Crossing THE CHASM

John F. Murray

PROCELA PARTNERS' STEPHEN RHYS THOMAS, PH.D., SENIOR PARTNER, LIFE SCIENCES INNOVATION AND TECHNOLOGY, AND JOHN F. MURRAY, SENIOR PARTNER, LIFE SCIENCES AND ICT, AUTHORS OF A RECENT RESEARCH REPORT ON EDC, DISCUSS WHAT EDC PROVIDERS NEED TO DO TO SECURE THEIR PLACE IN THE MARKET.

Dr. Stephen Rhys Thomas

I n the figurative but practical language of Silicon Valley marketing guru Geoffrey Moore, the leading EDC companies have "crossed the chasm" from the fluidity of the early adopter market to the more established needs of the mainstream market. This may be the dream of many an EDC company CEO, but it is not an easy transition, for as Mr. Moore's theory explains, many of the characteristics required for success in the early market change or even reverse in the main market phase.
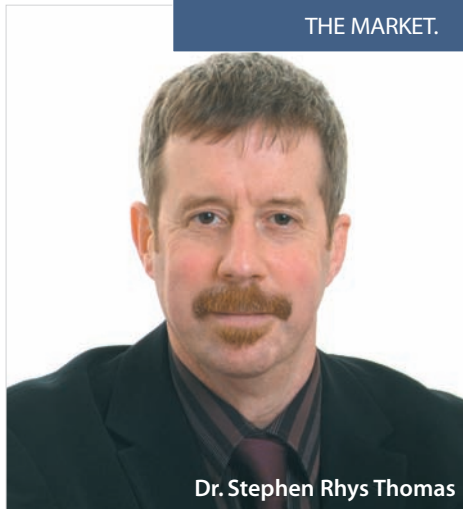
According to industry experts John Murray and Stephen Rhys Thomas, Ph.D., of Procela Partners, the transition of EDC from a try-out technology to an increasingly standard process-technology combination swept in during 2006, with all the leading vendors reporting major upswings in business. Based on the combined revenue of the leading players and the lengthy "tail" of small players, they estimate that the annual market for EDC in 2007 may nudge $750 million in direct software and services. Customers are switching their concerns from not being first to not being last.

"The swing to EDC has been driven most visibly by the established and recently arrived enterprise-class vendors — Phase Forward and Medidata — achieving a critical mass of enterprise-level deals with some of the largest players in the industry," Dr. Thomas says.

"If the domino theory applies, as it has with virtually all major software success stories in this industry — Oracle, SAS, MDL, Documentum — then EDC has passed its conditional stage, and the concern for sponsors now flips from not wanting to risk being first to not wanting to be left behind; actually everyone wanted to be second, not first," Mr. Murray says. "This brings us to the question of selection."

THE SEVEN DEADLY SINS OF SELECTION

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Although there's nothing about EDC in the Bible, biblical logic has plenty to teach about the Seven Deadly Sins vendors can commit in the eyes of the customer and the customer impression created.

vendors can commit in the eyes of the customer. (See chart on next page.)

"Of course, these sins are not the exclusive preserve of vendors, but the end goal must be to establish mutual trust," Dr. Thomas says.

"All aspects of the relationship, including negotiation on price, should reflect the intended quality of the relationship," Mr. Murray adds. "This may sound like 'motherhood' and may appear to be common sense, but its perfect execution is not as common as one might expect."

A significant aside at this point is the observation that traditional procurement processes delay the implementation of systems and hence the commencement of return on investment (ROI). Grinding negotiations designed (by the purchasing/sourcing func-
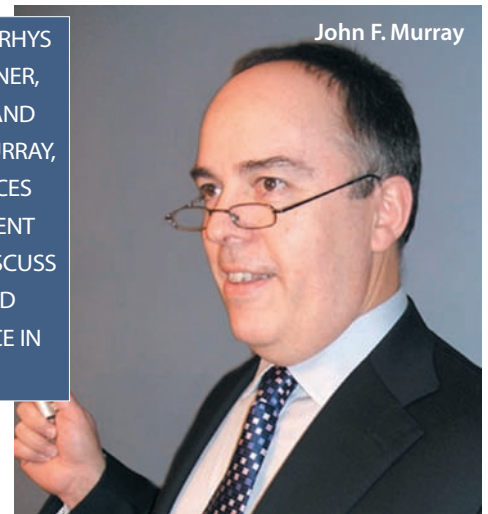
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tion) to extract the maximum product/service discounts hamper the business functions from realizing the benefits that should flow from adopting/exploiting new systems or services.

"Brutal discounts may seem superficially smart, but they can produce a spectacular goal if they hit the vendor's product development budget too hard," Mr. Murray says.

"This is ironic, given that the industry constantly has to explain the importance of good profit margins for healthy product development," Dr. Thomas says. "This is doubly ironic, in that along the corridor from clinical development will be whole departments of licensing or scientific affairs whose life blood is striking deals and partnering."

There are signs that enlightened procurement executives are realizing this and are taking steps to introduce a sourcing regime that facilitates a synergistic contractual interlock between the evaluation, pricing, and implementation phases of a project.

This is a positive trend that the two partners hope to see evolve.

THE SHAPE OF THINGS TO COME

EDC will continue to show rapid growth for

NOW THAT EDC HAS PASSED ITS CONDITIONAL STAGE, sponsors don't want to risk being left behind and are evaluating the right solution for their needs.

the next few years; existing enterprise players will grow and new players will establish themselves; Procela partners expect that packages and flexible deployment services will continue to dominate as EDC customers further flex their requirements for internal or external on-demand capabilities.

"Today's leading vendors are likely to remain in the top tier — they 'have it to lose' — though their relative positions will continue to evolve through vigorous competition and challenges from new or rising entrants," Dr. Thomas says. "Partnering and acquisition will continue apace in the quest for differentiation."

Furthermore, the partners believe that the diffusion of CDM functionality into EDC systems will continue, resulting in the continued decline of CDM-centric architectures, early retirement for installed CDMs, and the rise of repositories.

"There is an urgent need for an architecture supporting real-world, back-end integration; otherwise, orphan applications, such as CTMS, will struggle to provide the management dashboard necessary for the monitoring and marshalling of resources," Dr. Thomas says. "Disintermediation of the paper-based CROs appears increasingly likely, as electronic outreach to investigators and sites improves."

The partners also expect that integration will become more and more of an issue as the front-end-driven EDC architectures progressively stress existing infrastructures.

Meanwhile, according to the two experts, the absence of a master architecture or solution for the core platform remains a gaping hole.

NEXT-GENERATION TRIAL ARCHITECTURE

One clear requirement that is not in evidence today is a common overall vision of where EDC and the next-generation trial architecture might be headed, the partners say.

Their 'wouldn't it be nice if' wish list would include the following.

- A flexible, single-interface access to all key operations and operands in the clinical domain.
- A seamless repository with guaranteed integrity.
- An integrated next-generation clinical trials architecture that links patient, investigator, and sponsor for acquisition, control, and analysis and incorporates smarter (faster and/or more decisive) trial technologies with adaptive or predictive capabilities.

The partners see some of the desired facets of this vision are already falling into place, namely there is more certainty and stability in the vendor space and that enterprise-class infrastructures can be accessed at acceptable costs.

Mr. Murray maintains that there is more to be done on the investigator/site level. He adds that the analysis of performance parameters across trials and therapeutic areas is still a distant vision.

AFTER EDC: ELECTRONIC INVESTIGATOR INCLUSION (EII)

The general fluidization introduced by EDC begs questions of old processes and orga-nizational conventions, as formerly isolated data silos are inevitably connected. This extends outward, from the sponsor organizations, as well as across traditional internal silos.

"It may be that EDC sets the scene for new levels of investigator inclusion; this would seem to be necessary, as the vast majority of clinicians never participate in more than one trial," Mr. Murray says. "Electronic investigator inclusion and electronic recruitment and retention are natural outreach elements of a future e-suite."

The general architectural drift from internally focused data management — CDM — through boundary-focused data capture — EDC — to externally focused investigator support would seem to be a natural progression, the partners conclude.

Procela Partners, which operates globally from headquarters in Dublin, Ireland, bridges the chasm between technology and business, scientist and entrepreneur, vendor and customer to accelerate the generation of strategic value from the development, licensing, uptake, and application of new therapeutics and enabling technologies. For more information about the company and the 'EDC and After' report, visit procela.com.

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PharmaVOICE subscribers are eligible to purchase the research report "EDC and After: The Quest for Faster Adoption" at a discount price of $950. Use code PV_Pro07 when contacting the author.

SEVEN DEADLY SINS		
SIN	**DEFINITION**	**CUSTOMER IMPRESSION**
PRIDE	The cardinal sin, convinced that the vendor knows best and deserves an audience, does not listen to or ignores the client brief, and substitutes their opinion of what the client needs.	Arrogant
ENVY	The next greatest sin is to claim falsely an important function or feature that a competitor may have or to denigrate the value of such a feature.	Desperate or untrustworthy
SLOTH	Failure to respond to a reasonable request in a timely fashion conveys the impression that if this is the "dream," what will the "reality" be like?	Slack before the deal equals absent after the deal
GLUTTONY	Over ambitious scoping of a project will simply appear manipulative.	Will always be untrustworthy
WRATH	Throw-away comments or patronizing remarks can easily be interpreted as aggressive and arouse the reciprocal wrath of the customer.	From overly familiar, through casual, to rude
GREED	The most tempting sin, excessive pricing, never wins friends.	Every subsequent deal or extension a potential rip-off
LUST	Fortunately, we have not yet seen a case of this.	Would-be sleaze