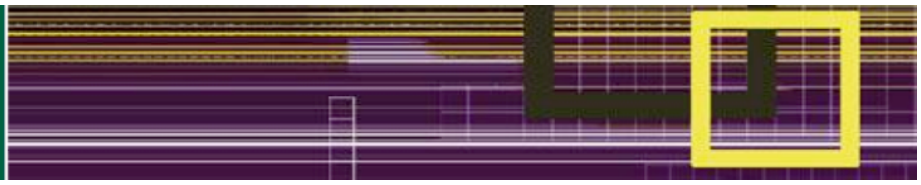

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NEXT GEN EDC

Helping EDC Scale Globally

By **David Stein**

There is no doubt that usage of electronic data capture (EDC) is growing, and rapidly. The question is whether there is broad awareness of new obstacles that its very success has created.

When EDC as a technology was primarily in ramp-up mode, pioneers were busy working out the kinks. They explored new features, workflows, cost justifications and other issues. Now, after a few years of that, more subtle and difficult problems are emerging. The key point is that delivering EDC globally, or "scaling" it, is a complex task with nuances that were not always clear when the technology was in its formative years.

Finding Expertise

The first challenge is the least surprising: expertise. Few biopharmaceutical companies have a large number of in-house experts. Most have a few champions with solid EDC experience. That has been invaluable to effective implementation. However, there are still large numbers of people who have very limited exposure to the EDC environment.

Despite years of tossing about terms like "paradigm shifts" and "process re-engineering," many still believe that EDC workflow is almost identical to paper-based studies. Wrong. Such misconceptions lead many to think that EDC implementation is simple.

Managing Users

Another challenge arises in dealing with user access rights and privileges. In pilot mode, user administration was fairly simple and most studies dealt with a small number of sites. Today, a sponsor may be dealing with thousands of sites and users. Adding new users, cutting off those who have left, dealing with site turnover and ensuring that all training is up-to-date for those who use the system is a huge task. While there are some support applications to help manage these activities, there is no magic bullet.

Global Training

Training is affected by scaling EDC. In pilot mode, it was easy to send personnel to each site to teach users how to access and use a given system. It was also simple to keep training records current for each person accessing the system. The personal touch does not scale well. A variety of other techniques, including computer-based lessons or recorded web sessions, are now being used across the industry.

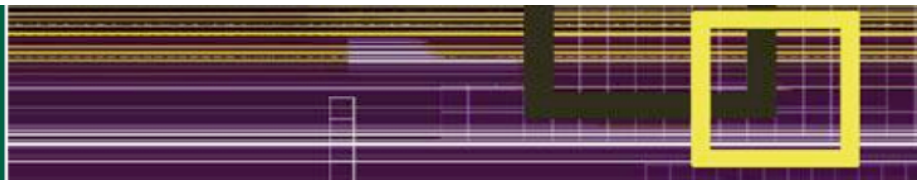
Opinions vary on how much training is required. The most important items are to ensure that anyone accessing the system is trained to use it as intended for their role—and that training and documentation are compliant with regulations.

Offshoring Anxiety

The growing number of EDC studies places a burden on the study design teams at a sponsor. To augment their staff in a cost-effective manner, many have begun offshoring some of the work, especially to India. While this solves many problems, offshoring also introduces new challenges.

India has a wealth of people who are technically strong. At the same time, experience in clinical trials is not as deep. This puts a burden on sponsors to train the offshore staff to enable them to build applications that are well-suited for the clinical trial environment. Such training requires significant investment.

Additionally, the growth of offshoring to India has led to high staff turnover. Once an employee gains a reasonable amount of clinical expertise, the acquired skills are sought by competitors. Thus, significant staff attrition rates must be anticipated when building up and training staff.



Despite offshoring challenges, many sponsors and vendors are having success in supplementing their staff in this way. The challenges are manageable if they are anticipated.

Integration Tactics

What's more, EDC in a global environment is never used in a vacuum. Rather, it is always used with other systems. Data streams are routinely imported and exported to and from the system. That may include lab work, randomization and drug supply information, and patient reported outcomes.

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

Integrating systems makes life a bit easier for users. Suppose a site enters demographic information and randomizes a patient, whether by phone or web. Why should it be necessary to re-enter the same data into an EDC system? It is more efficient to have this data auto-populate the eCRF (electronic case report form).

Eliminating Re-Work

The benefits also apply to sponsor and CRO (contract research organization) data managers. Each time the same information is keyed into different systems, there is an opportunity for a data entry error that could create disparities between systems. Data managers typically query and reconcile such disparities; doing so may delay the database lock. Since integrated systems use the same data, such data discrepancies are eliminated. Many companies are moving to middleware to achieve integration. This approach may be called a clinical trial Interchange platform (CTIP). In this model, each application connects directly to the CTIP which, in turn, handles all data transfers and mapping. This eliminates the need to create multiple point-to-point applications, each of which may be disrupted, in different ways, by one change to a component system.

Paper's Persistence

The last issue in scaling EDC is paper. Paper-based clinical trials are still with us. Even studies that use EDC may use paper forms. 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.

If an EDC system is being used to handle paper CRFs and queries, or data clarification forms (DCFs), 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.

Since paper-based data entry is a heads-down activity, the system should allow personnel to enter forms from the keyboard. It should not force them to use the mouse. Not all systems offer these crucial features. Despite these challenges, the good news is that these challenges are steadily being overcome and the promised benefits of EDC are being realized around the globe.

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