The END of the PAPER CHASE

Responses to an ongoing survey and face-to-face discussions with executives from pharmaceutical and biotech companies reveal their greatest concerns and hopes as they begin to streamline the clinical-trials process.

IN AN EXCLUSIVE WITH PHARMAVOICE, ELLEN SEMPLE, VP, MARKETING, CB TECHNOLOGIES INC. EXPLAINS WHY YESTERDAY'S ARGUMENTS FOR PAPER PROCESSES NO LONGER RING TRUE

Ellen Semple

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It's no secret that research is the foundation on which sound business decisions are made.

As is the case with all product-related markets, there is no better platform for success than understanding needs, usage trends and behaviors, and adoption drivers in technology-related products.

For anyone not familiar with electronic data capture (EDC) software, this application harnesses the power of technology and the Web to streamline clinical-trial processes for pharmaceutical, biotech, contract research organizations (CROs), and medical-device companies. EDC technology helps those involved in clinical trials to electronically collect, organize, and send clinical-trial data from investigators sites to a central database. Although industry estimates indicate that nearly 95% of trials currently are conducted using paper-based processes, the majority of leading pharmaceutical organizations are, at minimum, piloting EDC in clinical trials. Industry analysts such as Silico Research, Forrester, Gartner, and Frost & Sullivan report that some industry innovators plan to go 100% electronic within the next few years.

According to Ellen Semple, VP marketing at CB Technologies Inc., an independent research report commissioned by the company found that the emerging EDC market (currently estimated at about $60 million) is expected to soar to $1.3 billion by 2010, with adoption potentially estimated at 50% by 2005 (more than 10 times what it is today).

But the road to "2005" will be traveled only by proven EDC solutions that demonstrate value to sponsors and users. Specifically industry

insiders agree that EDC providers will need to address the demands of both clinical-trial sponsors and the technology users.

"The winning solutions will increase the efficiency of trials, integrate flawlessly with existing technology investments, and employ technologies that are secure and user friendly," Ms. Semple says.

A CLOSER LOOK

Behind each of these EDC mandates there is a need to increase efficiency in clinical trials and time and money.

"These are critical enemies of successfully bringing drugs to market," Ms. Semple says. "Any delay in a clinical trial can equate to loss of 'first mover advantage,' which generally correlates directly with higher volume and revenue potential. Also, as a compound painstakingly progresses through the various phases toward approval, its cost of failure rises substantially."

Ms. Semple says the sheer volume of trials is overwhelming. According to Accenture's report "Speed to Value," the industry's goal is to triple new chemical entities by 2008. With persistent performance and profitability pressures bearing down on pharmaceutical organizations, it is crucial to increase the number of drugs produced and successfully marketed.

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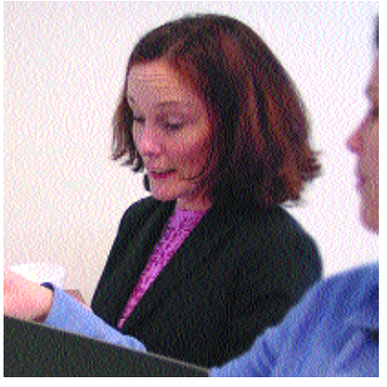

"Time to market is not just an internal process, reengineering and performance are big issues for pharma," she says. "With the escalating number of patients per trial, pipeline growth, and NDA filings, trial capacity has not kept up. According to PhRMA, due to sheer volume and heightened scrutiny (the FDA places roughly 9% of submissions on hold due to safety concerns), the FDA is taking more time to approve fewer drugs. In fact, the FDA approved 27 new drugs in 2000 compared with 35 in 1999 and 30 in 1998. In addition, the average approval time for these drugs was 17.6 months in 2000 versus 12.6 months in 1999 and 11.7 months in 1998."

ENTRENCHED PROCESSES

According to Ms. Semple, the industry is ripe for process improvement via effective use of information technology ranging from trial recruitment and EDC, to data warehousing, data mining, and Web-enabled research.

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What's holding back a more streamlined approach to clinical trials? "This situation is very similar to a cumbersome, paper-driven environment that drove the financial services sector less than a decade ago," she says. "However the financial services sector has emerged to become what many consider a best-practice case study in harnessing technology. Efficiencies gained through use of technology in the this sector are now widespread — funds are wired internationally and instantaneously every minute of every day. A truly global market has arisen thanks to highly secure networks. And financial services giants demonstrate the efficiencies and effectiveness of harnessing technology every day."

A MATTER OF TIME

Many pharma executives clearly see the need to increase efficiencies in some part of the clinical-trial process. At a high level, executives are concerned by the need to maximize return on research and development investments. On a more granular level, Ms. Semple says, executives are concerned with improving data quality, improving query processes, and speeding up back-end data processing. Viewing, capturing, and analyzing cleaner data faster are overwhelmingly a critical priority.

Ms. Semple cites a F.A.C./Equities report, which states successful companies will use the Internet and related information technologies to streamline the clinical-trial recruitment process of patients and investigators; lessen reliance on paper and manual entry in the research process; allow real-time data sharing among sponsor, investigator, and patient; and submit NDAs electronically to the FDA, among other tasks.

"Sponsors aren't alone in wanting streamlined processes," she says.

When it comes to EDC, Forrester's July 2001 study reports of a sub-

sample of 101 clinical professionals using Web-based EDC found that 61% had a strong-to-moderate preference for Web-based EDC. Only 15% of the subset showed a strong-to-moderate preference for pen and paper-based trials.

USER ACCEPTANCE

"The old EDC arguments such as 'users just don't want it!' seem to be fading," Ms. Semple says. "While there are, and probably always will be, those involved in the daily conduct of clinical trials who may never embrace technology, undeniable market and productivity pressures inevitably will force abandoning of paper trials for the Web.

"It's important to note that clinical-trials professionals don't dislike technology; in fact, they are waiting for the signal from above," she says. "Generally, data point to the fact that greater in-office efficiencies, fewer monitor visits, reduced queries, and related cost savings drive this openness."

The true success of transitioning clinical-trial data collection to EDC lies in how well the users embrace the technology. In CB's survey, user acceptance topped the list of concerns in using an EDC system (69% of respondents), and this attitude is reflected again and again by clinical executives.

But the second-highest concern is system performance, and these issues are very closely tied, Ms. Semple says.

Executives know that to truly drive user acceptance, the technology must be reliable and work when users need it. System performance drives at the heart of ease of use for the end-user and ultimately impacts how well users embrace a system. In fact, CB's data indicate that users at the site are concerned principally about how easy it is to enter data and answer queries.

"In today's fast-paced society, we have little patience for things that don't move along as expected," Ms. Semple says. "As bandwidth has become more ubiquitous (T1 lines at work, cable modems at home), we have high expectations for the speed of software applications. But depending on the architecture of the software used, collecting and transmitting clinical data over the Internet doesn't always happen with the push of a button. In meetings with clinical executives, a running theme was using EDC technology eventually to help recruit and retain the best investigators. But for this to happen, executives said they look to vendors to provide a technology with excellent performance that prevents excessive downtime due to Internet performance. By eliminating this frustration for the sites, the overall EDC experience greatly improves."

ELECTRONIC DATA CAPTURE TRENDS AND STATS

- **Although industry estimates indicate that nearly 95% of trials are currently conducted using paper-based processes, the majority of leading pharmaceutical organizations are, at minimum, piloting EDC in clinical trials. Industry analysts report that some industry innovators plan to go 100% electronic within the next few years.**
- **When it comes to EDC, Forrester's July 2001 study reports of a sub-sample of 101 clinical professionals using Web-based EDC found that 61% had a strong-to-moderate preference for Web-based EDC. Only 15% of the subset showed a strong-to-moderate preference for pen and paper-based trials.**
- **The emerging EDC market (currently estimated at about $60 million) is expected to soar to $1.3 billion by 2010, with adoption potentially estimated at 50% by 2005 (more than 10 times what it is today in just three years).**
- **CB's survey found user acceptance topped the list of concerns over using an EDC system (60% of respondents) and this attitude is reflected again and again by clinical executives. The second-highest concern is system performance.**
- **According to PhRMA, due to sheer volume and heightened scrutiny (the FDA places roughly 9% of submissions on hold due to safety concerns), the FDA is taking more time to approve fewer drugs. The average approval time for these drugs was 17.6 months in 2000 versus 12.6 months in 1999, and 11.7 months in 1998.**
- **Successful companies will use the Internet and related information technologies to streamline the clinical-trial recruitment process of patients and investigators; lessen reliance on paper and manual entry; enable real-time data sharing; and submit NDAs electronically.**

INTEGRATION WITH EXISTING SYSTEMS

Pharmaceutical organizations are committed to moving beyond stand-alone or pilot EDC implementations. Industry leaders are focusing on the tremendous value they see in creating a fully integrated clinical IT environment — thus maximizing investments in other technologies.

According to Ms. Semple, pharmaceutical executives consistently cite the need to integrate with various existing investments in back-end systems including data-management systems such as Oracle. (According to a recent Oracle media release, 65% of life-science companies are running Oracle technology.) Other systems investments where executives demand EDC integration include lab data, clinical-trial management systems, dictionary management systems, and patient diary technologies.

According to Ms. Semple, fully integrating these technologies brings a multitude of benefits, including scalability, speed, quality, security, and improved workflow.

"Systems integration for companies can be difficult, time-consuming, and expensive," she says. "While no single EDC system will come as an immediate plug-in to existing applications, it's clear that sponsors are looking to vendors to provide software that has taken systems integration into consideration by having an open architecture."

While the majority of companies are still using paper in some capacity in the clinical-trial data-collection process, success and growing confidence in EDC systems are driving adoption. Executives clearly see the benefits, and with the pressures to improve processes and cut development time, they are actively pursuing opportunities to save time and money. Like the example of technology adoption in the financial services industry, success begets success and efficiencies gained through use of technology will continue to build momentum for applications like EDC. As pharma and biotech industry leaders examine the opportunities that advance organizational efficiency and value, proven, user-friendly EDC technologies will surely be drivers of tomorrow's medical innovations. ✦

PharmaVoice welcomes comments about this article. E-mail us at feedback@pharmalinx.com.