EDC Means Higher Productivity, Not Fewer Jobs

With electronic data capture technology, companies can conduct more trials with the same number of staff.

By Leslie Bihari

Increasingly challenged to maintain profitable growth, biopharmas are turning to electronic data capture (EDC) to gain an advantage in clinical data management. While EDC delivers tangible benefits, successful adoption requires business-process changes that affect clinical trial staff — notably clinical data managers (CDMs), clinical research associates (CRAs), and investigator site personnel. These changes can cause some clinical staff to worry about their future employment.

For example, EDC shifts certain conventional CDM tasks, such as query resolution or data entry, to CRAs. This reallocation of responsibilities may heighten dissatisfaction among CDMs. While some biopharmas do cut staff after achieving efficiencies, at least as many begin moving higher volumes of trials through the development pipeline. These companies conduct more trials with the same number of staff.

Moreover, after CDMs gain experience with EDC, they often discover their new responsibilities increase their job satisfaction. EDC removes the tedium and time requirements of paper. No longer must managers manually route and deliver case report forms. With EDC, managers can access and view data immediately. Rather than spend hours faxing and following up via phone, CDMs can clarify data in minutes.

EDC transforms CDMs from strict data managers to information managers, a shift that makes CDMs key to EDC process redesign and therefore more valuable to sponsors. Free of the more granular aspects of data management, CDMs can focus on identifying and sharing information like query trends and trial metrics and thus help improve process efficiencies and staff effectiveness.

In contrast to CDMs' concerns of decreased workloads, clinical research associates may initially worry about having to perform added tasks, namely investigator training and discrepancy management. While training site personnel on EDC use is indeed an added task, CRAs tend to find that the extra effort EDC requires at startup is offset later in the trial, as investigator staff become more efficient and require less on-site assistance.

Similarly, while discrepancy management shifts to CRAs in the EDC model, EDC reduces the discrepancy volume by 70 percent or more through online edit checking. In addition, EDC renders discrepancies more easily resolved, as CRAs electronically initiate queries and review responses for the electronic case report forms they've reviewed.

Overall, EDC reduces CRAs' time onsite because it's Web-based, and therefore easily and widely accessible. CRAs can handle more issues from their desktops and limit their visits to sites needing in-person assistance. With the visibility EDC provides into patient visits, data entry, and query resolution, CRAs can also better time their site visits to reduce travel and maximize effectiveness while on site.

Because they spend less time onsite, CRAs can monitor a higher number of sites and spend more time cultivating relationships with personnel. Instead of being perceived as enforcers, CRAs become advisors.

In addition to enhancing job satisfaction, EDC makes CRAs more valuable to the clinical team because a CRA's site relationships often determine how quickly data clarifications close. Faster clarification of discrepancies can shorten the time to database lockdown. CRAs proficient in EDC can become key contributors to study design and process redesign.

Clinical research coordinators now realize that electronic entry of case report form data, which offers real-time edit checks, reduces the time they spend resolving discrepancies by drastically shrinking the number of discrepancies to resolve. Additionally, coordinators find it much easier to respond to queries that appear to them within hours or minutes after patient visits, rather than weeks afterward. With EDC, staff spend less time digging out old patient records and trying to reconstruct visits to answer queries.

EDC provides more efficient data management, increases harmonization between global teams, and creates more efficient communication channels — all of which boost clinical trial throughput and improve everyone's future.

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	Initial Concerns	Recognized Benefits
CDMs	• Job security or dissatisfaction • Must redevelop internal processes	• Cleaner, more consistent data faster • Fewer tedious tasks • Professional development opportunities
CRAs	• Often called on to provide investigator training • Must now act as discrepancy managers	• Lower discrepancy volume and faster resolution • Reduced on-site and travel time • Ability to monitor more sites and cultivate site relationships
Sites	• Required to enter data electronically • Need training on the technology • Need hardware provisioning	• Fewer daily interruptions from discrepancy managers • Faster sponsor payment • Competitive positioning for new trials

Clinical data managers and research associates are often concerned that electronic data capture will make their jobs harder or, worse, disappear. Trial sites are faced with training issues and new expenses. But according to the author, EDC eliminates tedium and speeds the time it takes to conduct a trial.