

Do More with Less: The New eRO Model

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Clinical departments are very expensive to run and maintain. They exist primarily to gain access to markets through product approvals. As corporate revenues are generally closely tied to or even dependent on new product releases, “tried and true” clinical methodologies tend to be preferred. They are perceived to entail less risk of failure. Unfortunately, the “tried and true” tends to be the least efficient, most time-consuming, and very headcount intensive—in other words, expensive. Increasing demands for outcomes-based evidence medicine from both users (physicians) and payers (CMS, insurers) have increased pressure on clinical departments and corporations alike.

These two factors – e-clinical expense and evidence – pose the greatest challenges to corporations in marketing medical products in the United States. At present, the current corporate mandate in the pharmaceutical industry is “do more with less,” and the hitherto untouchable clinical department has been challenged to improve productivity.

Essentially, companies seek solutions to meet the expense and evidence needs, yet remain risk-averse with respect to clinical work process innovation, not wishing – to place product approvals at risk. Stress is the fundamental evolutionary impetus for any organism or system – and the stress arising from the oppositional forces (under the tried and true methodology) of reducing expense while increasing evidence is producing change in the form of the emergence of the “eRO” (electronic research organization).

What is an eRO? An eRO leverages the best of both the CRO and EDC worlds to effect substantial cost-savings through efficiencies and speed to market. CROs have existed for some time, and have tended to essentially replicate the structure and form of in-house departments, such as highly specialized knowledge workers, labor-intensive methodologies, and risk-averse policies and Standard Operating Procedures. CROs are sometimes characterized as expensive, slow, bureaucratic, and inflexible, with a reliance on the “tried and true” to the exclusion of innovation. This is hardly surprising when one failed approval trial can terminate the future of a small company, cause major losses for large corporations, and destroy the reputation and credibility of the responsible CRO.

EDCs, on the other hand, are relative newcomers, characterized by innovation. During the dotcom era, a plethora of EDCs sprang up across the United States, and their function appeared to be little more than paper replacement. They required proprietary software, specific hardware, were difficult to use, had a significant learning curve, and required changes to work flow and practices. Many of the potential cost-savings posited

by EDCs were absorbed in meeting these new burdens. Commonly, the senior management of EDCs had little or no clinical/medical, research, or regulatory training and experience, and were consequently unable to advise sponsors on modifying their clinical work processes to take full advantage of the technology. As a consequence, they were poorly prepared to meet the demands of quality research and enjoyed limited success.

The eRO is emerging as a hybrid of the CRO and the EDC. The eRO marks a paradigm shift in the approach to clinical research-innovation married with expertise producing a “hybrid vigor.” The whole is considerably more than the sum of the parts, and is better positioned to meet the expense and evidence needs better than either CROs or EDCs alone. Customers are demanding increased cost-effectiveness, and hitherto conservative CROs are seeking out innovative EDC partners to remain competitive – the former supplying the expertise, the latter the technology. Conversely, with increasing research experience and hiring of key knowledge worker personnel, some EDCs have in fact evolved into electronic research organizations faster than the CROs. This is not surprising: existing paradigm in CROs has become so ingrained as “the right way” that it is difficult to even propose new methodologies, far less adopt them in favor of the “tried and true.” The eRO derives efficiencies from decreased administrative burden, rapid deployment, and “cleaner” data without proprietary software or hardware requirements.

In summary, when the expertise of a CRO is combined with the potential of EDC-enabled technology, promise becomes reality. Speed, flexibility, lessened risk, and the ability to “do more with less” whilst decreasing expense and providing robust evidence. From such customer needs emerges the eRO – the model for the future.

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¹ J.A. DiMasi, R.W. Hansen, H.G. Grabowski, “The Price of Innovation: New Estimates of Drug Development Costs,” *J Health Econ*, 22, 151-185 (2003).
² P. Bleicher, “Winning at EDC Implementation,” *BioIT World*, www.bio-itworld.com, May 2004
³ K. Koreith, S. Zisson, “CROs, EDC Companies Partnering for eClinical Trials Adoption,” *The CenterWatch Monthly*, 12 (2), 1-10 (2005).