

Functional Outsourcing: a better alternative to traditional outsourcing and EDC By William Claypool, M.D.

The pharmaceutical industry has demonstrated a large and growing enthusiasm for outsourcing many elements of the clinical trial process. For some companies, this is a strategic approach, having made the decision that the outsourced function is not "core" to their business. For other companies, this is a tactical approach to address a short-term need. In either situation, if an outsourced service or technology is clearly better than the prior way of working, it will eventually become part of the routine processes of an organization. This is what is currently happening with an integrated approach to electronic data management.

The advantages of Electronic Data Capture (EDC) have been touted for years. However, the adoption of these technologies has languished far behind that of outsourcing in other areas of the drug development process and would appear at face value to belie the hype. The reality is that large Pharma companies, that can devote significant resources to the implementation of in-house technology transfers, have different needs and capabilities than smaller companies who require a greater service level approach.

EDC vendors have been focused on the capabilities of their technology and not on the needs of the customer. "Buy our software (it's the best!), and build and run your own trials" may be an appropriate mantra for a sponsor who can afford to devote many staff to the technology effort. For most companies, this is not the most cost effective use of resources. Documented case studies indicate the time investment required spans 18 to 30 months. New personnel are required to build studies, operate infrastructure, and train and support the users of the system. And the "one software fits all studies" scenario has proven to be a myth for many organizations, making it likely that an organization will have to master a number of applications to effectively bring the function in-house.

An easier and more cost appropriate approach is to engage a vendor with a mix of outstanding technology and a menu of key services that augment staff skills. Small to mid-sized sponsors are better served with a wider array of offerings that can be provided by a vendor with expertise in the assembly and delivery of each of them. Simply buying good technology doesn't produce great results. And technology alone won't resolve concerns about whether there are sufficient internal resources to manage the processes. This is why many companies are now choosing functional outsourcing solutions that deliver technology expertise and clinical experience as a unified package.

What specific approach to EDC does make sense, since bringing technology in-house requires a significant investment in time, training, and support before the return begins? The answer is that outstanding technology and deep domain experience in the disciplines offered provide the best alternatives to sponsors. When considering clinical data capture services, the most effective approach is known as "Full-service EDC." Full-service EDC couples EDC technology with the tools and talents that make data management and data visualization more available to the sponsor.

By handling all the tasks associated with the system, functional outsourcing solutions like Full Service EDC enhance and augment what other staff members can do. For example, when one person manages a paper-based clinical trial, the span of control is limited because there's so much manual, routine work. However, when one person manages clinical trial data collection electronically, their span of control is greater, and their individual productivity is tremendously enhanced.

Combining clinical data management expertise with the right EDC technology ensures that sponsors get the information they need about their studies faster, with better monitoring of subject safety and overall better control of the study. It is not an all-or-nothing decision -- it is an intelligent choice that empowers the sponsor to put together the right combination of technology and services that most completely meets its needs.

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