



Featured Article

An Honest Look at the eClinical Process: What Can We Learn from Best Practices Outside the Industry?



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Achieving a true end-to-end eclinical system remains elusive in the drug development industry. The blame can partly be assigned to hazy and overhyped definitions of eclinical, ranging from EDC to a utopian, standards-based platform that interoperates with all systems. Part of the blame can also be attributed to the industry's apparent resistance to embrace the latest technology platforms. These mature and standards-based technologies have catapulted enterprises that heavily rely on the capture and analysis of massive amounts of data, such as the airline industry, insurance companies and supermarkets.

Let's look at how the industry has been approaching the eclinical processes. Some folks equate eclinical with EDC, and while EDC is certainly a segment of eclinical, it is naturally limited in its scope and functionality. EDC has been an initial step in the right direction, but the big pay-offs of saving time and money have not been fully realized. In fact, various surveys indicate that some companies have actually experienced an increase in costs when implementing an EDC system.⁽¹⁾

The overall results of EDC have been disappointing for three main reasons:

- 1) The continued reliance on a paper-based workflow
- 2) The lack of attention to other clinical trial workflows, and therefore lack of integration
- 3) The lack of true process change needed to revolutionize the way clinical trials are conducted.

These same arguments can be made for interactive voice response systems (IVRS) and other isolated clinical trial management systems.

Simply overlaying technology on traditional paper-based processes is certainly not the most efficient approach. Some degree of change management is critical to implement these processes in a more progressive way. To quote Ron Waife, president of Waife & Associates, at Bio-IT Expo 2008, "We've been shoehorning computer technology into a paper-based organization, which uses a paper-based work flow. We have an Internet veneer over a 1970s furniture suite."

Now let's look outside biopharma to see how other industries are taking a more holistic approach to electronically managing data. A major reality check is to comprehend the massive amounts of data some industries handle on a regular basis, which certainly puts clinical trials data in perspective.

U.S. airlines industry: 87,000 flights per day

Insurance agency: 1 million pages scanned per day

Supermarket chain: 2,000 suppliers with 35,000 products and 800 million cases of product each year

Considering the different layers and formats of hardware and software used by these industries and how they must be integrated with each other, these numbers are staggering! Leading companies in these industries also faced huge and disparate systems with separate data sources, which made management and analysis very difficult. Sound familiar?

Take the UK-based Sainsbury's supermarket chain example from above. They were getting hammered by the competition, mainly due to its outdated and extremely complex IT infrastructure that couldn't keep up with market dynamics. They essentially had a paper-based system that lacked good visibility on inventory and led to a problematic replenishment process. Management had little real-time data with which

to make sound decisions. Recognizing that IT was critical to their survival and growth, Sainsbury's worked with world-class IT partners to devise a plan for "an agile IT infrastructure built on an open, adaptive, scalable architecture with hardware and software systems that would give very high performance, strong data security, and low total cost of ownership."⁽²⁾

This plan did indeed help Sainsbury's migrate from a proprietary, centralized environment that was paper-based to a paperless system integrated into the supply chain and operating in real time via a Web browser. It has allowed Sainsbury's to master 2,500 transactions a second through the system.

Another example of tangible efficiencies from an enterprise-wide system is with an insurance company that went strictly paperless. They experienced a 60-90% cost savings from electronic filing retrieval and archival data management system! No longer did they have to maintain physical storage space or have staff dedicated to finding bits of paper. With all data indexed in a centralized system, they simply conducted a search to retrieve the exact piece of information they needed.

One might argue that the biopharm industry is simply behind industries that have led the IT revolution, particularly since our processes are so heavily regulated.

In a well-read and debated article from the Harvard Business Review, author Nicolas Carr claims IT is following the same trajectory as major, paradigm-shift innovations, like the telegraph and electricity. He outlines the rise and commoditization of these inventions. They each went through a period of disruption and transformed fundamental business practices. Early adopters enjoyed a competitive and economic advantage. (Think Wal-mart, FedEx and eBay.) Over time, the technologies became commonplace and proprietary methods gave way to more productive standards that are even more effective when shared. His final point is that he believes IT is no longer a strategic decision, but rather that it should be viewed as a way to lower costs and increase efficiencies – not reinvent a business.⁽³⁾

I reference this theory to suggest the biopharm industry is going through its own natural IT maturation period, and we are still in a window of opportunity to take advantage of the incredible technology available on the market today. I think we can all agree that the technology and expertise exists. What's missing is the vision, desire and drive for change.

To help jump start our own revolution, I believe we should invite IT experts outside of our industry to learn from their successes and failures. Understand how they use one centralized repository for all data, integrate multiple data capture tools and enable two way data flow. Adapt their methods for integrating all key functions on the same platform, understand true document management systems without the paper and compare realities of "real-time" data capture and reporting capabilities.

Dr. Nick Lucas will be presenting more on this topic at EuroDIA on March 24 in Berlin.

Nick Lucas, PhD, Vice President, Global Data Management, has over 18 years of experience in data management. Dr. Lucas is responsible for both the European and US operational units at INC Research. Prior to his tenure at INC Research, he served at BRI, Parexel, and Quintiles, managing staffs of up to 600. Dr. Lucas has headed a number of initiatives, including implementation of Web-based data capture and Process Improvement, and formulated the Data Validation & Reporting module for the ACDM/Kingston University Post-Graduate qualification. Dr. Lucas is a regular speaker at professional conferences.

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