allow personnel to enter forms with the keyboard. This sounds basic but is often overlooked. EDC systems should not force anyone to use the mouse in "paper data-entry mode."

There are many more issues of scale that biopharmaceutical companies, CROs and vendors are tackling as EDC adoption continues rapidly. The good news is that these challenges are steadily being overcome and the promised benefits of EDC are being realized around the globe.

David Stein is VP of product management at ClinPhone, where he plays a pivotal role in managing ClinPhone's products and services, as well as developing new technology solutions to improve the clinical trials process.