



The Future is Now

Gregg Dearhammer of i3 Statprobe illustrates the need for EDC systems that use technology more efficiently in order to better manage the process of a clinical trial

The long-awaited electronic data capture (EDC) revolution seems to have arrived. Hard evidence can be seen in the steady rise in the percentage of clinical trials using EDC. Survey results presented at the DIA 3rd Annual Clinical Forum in October 2009 showed that 58 per cent of clinical trials use EDC, up from 13 per cent in 2001. Ninety-five per cent of respondents had experience with EDC, up from 52 per cent in 2001. Less objective data also support this; we all know of companies that pledge their future trials will be 100 per cent electronic.

EDC has reached a level of general acceptance and is here to stay. So what's next? What might the future look like as technology evolves to make the world of clinical trials more efficient? We can answer that question by looking at near-, medium- and long-term solutions that are in the pipeline.

QUICK FIXES

Immediate, 'tactical' improvements will enhance the EDC systems of today. Investigative staff, for example, complain of less-than-intuitive interfaces which decrease the speed of data entry, increase the probability of mistakes in data capture, and increase the overall workload. On the other side of the process, both sponsors and CROs using EDC technology to conduct trials continue to search for ways to reduce the time to get a database to production and ensure that reporting outputs are complete. EDC systems of the

future must find that balance between ease of use and fast implementation, while maintaining the robust and highly technical features necessary to conduct a trial. At a minimum, these systems should include high validation and security, edit programming, data integration tools and reporting capabilities.

EDC systems that are built with input from all stakeholders – investigative sites, data management, clinical personnel and IT – will be more successful, since they will have an intuitive comprehension of their users' desires.

MEDIUM RANGE GOALS

Other, intermediate improvements should be incorporated into EDC of the future:

- ◆ Support – EDC solution providers will be focused on improving help desk support and training, which is still a concern for EDC users
- ◆ Global integration – with the expansion into new markets, such as the Asia Pacific region, Africa and Latin America, ensuring systems work in these environments and can support local languages will be critical
- ◆ Flexibility – the current EDC environment is very 'one-size-fits-all'. All trials have the same basic steps, but sponsors are wedded to their own internal systems and processes. The ability to customise a system to fit those processes will be a differentiator. Systems of the near-future must be capable of adapting to a variety of types

Figure 1: Removing the silos to achieve an integrated system

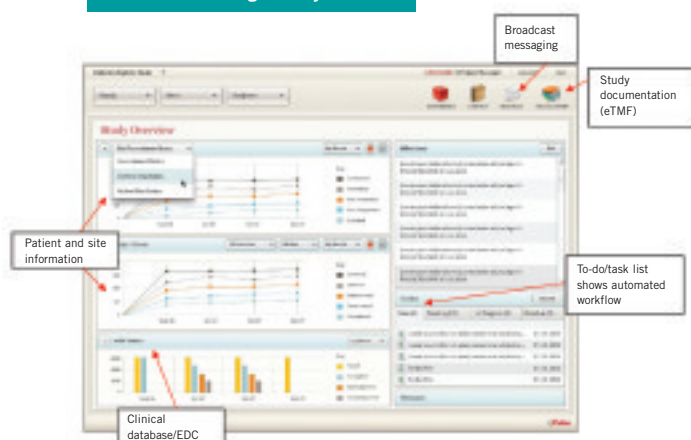


Image: i3

of clinical trials – from early phase trials to post-marketing observational studies. EDC systems will be most powerful when they can be modularised – or easily configurable – to include or exclude features depending on the type of trial, yet maintain solid integration between modules

- ◆ Integration – data from a variety of sources such as electronic patient reported outcomes (ePRO), IVR and the central laboratory must be able to be routinely integrated, yet the system must be flexible enough to accommodate the disparate formats in which it is received
- ◆ Compliance – EDC tools must be able to use standards that develop in the market as a way to drive efficiencies, speed and quality as part of the process

IN THE LONG TERM

Sponsors currently complain of siloed systems that house their trial information. Today, data usually exists in multiple systems, each with its own function and serving its own users: the EDC system captures the prospective clinical trial data; the IVR system collects the randomisation and drug distribution data; site monitoring information may be housed in a clinical trial management system (CTMS) application; and regulatory documentation may reside in still another system specific to that function.

The EDC environment must evolve into a more comprehensive and integrated one in which those silos of information are brought together into a single system supporting a variety of trial types with one data repository; data from multiple sources over the course of a trial – and even the course of many trials throughout the compound's life cycle – should be easily retrievable and manageable.

Clinical trial information is closely related and important to the conduct of the trial; it should all be available for reporting purposes, to the right audience, in real time. Decisions can be made more effectively if the data required can be pulled from one source and reported in a standard, intuitive and workable format. This can best be accomplished if the underlying platforms which house the data are integrated at the most basic level. Instead of differing technologies exchanging data through programmed interfaces, a system built on one platform designed to house, integrate and report data from all facets of the clinical trial will provide higher quality, more immediate reporting and more efficient decision making.

The best EDC systems of the future will use technology more efficiently to better manage the process of a clinical trial. Each study is different, but underlying processes are

common to all trials. Every trial involves: identifying, recruiting and contacting qualified investigators; enrolling patients; capturing clinical data; conducting safety surveillance; and monitoring, analysing and reporting the information for final regulatory submission. Each of these activities varies by protocol, of course, but all trials include these fundamental activities.

Using workflow-driven software, an EDC system could, during development, be built to route documents and information to the appropriate people at the appropriate time. Workflow could be completely customisable for each trial, but once created, would remove the dependence on manually moving the clinical trial process forward. Although protocols must be reviewed and signed off before case report forms (CRFs) can be created, an integrated, workflow-based system would identify who – by role or name – is responsible for protocol review. After review is complete, forms would automatically be routed to the correct party for approval. Upon approval, the data management department would be notified to begin CRF development. When the clinical trial process is viewed in its entirety, the software can be used in a more efficient and effective manner.

CONCLUSION

EDC systems of the future will make incremental gains in the near term with regard to ease of use, speed to deployment, integration of data and transparency in reporting. Longer term, market efficiencies will be generated by those companies that can create technologies that more holistically address the clinical trial process and the information exchanges that occur within it. A system that is workflow-driven and integrates data from all aspects of the trial into a total view for the user will generate time savings, improve quality, reduce cost and provide a more positive experience for all of its users.

About the author



As the President of i3's data services business unit, **Gregg Dearhammer** is responsible for managing client relationships at a strategic planning level, overseeing process improvements and standardisations from an executive level, facilitating client discussions with other parts of the corporation, and providing the direction and vision for data services. An accomplished leader, Gregg brings 10 years' experience in senior management positions in data services to i3. Prior to joining i3 Statprobe, he was Kendle International's Vice President of Global Biometrics, responsible for establishing Kendle's global biometrics processes and systems. Additionally, Gregg expanded the organisation through strategic planning, which included assessing and implementing new technologies and leading the integration and development of company acquisitions.

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