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NEXT GEN EDC **EDC Training Challenges**

By **Paula McHale**

Electronic data capture (EDC) has many powerful features. But users cannot learn about those features using Google or telepathy. Intensive training is required, and an oft-overlooked element of EDC success. Sponsors today have many choices about how to conduct EDC training: the web, face-to-face meetings, DVDs, and one-on-one sessions. That choice brings confusion.

Several factors must be considered to appreciate which type of training is right for different types of users. In some instances, a single solution can achieve the desired results. In other instances, a combination of various methods will be most effective.

Meta-Lessons

The first issue: how much training will be adequate and practical for each user role? Investigators do need training to review data and provide electronic sign-off. But they simply cannot be expected to sit through an extensive training session. ClinPhone's experience is that investigator training, including any quizzes for certification, needs to be finished within 20 minutes. No more!

Coordinators need considerably more training. That's because of the level of detail involved in their role. How much? Perhaps two hours. Perhaps more.

Key Ingredients

All users need to be trained on the basic EDC system. Such lessons may include how to enter and change data and how to create or answer a query.

But users also need to be trained on the study-specific aspects of an EDC system, which allows them to become familiar with the actual electronic case report forms (eCRFs) they will be using. This instruction reviews the trial schedule and eCRF content—and ensures that users understand how to complete the forms accurately.

Face-to-face training is often well received by users and can be conducted at investigator meetings and site initiation visits. This method can be the most expensive because of factors that are outside the direct control of the sponsor, contract research organization (CRO) or EDC firm.

In the Flesh

Budgeting for training may not be simple. Investigator meetings often have to be extended by an additional night to accommodate training. In addition, there can be extra cost for the facility: internet access, audio-visual system set-up and additional staff.

Beyond that, multiple training sessions might be necessary if the study is especially large. And since there is no guarantee that all site personnel will be able to attend a face-to-face investigator meeting, a back-up instructional method must be established. That incurs additional cost.

On-site training to coincide with the initiation visit has similar challenges. In our experience, it can be difficult to get enough quality time with site personnel to adequately teach them. Money could be spent to send the trainer to the site. But if such tutorials are not attended by all personnel, further training may still be necessary. Some train-the-trainer programs work well. But clinical research associates (CRAs) may not be best suited to be EDC system trainers. Consider using trainers who know a system inside out.

While face-to-face training is the preferred method for many, it is not always the most

practical. That is especially true on large studies. As clinical trials seem to become larger and larger, and as sponsors use an increasing number of sites for additional trials, this personal touch can be very costly to implement. So larger sponsors should be prepared for increased use of web- or DVD-based training methods.

The internet offers some obvious advantages for EDC training. E-learning is well suited for teaching the basic features and tasks of an EDC system; such training is typically designed to address each role in a study. Good e-learning tools often include an assessment or test that will measure the comprehension level of the trainee.

But web-based training is not a panacea. It is often too costly or time consuming to create a unique e-learning package for each protocol. So additional study-specific training is invariably needed to be certain that site personnel understand the eCRFs and study completion guidelines.

Details Matter

Web-based training also requires more than one session to accommodate multiple time zones and schedules. For best results, we try to set limits on the number of attendees to be sure there is sufficient time to answer questions from all who attend.

After the initial training, however, the web-based method is especially attractive for re-training users who have not used the system in a while, as well as providing a refresher course for other users. New users added to the study, due to site turnover, can also be easily trained and brought up to speed quickly via web meetings. Some protocol amendments and other post go-live changes may

require training of the sites prior to implementation. A web meeting is often an excellent way to provide this vital information so the changes can be implemented.

Admin & Oversight

One of the most crucial and onerous aspects of training is keeping track of who has received instruction and when their training was completed. Since users should not be allowed access to the EDC system until they have completed the training and can demonstrate competence in utilizing the system, it is critical to the start of a study that this information is tracked and managed closely.

To avoid delays, it is also important that all sites know exactly when they must complete their training. This ensures that study initiation visits can be scheduled and carried out in a timely manner. Mismanagement of this process can delay the study start and ultimately impact the entire study time line.

Integrating an EDC system with e-learning and a clinical trial management system (CTMS) may be the preferred solution for tracking training data. Combining data from all three (EDC, CTMS and e-learning) systems and creating dependencies can streamline the overall training and study access process. Some EDC vendors are already integrating these systems to provide a smoother start-up experience, allowing both sponsors and sites to reap the rewards of investments in EDC.

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