

Electronic Data Capture:

Expediting Accuracy



It's one of the greatest oxymorons. Pharmaceutical, biotech, and medical device manufacturers – perhaps the most innovative and cutting edge companies in the world today – who rely on manual, paper-based processes for critical time-to-market initiatives.

With skyrocketing costs – up to \$1 billion to bring a new drug to market, \$500 million-\$700 million of which is spent on clinical trials – companies are seeking faster access to cleaner clinical data. Despite its slow adoption, Electronic Data Capture (EDC) is finally taking its rightful place within the clinical landscape. Implementations are on the rise and companies are acknowledging its powerful potential. Consider Eli Lilly,

for example. According to their regional operations manager, their use of EDC has resulted in a 70-80 percent reduction in queries with over half of all queries resolved on their own.¹ Other companies have uncovered additional benefits, including:

- Case report form (CRF) processing in as few as 2 days, with cleaner data entry from investigator sites
- Flexible and enhanced monitoring activities
- Fully integrated and coordinated subject data in one easily accessible database (lab reports, interactive voice response systems (IVRS), electronic diaries, etc.)
- Real-time reporting on both operational and clinical data
- Instant validation, a higher level of data quality at a reduced cost without delay
- More informed decision-making power
- Reduced frequency of site visits

EDC business transformation improves data quality, accelerates data acquisition and management, and reduces clinical phase costs. In fact, a recent analyst report concluded that e-clinical solutions, in particular electronic data capture and clinical trials management systems, could save companies \$10-\$15 million a year on paper and postage alone.²

So it's no wonder that it's become less a question of 'if' or 'when' companies will begin an EDC initiative, but 'which' vendor(s) they should use and 'how' they should proceed. With over 50 vendors in the EDC space today,³ selecting a well-qualified, experienced one that's right for your business can be a daunting task.

To find out the best way to select a vendor and how to apply lessons learned from earlier EDC adopters, we reached out to Paul Allen who leads our life sciences vertical and our clinical development team.

EDC has been around for years, so why has the pharmaceutical industry been so slow to adopt it?

Unfortunately, I think there was a misperception that EDC was just another piece of software that would help research professionals perform their daily tasks more easily – like MS Word or e-mail. Over and over, early on in the adoption process, companies were trying to fit an electronic technology into a paper-based process which actually yielded less efficiency and more costs. Basically, buyers were looking at the true benefits of EDC too narrowly and whether to pursue it became a simplistic business decision rather than one that considered pervasive benefits across the enterprise.

And change was the other factor. Quite literally, the cost of change. Many companies were simply unwilling or unable to invest the dollars and resources to effectively integrate an EDC solution. Stemming in many cases from an "if-it's-not-broke-don't-fix-it" mentality, many organizations didn't want to make the fundamental shifts in the logistical conduct of clinical trials. But today, with many of the top fifteen pharmaceutical organizations reaping the benefits, companies are realizing they need to adopt EDC to remain competitive.

“Electronic data capture (EDC) has emerged as a proven tool for sponsors of clinical trials. Understanding EDC principles is more important than ever for clinical data management professionals.”

In your opinion, how should executives look at EDC solutions?

Without question, EDC solutions are not technology upgrades, or about adding new functionality to a business process. When companies look at the changes as solely a data management issue or an IT issue, that's when things started to unravel. EDC, at its true benefit level, should be thought of as a robust business transformation that can lead an organization to a powerful paradigm shift in how it performs its clinical trial operations—a shift that can drive extraordinary results.

To be successful, you need comprehensive representation. You need to involve everyone in your trials process – your project managers, your investigative sites, your clinical monitoring team, your drug safety/pharmacovigilance specialists, other external data providers, data management and statisticians, as well as IT. Understand and address everyone's unique challenges and needs. Incorporate everyone in the decision-making and pilot process. Consider using a project management office (PMO) approach to facilitate communication, appease fears and insecurities, rally the team for higher levels of commitment and stakeholder buy-in, stave off any resistance, and stay within your timeline and budget. An EDC implementation can be overwhelming; however, if treated like any other large, complex project, you can move from an antiquated, rate-limited process to an efficient, effective and time-saving business solution without major hindrances to your current organizational operations.

In terms of vendor selection, many companies are selecting larger, more well-known EDC vendors. What are the potential advantages, if any, of using a smaller EDC vendor?

There are many benefits to selecting a smaller EDC vendor including a potentially lower pricing model, increased flexibility, more personalized customer service, and in some cases technology superiority. Larger vendors may use stricter implementation methodologies and are less apt to customize their solutions. But the real criteria for selecting a qualified EDC vendor should be whether or not they can provide a COMPLETE solution that fits your organization's needs. The vendor should be prepared to provide a holistic approach that goes beyond the core competencies of a simple software solution.

What do you mean by a holistic approach?

Aside from selecting the right technology itself, it's imperative to look at your current business processes as well as your resources. Beyond new workflows and templates for deliverables, you need to be keenly aware of your employees in light of the changes that will be taking place. Effective change management and open lines of communication throughout the entire EDC implementation lifecycle are essential. Without beginning-to-end support, team members tend to forego any training and resort to doing what feels 'safe.' And unfortunately in the clinical trials industry that means putting pencil to paper in lieu of a high-end graphical user interface (GUI) and a computer system.

Is using a vendor and/or consulting firm that is not savvy in change management the biggest risk for an EDC implementation?

If it's not the biggest, it is definitely in the top two or three. It doesn't matter how much you invest in EDC and process redesign if your people can't see the long-term benefits. Change is difficult, there's no way around it. However, if you select an EDC implementation team that is multi-talented in many areas, the change will be manageable. This team should be prepared to drive the 'right' software solution and best practices; help ensure this new way of conducting business aligns with your company culture; and help all parties affected by this transformation recognize that the shift is beneficial functionally, operationally, and financially. At that point, you have a true 'win-win-win' scenario.

Do you have any final words of advice for companies about to embark on EDC adoption?

Yes, perform a comprehensive due diligence – not just on your data management or clinical monitoring functions, but across your organization. Recognize that an EDC solution requires selecting the right technology; thoroughly analyzing your R&D business processes; and taking human capital management into consideration during the entire process.

Also, don't underestimate the level of effort and support you'll need to successfully integrate your EDC solution. Ensure that you have corporate sponsorship for this transformation and your commitment and investment will translate into bottom line savings and most importantly, the quick delivery of safe and effective treatments and therapies into the hands of those who need it most. ■

References

- ¹ "Lilly on EDC Changes." ClinPage. 28 April 2008. <http://www.clinpage.com/article/lilly_on_edc_changes/c5>.
- ² Pizzi, Richard. "Millions Could Be Saved with 'Paperless' Clinical Trial." Healthcare IT News. 8 August 2008.
- ³ Handelsman, David. "Electronic Data Capture: When Will It Replace Paper?" SAS. <<http://www.sas.com/news/feature/hls/sep05edc.html>>



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