



# Looking into the future

## Beyond data capture: the promise and limitations of technology

**V**irtually every pharmaceutical journal is brimming with adverts from companies claiming that their system can reduce the time required for clinical evaluation.

These all focus on electronic data capture (EDC) technology in the spate of companies promising to apply technology to reduce the time required for clinical assessment.

These claims are reminiscent of those promulgated several years ago—by the same companies, in some cases—when remote data entry (RDE) was first marketed. RDE systems largely failed to deliver on that promise, and we are now faced with the question of whether current EDC can.

The starting point for these messages is one that the pharmaceutical industry recognises as important, even critical, to the way they work. That new drugs now take seven to ten years for full

development and cost in excess of \$600 million is commonly recognised.

But the central issue is whether this represents difficulties and complexity inherent in the drug development process or that it reflects inefficiencies amenable to improvements.

Lessons from other industries, some considerably more competitive, suggest that technology has been underutilized by the pharma industry and may profoundly change development cost and timelines.

### HOW TECHNOLOGY CHANGES THINGS

For the most part, the current choice of electronic tools is limited to data collection. While this is an important part of the research process, it fails to consider that development and even utilisation of data rests on other components, some of which are more

important than minimising the time required for research data to reach a central processing point. Bottom-line success rests on being able to interpret and act on timely information.

A common failure of previous data collection systems such as fax-back systems is that they transmitted data quickly to a central point, but from that point on the usual bottlenecks ensued. For example, data might reach a sponsor the same day a patient was seen, but hand entering data and running validity checks often took a month or longer.

Or, to put it another way, collecting the data is relatively easy; putting it to good use is considerably more challenging, in part because use of any tool depends on the manner in which it is used. The best of tools will always be sub optimal if there is not a context that allows them to work to full advantage.

Many pharmaceutical companies

prove to be the equivalent of large ships for which turning in a new direction has proven at best slow and at worst ineffective. There is a case to be made that this problem is inherent within organisations purely as a function of their size and that perhaps they should be looking increasingly outside for solutions.

A key point in realising the potential of technology is its ability to smooth the flow of information between what have to this point been discrete functions. For example, data management if often completed before project management can examine performance indicators or biostatisticians have a chance to begin examining data.

Present vendors of electronic systems tend to perpetuate these problems by marketing systems that deal with discrete pieces that represent incremental change such as recruitment, clinical trial supply and distribution, and data collection. The greatest gains from technology come in the realisation that it changes the processes, not just speeds up existing ones.

## APPROPRIATE USE OF TECHNOLOGY

The recent focus on data collection also creates the temptation for companies to purchase a piece of software and expect to drop this into their operations and quickly gain the advertised advantages. In practice, however, this is rarely the case; most often, the purchaser realises that there are many other complementary pieces of the process that need to be aligned, and these changes ripple through the organisation and end up being considerably more profound than anticipated.

Thus, the real challenge lies in being able to change the other parts of what they are doing to enable the new capability to function well—and most often, this daunting task proves considerably more difficult than anticipated. Electronic vendors end up being victims of their own promotional claims, because they encourage an overly simplistic view.

Readers old enough to recall desktop computer software from several years ago, with separate word processing, spreadsheet, and database applications that did not effectively communicate with each other, will recall the lesson: bottom-line results depend on all systems working well together.

Some applicants also fail to adequately consider who will be using

the system. The sites themselves are often the limiting factor, because most are simply not comfortable and fluent with use of computers and software in an everyday setting.

This limitation can range from personnel who are not conversant with the Internet to lack of adequate technical support for computers and systems at the sites. The common complaint of sites is that every study requires a dedicated computer, telephone lines, and storage space.

When problem arise, ranging from frustration with poorly designed software to cryptic error messages, frustration levels are high, tolerance is low, and poor data result. This realisation is

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so important that some recent studies, started with EDC systems, have failed to deliver on the end result of faster provision of data.

Appropriate use of technology also means that a simple, no-tech solution may be the better choice. For example, a simple diary is far easier for most people to fill out with a piece of paper than a device that has to be started, navigated, and have information entered—sometimes with a stylus or keyboard that they may never have seen before.

Voice response systems work well for a limited number of simple questions—but anything more is often asking for trouble. Ask the company who was talked into use of an IVRS system for collecting key outcome data. It found after the completion of the study and during audit that people had become so frustrated with the system they resorted to pushing any button to shut the thing up and move on with their daily activities.

## APPLYING TECHNOLOGY THOUGHTFULLY

Any technology-based system has several basic requirements. These are:

1. Technology must be applied appropriately: lo-tech can often work better than slick technology.
2. Consider the users: everyone must be comfortable with technology and able to use it effectively.

3. Technology must allow easy customisation to accommodate a range of drugs, routes of administration, sponsors, and other issues.

4. The system must be flexible enough to incorporate changes on the fly. Change is inevitable in complex processes such as clinical trials. Good systems accommodate them.

5. The system must function as an integrated unit, not simply one piece of the puzzle such as data collection. Rapid collection means nothing if data cannot be cleaned and used quickly.

6. Technology changes many related processes. For example, teamwork must be redefined. The foundation of a team approach is effective dissemination of information within the correct context, but few companies are good at this aspect of management.

7. The organisation must be capable of reacting appropriately to incoming information. This includes quickly spotting trends and addressing issues before they become problems, as well as interpreting the information coming in to make earlier, better strategic decisions.

## THE BOTTOM LINE

The real test of any system is the end results, in this case faster submission of regulatory applications. As we have observed from EDC systems, it is possible to improve individual components without improving overall performance if the bottleneck lies elsewhere.

In the final analysis, appropriate use of technology is the keyword. Use of technology that is inappropriate or fails to deliver on its promise is no longer acceptable in the rapidly changing business environment now faced by the pharmaceutical industry.

Just as other industries such as the automobile industry has markedly changed in response to such a challenge, we believe that the pharmaceutical industry will in turn undergo a profound change in the next few years based on technology adoption.

Charles Darwin's prophetic conclusions of more than a century ago remain remarkably true today: "It is not the strongest of species who survive, nor the most intelligent, but the ones most responsive to change."

## THE AUTHOR

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