

It's Not All About "e"

Paul Cisternelli

For 25 years or more, pharmaceutical executives have been inundated with promises of the latest technological breakthroughs that will speed up the clinical trial process. It would be a safe bet that, if you polled a group of them, any one of them would have heard this enough times to recite it from memory:

Our new [fill in the blank with your favorite new technology] will help you speed up the clinical trial process. By increasing the speed at which you currently process data, this new technology will move your trials to NDA faster, thereby maximizing the marketing time under patent. Given the fact that blockbuster new drugs can earn \$1 million to \$5 million per day, our new technology could generate tens of millions of dollars in increased revenue.

Thirty years ago, the high-tech breakthrough was the popularization of mainframe computers and centralized computing. Then came the first commercial software packages for advanced project management. Then the PC revolution decentralized systems and empowered workers to perform more

efficiently, which started the first great "gold rush" to electronic data capture. This was followed by more commercial software from imaging to document management. Then we all jumped on the Internet and World Wide Web bandwagon, returning to the concept of centralized systems.

Now we have the latest, and potentially the most powerful, breakthrough: "e." This new advance is so big that it is hard to define. "eBusiness" is used to describe many different things: application service providers (ASPs), the Internet, a browser, wireless, or whatever you want it to describe. As long as it has an "e" in front of it, it must be good. The latest application of "e" in the pharmaceutical industry is EDC (electronic data capture). As in, "EDC will help speed up the clinical trial process by enabling the sponsors to capture data faster, thus getting to database lock sooner and thereby generating tens of millions of dollars in increased revenue."

How many people really believe this? If I had a nickel for every time this type of pitch was made, I'd be retired and playing golf every day. I ought to know, because I've made this pitch more than a few times myself

over my 17 years as a high-tech marketing executive.

It is not that these new technologies are not useful. Through the adoption of new technology, business processes have been greatly enhanced, even transformed, over the years. But just as "e" is only one letter of the alphabet, the solution to enhancing the clinical trial process cannot be based on any one element. Simply collecting data faster does not necessarily result in faster trials. Real bottom-line enhancements will come from a more comprehensive view that enables new processes to evolve. Is EDC, or "e," a part of this solution? Absolutely.

Technology in drug development

During the development process for new drugs, biopharmaceutical companies use many different technologies. Typically, technology applications are narrowly focused to meet the needs at a specific point in the process. In the early stages of drug development, applications may be designed to perform target analytics and modeling to assist during the discovery stages. As the process enters the clinical phases, applications focusing

We don't call phone calls "e-conversations." Let's start taking "e" for granted and look instead at the features we really need in clinical technology applications.

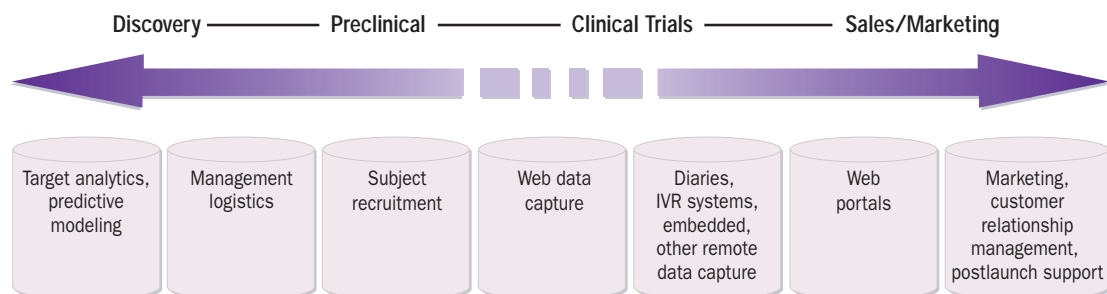


Figure 1. Technology applications used during drug development.

on site development and subject recruitment become important. As the process advances and the trial gets underway, various applications might be used to capture data, such as subject diaries, Web-based systems, interactive voice response (IVR) systems,

cations alone will significantly improve the overall project is a pretty bold statement. The critical path for projects differs from one study to the next. It would be very difficult to predict which specific application area would be the determining factor in improv-

It's just the Web

Somewhere along the line, it seems, we confused the communication vehicle for delivering applications with the actual applications. The Web is a great tool, no doubt about it. But let's not confuse the technology with the

capture applications without reiterating them here. The key point is this: If you analyzed the 50 or so different EDC applications on the market today, the main differentiator would not be the Web; it would be the features of the applications.

The Web is ubiquitous. It is quickly becoming a commodity. Eventually, although not nearly as fast as most vendors would like, all trial data will be captured electronically—if not on the Web and the Internet, then through telephones and wireless PDA (personal digital assistant) devices. In the not-too-distant future, it is even more likely that most data capture will be received directly from implanted microprocessors. Then we will really “speed up the clinical trial process by enabling the sponsors to capture data faster, thus getting to database lock sooner and thereby generating tens of millions of dollars in increased revenue.” But you've heard that before.

It's just the Web. Useful applications dealing with subject enrollment issues, effective

Confusing the technology with the application is like confusing the telephone with the conversation.

direct-from-device, lab data, or traditional paper. Regardless of the means of capture, data is typically gathered into a data management system for processing and eventual submission to the regulatory agencies for approval. In the case of those fortunate few drugs that are actually approved, more applications are then used to help market and sell the new products.

It is not uncommon for biopharmaceutical companies to use 10–15 different applications during the drug development cycle (Figure 1). So, making the claim that any one of these appli-

ing the overall results.

These claims are now being further exaggerated by simply inserting the letter “e” in front of the application. “eTrial Management” will speed up the development process. “eData Capture” will speed up the development process. “eWhatever application” will speed up the development process.

I don't want to appear too cynical regarding this new technology era—it's actually my job to promote it. My objective here is simply to quell the hype that has developed around “e,” the latest point along the technology evolution timeline.

application. That's a little like confusing the telephone with the quality and value of the conversation.

At the end of the day, the goal of a pharmaceutical company is to develop a new drug. A big part of this effort is collecting and managing data from the subjects involved in the studies. Without question, the Web can enhance this process. It can minimize, if not eliminate, the challenges of collecting hard copy CRFs from the investigators, shipping them to sponsors' sites, and entering them into the data management system. I think we can all agree on the benefits of Web-based data

continued on page 64

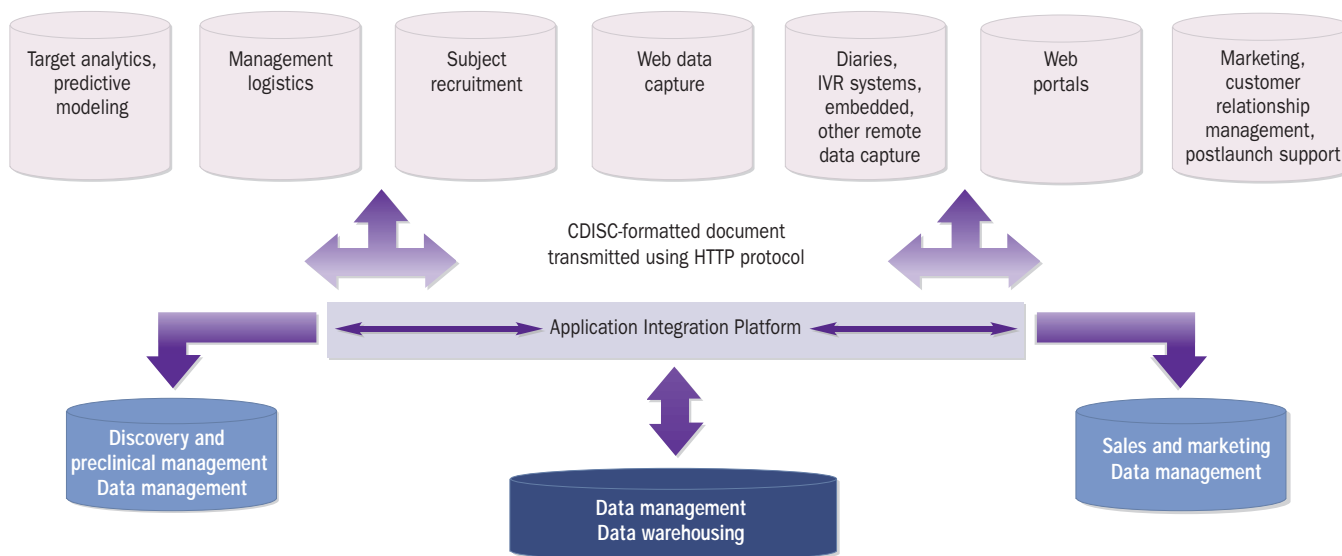


Figure 2. With the aid of emerging technologies and standards, all the applications used in drug development will communicate seamlessly through an application integration platform.

Launches

Taratec Development Corporation (Bridgewater, NJ), a provider of integrated e-technology and regulatory solutions for the life sciences industry, launched Taratec University, an educational environment designed to help pharmaceutical, medical device, and biotechnology companies improve corporate training programs and to comply with FDA regulations.

BBK Healthcare, Inc. (Newton, MA) released a guide for providing information on recruiting and retaining subjects for clinical trials. The resource, *A Guide to Patient Recruitment: Today's Best Practices and Proven Strategies*, covers such topics as budgeting and contracting, ethics and confidentiality, media strategies and tactics, recruiting subjects on the Internet, retention and subject satisfaction, and recruiting

pediatric subjects.

Aventor (Washington, DC), a consulting company, has entered the medical technology industry. The company provides integrated, single-source solutions for regulatory, reimbursement, and political challenges that influence the introduction of new drugs, medical devices, and biologics into global markets.

The Coalition of National Cancer Cooperative Groups, Inc. (Philadelphia, PA) launched the Web site www.cancertrials.org to help increase the number of adult subjects participating in cancer clinical trials. The site offers a list of available cancer trials being conducted by the seven cooperative groups in the coalition, basic information on clinical trials for potential subjects, and information on patient advocate groups.

e-Trials

Research Triangle Institute (Research Triangle Park, NC) released version 8 of its statistical analysis software SUDAAN. The new version features expanded analytical functions and improvements in the ability to coordinate with other packages such as SAS and SPSS.

QED Solutions, Inc. (McLean, VA), a provider of drug safety management products, and **Relsys International, Inc.** (Irvine, CA), a provider of fully validated software solutions for the pharmaceutical and medical device industries, entered into a strategic alliance to make QED's Qscan and Relsys' Argus Safety and EasyTrak software available to biopharmaceutical companies for monitoring adverse events and for worldwide regulatory reporting in real time.

CDC Solutions, Inc. (Consho-

hocken, PA) and **First Consulting Group** (Long Beach, CA) formed an alliance to provide an integrated content management solution designed to meet the business needs of submission assembly and publishing in the life sciences industry and to meet the regulatory guidelines for electronic submissions, including 21 CFR 11 compliance. The solution will combine the former company's EZsubs for submission publishing with the latter's FirstDocs for research and development.

Phase Forward Incorporated (Waltham, MA) and **Relsys International, Inc.** (Irvine, CA) entered into an agreement to integrate the former company's InForm Web-based clinical trial management platform with the latter's Argus Safety surveillance software for pharmacovigilance.

QUMAS, Ltd. (Cork, Ireland) and **Liquent, Inc.** (Fort Washing-

Guest Editorial continued from page 26

coding applications, intelligent analysis tools, dynamic workflow applications that process and correlate the data—these are the systems that will enhance the clinical trial process. The fact that they are delivered via the Internet will be taken for granted. The important new breakthroughs will be in the underlying technologies that enable all these disparate applications to communicate seamlessly with each other. The early efforts of the Clinical Data Interchange Standards Consortium (CDISC) in designing a standard XML format for the clinical research industry may represent the beginnings of this next era. New application architectures that enable single-point data entry and validated sharing of data soon will be available. This will allow companies to select the best possible applications for their

specific needs while gaining the efficiencies of a common data structure (Figure 2).

It's not all about "e"

It's not all about "e." It's about the features and functions of the various applications and how they enable people to perform their jobs better and faster. In the years to come, the concept of EDC—electronic data capture—will seem a bit strange. The important part of the statement is data capture. Soon we'll take it for granted that it is done electronically. If I'm working in my office in Boston and need to have a conversation with a colleague in Seattle, of course I'm going to use the phone, but I don't call it "e-conversation."

Paul Cisternelli is vice president, marketing and business development, at Clinisoft Corporation, 10 Maguire Road, Suite 110, Lexington, MA 02421, (781) 778-3700.

Minimalist Mindset continued from page 30

The article "Minimum Requirements for PIs" (*Applied Clinical Trials*, July 2000) prompts a consideration of how minimum standards may also be part of the mindset of a sponsor or contract research organization. Certainly the regulations are written in such general, nonspecific terms as to permit wide latitude in the conduct of many aspects of the research process—clinical investigator selection; clinical study initiation, conduct, and monitoring; and data collection, correction, and reporting.

When no regulation *specifically* requires a particular practice, every sponsor or CRO (contract research organization) must weigh the value of additional training, additional oversight, additional subject safeguards, and additional costs against the time and resources (budgetary, personnel) to complete a study. This article examines some areas in which adopting a mindset for maintaining only minimum standards is counter-productive toward the goal of generating quality data. Specifically, quality data is essential to produce a dossier that can withstand the rigors of review by health authorities—for example, FDA (Food and Drug Administration) and EMEA (European Agency for the Evaluation of Medicinal Products)—and to protect subjects' rights, welfare, and safety. This article addresses three areas (protocols and case report forms, information provided to the subject, and protocol waivers) where a sponsor's or CRO's minimalist mindset can have serious negative effects, and where minor efforts to improve processes can reap great rewards.

Protocols and case report forms

Protocols. A study protocol provides directions and instruction for