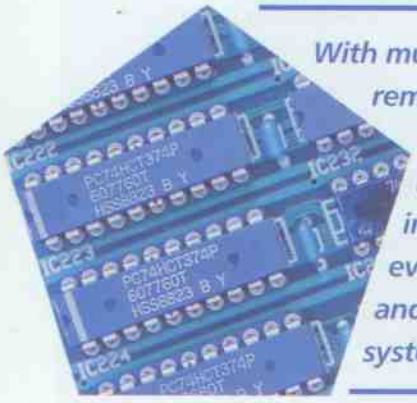
Making the most of clinical data managers

Electronic data capture can be seen as a way to cut staff numbers in data management. Not so, says **Leslie Bihari**. Rather than being a surrogate for clinical data managers, EDC simply removes the mundane aspects of their work, allowing them to develop their roles and put their skills and knowledge to much better use

Drug development companies are increasingly using technology to make clinical trials more efficient. It is only natural for staff to view this trend with a cautious eye as their employers may tout systems such as electronic data capture (EDC) as a way of cutting jobs. Far from being a threat to job security, implementing an EDC system is very labour-intensive, requiring the clinical data manager's (CDM) in-depth knowledge of existing clinical data systems to facilitate the transition from paper to electronic data capture.



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Indeed, the CDM's expertise is in great demand during software selection. Anecdotal evidence suggests that during the software evaluation, CDMs are increasingly being lent to global steering committees where they are asked to perform impact analysis on how new product workflows match existing clinical ones. Once the evaluation is complete, the CDM can gauge how much reworking of existing clinical workflows will be required.

Another of the considerations that must be taken into account when software is chosen is whether the new product can be integrated with the company's existing systems. Once the software is chosen, global standards and processes must be defined. The CDM's knowledge of the format of clinical databases will eventually be invaluable to this effort.

During validation and implementation, the CDM tests the workflows devised during evaluation. At this point, CDMs may help generate best practice for configuration and development. Libraries of software components are assembled, and CDMs are frequently selected as librarians of these repositories and, in that role, may develop the selection criteria for new components and management processes around the library.

With EDC, data managers continue to protect the integrity of the study data, but discharge their responsibilities differently. Paper CRFs are replaced by electronic case report forms (e-CRFs), a significant change in that investigative sites are now responsible for data entry, thereby eliminating the CDM's supervisory role checking for errors and inconsistencies. Discrepancies are checked during automatic editing or, in some circumstances, manually entered by the CDM, and handled by site personnel via the Internet. The CDM is spared the day-to-day tedium of faxing discrepancy forms, struggling to read illegible paper CRFs and discrepancy responses, and telephoning or e-mailing sites to track expected forms.

With these responsibilities removed, CDMs can turn their attention to new and more interesting tasks – evaluating, validating, and implementing new systems, producing reports that track metadata, helping integrate disparate IT systems across the organisation and much more. As a result, the focus of the CDM's job shifts away from data handling and towards improving the flow of information within the organisation.

When e-CRFs are implemented, metadata – information about data – becomes available and can be used to measure trial efficiency. Metadata are a source of statistics on case book completion, subject, form and query status, and specific user activity. Since a timestamp is generated whenever data are entered on the system, data managers can look at real-time site-performance metrics, and see how long

it has taken to enter data, the amount of data each site has entered, how much monitoring has been performed, how many e-CRFs have been completed, the status of discrepancy resolution and what types of users have performed which activities.

Participating in the system-wide effort to integrate disparate clinical databases is an important new role

Such information has been available with paper systems but it has been difficult for sponsors to process it because the records cannot be searched electronically. Some of these data were collected using customised collection forms but they were never available in anything like real time. With EDC, they are automatically available in the database as part of the application.

The clinical data manager will also be needed to help draft strategies for organising, managing and sharing information quickly and reliably throughout the clinical development process. To improve the flow of information, the systems, many of which are standalone, must eventually be integrated. It is not unusual for sponsors to house large numbers of clinical data-management systems and separate databases for serious adverse event reporting, project management and regulatory affairs. Typically, these systems, which have emerged over long periods of time, were designed for specific functions, and often use numerous formats.

Participating in the system-wide effort to integrate these disparate clinical databases is an important new role for the CDM, one that is likely to grow as other functions – research, development, finance, accounting, marketing and regulatory affairs – begin to support system-wide information flow.

A word of caution is needed. Taking part in multiple initiatives, such as moving from data collection on paper to EDC, followed by the integration of clinical trials databases within clinical development departments and throughout the research organisation, puts tremendous pressure on clinical data managers. A CDM who is evaluating new technologies, supporting more clinical trials at greater numbers of investigative sites and handling larger volumes of patient data can easily become overwhelmed. Once the transition from paper to electronic data collection begins, the CDM will be overseeing implementation while maintaining the older paper-based systems. After implementation, integrating the various clinical databases results in the data-management team servicing more customers, internal and external.

To handle such variety of new tasks within tight timescales, CDMs may initially rely on outsourcing and make use of consulting partners' expertise. Issues relating to bandwidth may be addressed through outsourcing, and the need for core skills, such as business process redesign, technology, and computer system validation, may be best handled with such help.

But simply participating in a software implementation and integration exercise will not be enough to show how much CDMs can contribute. And if the organisation does not understand or is not aware of what CDMs can bring, it will be much harder, if not impossible, to involve them later on. In many organisations, CDMs are currently advertising their skills in order to attract the interest of a broader audience within the sponsoring body. The methods used generally depend on the size of the organisation, for example clinical teams in most pharma companies publish newsletters of recent success stories and give presentations to traditional and non-traditional customers. In larger organisations, departmental fairs provide opportunities to showcase accomplishments and the services that the data-management department can provide. These are typically planned in conjunction with human resources.

CDMs who participate in task forces dedicated to bringing much-needed IT systems to their organisations should not fear this change as it may offer great opportunities for their professional development. They will learn new skills while demonstrating how their knowledge of clinical data systems helps the transition to EDC and systems integration. They will discover that in eliminating the more mundane tasks linked to paper-based systems, they will be free to adopt increasingly high level and challenging responsibilities. Ultimately, the CDM's job will be less about the details of data handling and more about improving the flow and quality of information. GCP

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