

E-clinical providers are fighting to reposition and re-assert themselves amid changing customer needs and a dizzying pace of technological change.

Peter Mansell reports

Tilting in a new direction

The eClinical sector has expanded far beyond its roots in electronic data capture to offer technology platforms across the spectrum of clinical trial design, execution, monitoring and analysis.

In fact, the industry has managed to weather what has been described as “frankly the worst period of pharmaceutical development in probably two generations” partly because the new technologies, such as remote monitoring, project management and global site enrolment, are starting to infuse clinical operations.

So while technology sectors generally experienced “some decline” during the recession, the impact “was not significant in the eClinical space, and purchase of these solutions has continued”, says Steve Kent, president of Parexel subsidiary Perceptive Informatics. Indeed, the overall market for eClinical solutions is projected to grow at 10% a year through to 2013.

But what did look like a potential game-changer, and a harbinger of further consolidation for eClinical players, was software giant Oracle’s recent acquisition of Phase Forward, the US-based provider of data management solutions for clinical trials and drug safety. One striking element of that deal was the speed and determination with which Oracle – traditionally an “IT installation company” – has muscled into the eClinical space.

Oracle only set up its health sciences global business unit in June 2008. By March 2009, when it bought safety solutions provider Relys International, the company already claimed to have

“the industry’s most comprehensive suite of software applications for clinical development”. Now, bolstered by its acquisition spree, the company’s integrated capabilities stretch all the way from Phase I trials through regulatory filing to post-approval monitoring.

Yet if this promise of ‘end-to-end’ services beyond the scope of clinical or even post-marketing trials throws down a gauntlet to Oracle’s competitors, they remain sanguine.

The value of integration?

This convergence between technologies and services is what would be expected in any efficient, data-intensive business, says Kent, who defines the current landscape as “moving from a series of best-in-class solutions in each of the verticals to a market where these solutions converge and integrate”. This trend “is clearly underway in the clinical trials technology market, and is a driving force behind the rapid consolidation we have seen over the past two years”, but he stresses the company’s belief that the market opportunity for

pure technology companies in clinical development is limited.

Chief executive officer of PharmaVigilant Jim DeSanti’s view of integration is that “there are people who are doing it and people who are talking about it”. When he set up PharmaVigilant in 2005, the vision was “not just to build another EDC company but to build what we felt was a truly integrated technology company”. The contrast is “an amalgam of different systems that people integrate – which is really no different from what pharma has been buying for decades”. These “cobbled together” systems will eventually stumble in the market, he believes.

Phase Forward had “a fairly robust footprint of integrated solutions to begin with” and has used acquisitions to “pull in the pieces they did not have”, DeSanti notes. Oracle, on the other hand, had already “bought in a lot of disparate systems” and Phase Forward “is just another piece of that”.

It is certainly more difficult to integrate disparate technologies, “since the underlying architectures are

What is eClinical?

Originally, eClinical was used to refer to any technology application in use within a clinical trial. The usage of the term eClinical has evolved to a more specific context focused more on business process than on individual technologies.

Increasingly, the term is being adopted to convey the concept of integrated technologies utilised in clinical trials – technology products working together as solutions, sharing data, eliminating duplication of activities, and streamlining the use of multiple technologies for end users. Therefore, an example of an ‘eClinical solution’ is the combination of EDC and interactive voice response systems where common data are shared in a way that eliminates the need for users to enter the same data or perform the same action in both applications. The shift in the definition of eClinical has been a natural part of the industry’s evolution to seek better ways to utilise multiple technologies together within a clinical trial.

(Source: Wikipedia)



Case study

Oracle gathers pace in healthcare

The acquisition of Phase Forward gives Oracle a lot more to play with, notably a SaaS (Software as a Service)-based integrated clinical research suite that incorporates electronic data capture, interactive response technology, data and statistical analysis platforms, safety services and electronic patient-reported outcomes.

With the Health Sciences Global Business Unit it set up in June 2008 already encompassing clinical trial design and management, healthcare data, clinical and healthcare analytics, and healthcare interoperability solutions, the acquisition was also couched in a broader healthcare context.

Phase Forward and Oracle products would both accelerate delivery of innovative therapies and help control healthcare costs by giving customers "greater insight into patient outcomes during drug development and during the provision of healthcare services", Oracle declared.

different", Kent acknowledges. "Even if technology pieces are acquired, the effort to make them interoperable and aligned to a common endpoint takes time and diverts development effort away from other enhancements to the product line".

The "rhetoric" coming out of Oracle-Phase Forward is of "pulling together the data within a clinical trial and making it into one-stop shopping". To date, though, Oracle has really taken a vertical approach to the clinical trial process, Datatrak's Laurence Birch, chairman and chief executive officer contends.

The ultimate ambition in realising a fully integrated environment is to streamline workflow and support real-time data interchange to help companies make better, faster decisions that mean trials are run more efficiently. In a recent survey of biopharmaceutical professionals by Perceptive Informatics most respondents (71%) said they have integrated, or are in the process of integrating, a number of systems to improve processes and overall trial data accuracy. A smaller group of respondents (21%) claimed to see the value of integrating their systems, but had not yet done so. Only 8% had developed established integration standards they expected technology vendors to adhere to.

From tactical to functional

What is now emerging in eClinical, Kent believes, is "a genuinely convergent solution" whereby the individual functionality of the old application silos becomes less important and the integration between the different components and the attendant workflow becomes far more critical in how useful the system is to the user.

This also suggests the sector may be tilting in the same direction as the CRO market by graduating from tactical outsourcing to functional and strategic relationships along the lines of the Lilly-Covance tie-up.

Certainly Birch believes a more strategic emphasis will come to eClinical. Its role, he says, is to adapt to the marketplace: "We're a back-office operation... the people who are developing the drugs and the medical specialists who are developing the testing, they're at the forefront... First find out how the sponsor companies want to manage their trials."

Kent regards strategic relationships in the eClinical space as a natural outgrowth of what is happening with CROs; essentially this means closer integration between service provision and technology, allowing firms to generate more benefit to sponsors.

Part of bringing greater benefit means extending forward into the post-approval market. "You want to make

sure the Phase III data that brought your drug to market is [supplemented with] lots more data related to an open-market sell, that you're constantly evaluating what's happening – particularly the safety aspects," Birch explains.

And in the wider healthcare context, Birch notes that "right now there's a disconnect between the clinical trial process and dealing with real patients who have other healthcare needs. Is there a way for us to take the benefits of eClinical data management and move from the testing stage to the clinical stage?"he asks.

Though consolidation "is a natural event in any industry that mirrors ours" the true value of these strategies remains uncertain. But what is clear is a bottom-up approach is no longer an option in the fast-paced world of eClinical. "The systems in the market today from the larger established vendors are sophisticated applications with many thousand years of software engineering in them," Kent comments, making it unlikely that any company starting from scratch will be able to develop new innovative functionality that will enable it to catch the leaders.

With the pharmaceutical market witnessing a unique set of challenges in R&D and clinical, there would appear to be no better time for eClinical providers to show how they can assist in pharma's pursuit of the ultimate in clinical trial efficiency. **PT**

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- EDC now used in nearly 60% of clinical trials

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