The Case for Functional Outsourcing of EDC
Summary:

This white paper is intended for clinical operations managers who are either considering their electronic data capture (EDC) options for the first time or re-evaluating previous decisions. This paper looks at the primary approaches for acquiring, implementing and applying eClinical technologies with a particular focus on choosing the approach that best matches your organization’s goals and capabilities.

To paraphrase advice from the Gartner Group: understand first why you want to source an IT or business service before you decide what to source. Next decide who should do the work and how and where it should be done—internally or externally. Then make the business case.

And from Health Industry Insights – “The premise is simple: The less time and money companies spend on purchasing, implementing, administering, and maintaining IT, the more they will have to focus on core competencies vital to long-term success, like R&D. With drug development now averaging over $1 billion and 12–15 years per drug, every hour and dollar saved truly counts.”

(Commercial IT Outsourcing in the Pharmaceutical Industry, Eric Newmark, February 2008)

The Current State of EDC

Two business models currently make up the usual choices for acquiring EDC: buy technology and figure it out or outsource everything to someone else to figure out.

The technology model includes licensing the development software and creating custom EDC solutions including forms and edit checks. It has delivery nuances, but in this approach, the responsibility for EDC success is ultimately owned by the sponsoring organization and not the EDC vendor.

The outsourcing model includes the previous technology elements, plus services from CROs that supply services to implement and use the software that most technology vendors do not offer. Recently, several large pharma companies have announced broad outsourcing deals for all their clinical trial operations – typically to India or China-based companies, including EDC and related clinical data management processes. This model transfers the responsibility for EDC success to the outsourcing organization.

Both these models have achieved success in large part because of their suitability for the early adopters of EDC—primarily large Pharmaceutical and Biotech companies.

Next we’ll examine each of these choices in more detail.
EDC via the Technology Transfer Model

“The answer to what makes for a good EDC system is … you. You select the system that meets your needs. It must conform to your work flows and technology toolbox. You must capitalize on the system’s strengths and develop workarounds for the weaknesses. You make the commitment, provide the training, and sell the benefits to the rest of your organization. You make it work.”


The EDC technology model is founded on a software sale. Vendors create a software platform and offer tools, training, and support that enable customers to use their software. In practice, few sponsors choose to purchase the software and actually manage the EDC infrastructure directly. Instead, most choose it to be delivered as a vendor-hosted application. For the purposes of this document, when we say ‘in-house’, we are referring to the study start up, operation, and close including the creation of EDC forms and edits, and managing queries and databases.

The major support requirements for the Technology Model include:

- Software and hardware purchase
- Purchasing and managing upgrades
- System / Architecture Validation
- Site Support Services
- Study Builds
- Training and Process Change
- Hiring and Retaining Expertise

Software and Hardware Infrastructure Purchases

The most scrutinized cost for EDC is usually the procurement of the software and related infrastructure. Different vendors employ different pricing models that can make comparison difficult. Unlike an off-the-shelf software product, even ‘enterprise licensing’ entails a per study charge. To this add hosting fees, study design and build fees, or ‘data element’ charges for each field on every form. And this is just for the vendor-hosted implementations.

Software/Browser/ Hardware Upgrades

When a sponsor or CRO brings EDC technology in-house, they assume responsibility for supporting a complex application that touches many other systems, is primarily used by personnel who are not direct employees, and which is the subject of strict regulations.

The infrastructure design must be supported by the software vendor who is prepared to help troubleshoot in the event of problems. Like any clinical system, new patches and versions should be thoroughly tested before putting them into production. Note also that even if the application is a ‘zero footprint’ design, that new and existing browser versions and application interfaces should also be tested to ensure compatibility with each new release. The hardware must be set-up and routinely monitored to assure that the resources are being utilized as expected.
Validation
As with any clinical system, an EDC implementation must be validated. The guidance for validation is well known – it also applies whenever the system is substantially modified (see previous hardware or software upgrades section). Each validation is costly and can take many months. If the design and deployment of the system serves and stores the data across many servers and locations, the sponsor should carefully evaluate the necessity of auditing and validating these ‘transient’ data repositories.

Study Builds
Choosing to use a vendor’s hosted infrastructure may avoid some of the complications previously outlined. There is, however, no choice but to employ the EDC vendor’s tools to create new studies. Commitment to this method of operation requires a significant investment in personnel, training, and time before it begins to predictably deliver good results, as outlined in the following sections.

Building studies requires separate skills than actually using the EDC application or reporting interfaces. Both skill sets must be maintained through experience and regular usage to be effective. If the volume of trials is insufficient, it may be hard to justify dedicated personnel and keep their skills honed.

Efficient study builds often rely on standardized libraries of forms and edits to maximize re-use and minimize resource time. The commitment to utilizing and maintaining standard forms and edit checks requires additional resources that are familiar with all of the current standard guidelines (e.g. CDISC, CDASH, etc.).

Training and Process Change
There are three primary groups that require training to effectively run EDC studies in-house: IT Staff, Clinical Staff, and End Users.

After the initial training, IT Staff and Clinical Staff need to be trained whenever personnel change and when new revisions of software are released. In addition, it is very likely that any pre-existing processes, whether based on paper data collection or another system, will have to be modified for any new technology. Several consulting organizations currently thrive on a steady diet of organizations challenged by this change. Due to these process changes, sponsor companies often reap fewer benefits than anticipated from their investment. Since trials are frequently conducted over months or years, training may also be required for several releases to ensure full competency. End Users may include site staff, investigators, data managers, monitors, and/or contractors. End Users will not usually require training for new releases, but personnel turnover often necessitates training several times over the course of a longer study. The sponsor is responsible for maintaining training documentation for all personnel.

As an example, according to a vendor case study of a technology transfer at Bayer Healthcare AG (completed in 2006 and published in 2007), Bayer maintains a staff of 30 trainers to support approximately 50 clinical trials annually. This same case study documented that it took 19 months for Bayer to complete the technology transfer process.

Retention of Expertise
Managing an electronic trial requires a variety of roles to be acquainted with, or better still adept at, the specific technology employed for that trial. Some of these roles may be direct employees of the sponsor, while others include subcontractors and site personnel. When estimating the training requirements and the subsequent productivity of these personnel, it is necessary to account for the turnover expected
EDC via the Technology Transfer Model

over the life of the trial. For longer trials, it should be expected that some roles will have to be trained multiple times. Training costs are based on the assumption that qualified personnel (trainers and trainees) are available. Retention involves the incentives to keep expertise, the cost involved in recruiting new personnel, or transferring the responsibility in mid-study.

Site Support

Everyone recognizes that most of the ‘users’ of an EDC system are the sites and monitors and not direct employees of the sponsor. Supporting sites begins with the site selection process and site assessments to ensure technical compliance with whatever technology will be used. EDC system training will be required for site personnel and monitors. It is prudent to plan for re-training due to personnel turnover and refresher courses if the study is a long one. As noted previously, re-training may also be required when the protocol is modified or if the system changes significantly. Many sponsor IT organizations are not equipped or staffed to support non-employees.

EDC implementations must support sites via a Help Desk infrastructure to be successful. People will forget passwords or how to access certain functions. The Help Desk must be able to help the sites troubleshoot network, browser, and connectivity issues as well. Ideally, this support will also extend to other applications the site may use in conjunction with the EDC system, including common desktop applications and printing. 24X7 availability is the standard, and an absolute requirement for global implementations, along with multilingual capabilities.

When a sponsor chooses to run the EDC system in-house, all of these aspects must be addressed. If any portions will be subcontracted or purchased from the vendor, make sure your business case allocates realistic costs for acquiring and managing these elements. It is not at all uncommon for sponsors to discover that a single technology is not really the best alternative for all their studies. Bringing two technologies in house is probably unthinkable for all but the largest organizations. The technology transfer option for EDC is a choice that best fits large clinical organizations with abundant IT and programming support. This model requires a steady flow of clinical trials and strong centralized control to prevent resource bottlenecks. It works best if many of the studies are similar enough to benefit from forms libraries (if supported by the software) and sharing between study teams.

The usual alternative to assuming a lion’s share of the responsibility for making the technology work is to outsource it. We’ll discuss this option next.
Outsourcing is a fact of modern clinical trial management; it’s successful because it works for many sponsors. Some outsourcing companies specialize vertically (by therapeutic area) or horizontally (by function, e.g., statistics). Contracted services provide access to capacity and skills, minimize risk, and help conserve vital capital. But outsourcing comes in several flavors that should be carefully considered when choosing how to best manage an electronic trial and achieve your company’s goals. The choices include:

1. Outsourcing individual services
2. Selecting several partners for key functional areas of expertise to create a network for a particular project or program
3. Full-service outsourcing, where a single CRO conducts the entire clinical project

In this section we’ll examine whether a Full Service CRO might be the best option for your organization, specifically as a choice for EDC studies. The major factors to consider include:

- Access to Data
- Control/Contract Complexity
- Barriers to Flexibility (Change)
- Cost
- Access to Expertise

Access to Data
Monitoring CRO performance and compliance is crucial to mitigating the potential risks that sponsors face in any study. Access to your data should not be delayed or costly – it should be immediate, available with unlimited access, and free. Ultimately, your company’s fortunes are riding on every study. Anything that limits your insight or analysis prevents full understanding of precisely how your trial is being managed and of the success or risks with your compound. Conversely, access to your data including study metrics and summary data will help ensure that any issues in the study will be identified and resolved immediately. There’s probably no such thing as too much access to monitor your study and report to management and stakeholders.

Control and Complexity
As with any third-party services sponsors should assess their risks before entering into a contract. Generally, the broader and more complex the tasks covered under the contract, the greater the risk. Make sure to account for the costs and contingencies associated with vigilance and involvement for the entire engagement. The resources required for managing a vendor who handles many tasks is usually only slightly less than coordinating several ‘best-of-breed’ providers. But make sure not to spread your resources so thinly that your control is compromised. Clearly define the KPI’s (key performance indicators) you need to manage up front. A comprehensive contract with these details defined will take longer and be more complex, but take the time—your negotiating position will be much weaker after the paperwork is signed.

Barriers to Flexibility
Choosing a single outsourcing partner makes it difficult, if not impossible, to switch service providers in the middle of a study, or in the middle of a program. Even if there is one functional area which you like and another is not meeting expectations, it is extremely complicated and expensive to change the contract and either directly assume those responsibilities or switch to another service provider. If you decide that one provider looks like your best option, make sure to conduct thorough due diligence: including references and ‘other’ previous clients.

Cost
Full Service CROs are by definition convenient. Convenience usually comes with a price tag; therefore low cost is seldom associated with this characteristic. Clinical studies are by definition
unpredictable – if they were predictable, they wouldn’t be necessary. So, it should come as no surprise that when convenience meets unpredictability, the result is even more expensive. One of the consistent gripes with life sciences outsourcing is the cost, delay, and effort associated with change orders. Though change is inevitable, some change is predictable and the cost can be mitigated – but only during the contract stage. Understand the separate elements that are often bundled and try to separate the pricing. Look at alternative providers for examples that apply to your situation. Some services may be available as fixed price engagements and others can be capped. EDC in particular should be competitive with pricing for paper CRFs in most cases, and should substantially reduce data management costs.

Access to Expertise

Unless you are outsourcing enough volume to command attention, it can be impossible to get the “A” team from a large full service CRO. The only way to ensure that you do is to specify the resumes that you want, by name if possible, and for a minimum period of time as part of your contract. On the other hand, many midsized CROs, not unlike biopharmaceutical companies, have core competencies in which they excel. However, most have become full service providers out of necessity and may not have deep expertise at the broad array of disciplines that your study may require. If you choose to outsource EDC, make sure that your due diligence looks specifically for extensive EDC expertise.

Though increasing, most CROs still have fairly limited expertise in EDC and even less experience with any particular EDC technology. The largest CRO companies have typically conducted fewer EDC trials than small or mid-sized EDC vendors. CRO experience is often deep in paper-based processes, but their EDC experience is concentrated in a few people and spread across a variety of software technologies. Again, if a full service CRO is right for your situation, make sure they have the expertise and make sure that it is available for your study -- by contract. Look for CROs who have preferred provider status with your choice of EDC technology vendors. Ask about and understand the training programs, certifications, escalation procedures, and support relationship between the CRO and EDC vendor that affect your results.
Most sponsors develop indication-specific compounds based on a particular science. In the view of many, sponsors should be hesitant to add any permanent staff that is not essential to the core business of creating compounds. This means focusing on the science, the efficacy and interactions, and managing specialists who handle the details and the heavy lifting. Though the work is important, the environment complex, and the results are vital, the fact is that, for most companies, being good at EDC and data management is not a competitive differentiator. The key to EDC success is choosing the best way to make sure that it meets your timeline and budget, with a minimum of risk and a maximum of control.

Is Functional Outsourcing right for your organization?
Do you already have resources who could do some of the work or do you desire more insight and control when you outsource?

Will mastering EDC technology or managing the data cleaning give your company a competitive edge?

Is the investment and maintenance worth the return?

In this section we’ll examine the fast growing option of Functional Outsourcing for EDC, and provide some tips for selecting partners to optimize study results and manageability. But first, a definition: EDC Functional Outsourcing is a bundling of all the technology and services required to collect and clean the data associated with a clinical trial. It replaces the “data management” line item found in many outsourcing bids with: EDC technology, all the support to build the study and support sites, plus electronic Data Management services to review the data and code as required. The result is that a sponsor gets clean data, while reaping the benefits as if they had years of experience with EDC. And they regain the time to concentrate on the scientific and recruiting challenges found in every trial.

Some of the major elements for evaluation in an EDC Functional Outsourcing Model include:

- Access to Expertise
- Faster Study Starts
- Access to Data
- Efficient Use of Existing Resources
- Flexibility
- Control and Manageability

Access to Expertise
Under this model, since the outsourcing organization is focused on a specific functional discipline, one of the immediate benefits is the depth that the purchaser gains from this focus. Everyone from the study build, to deployment and support, through database lock, is focused on one goal – getting you the clean data from your study. Data managers know how to get the most from the software and every sponsor can benefit from the total pool of experience the vendor gains from working with a variety of sponsors.

Access to Your Data
One of the core tenets of EDC is open access to your trial data. Whether you choose to use that information for interim analyses, site incentive programs, vendor management, or enrollment progress, the functional outsourcer should be able to demonstrate how their processes and business model facilitate access for whatever purposes you need.

Efficient Use of Existing Resources
Even smaller or virtual organizations frequently have expertise in key areas of the clinical process. The functional outsourcing option makes it easier to use existing resources, where available, while filling an important gap for many companies. Many
organizations say that they are more involved in the trial and can head off problems and optimize processes faster because they can be closer to the action, without owning all the tasks.

Lower Barriers to Switching
Since the functional outsourcer handles only part of your clinical needs, the prospect of changing providers is nowhere near as formidable as with either a technology transfer or a full service CRO. You haven’t invested months or years into the learning curve on a technology, and you don’t have to change everything to look at another vendor. As a constant performance incentive, the functional provider knows this, too.

Control and Manageability
Clearly defining the expectations and responsibilities for a functional area is much easier and more manageable than a totally outsourced engagement where the measurement can be difficult until it’s too late. If you decide to outsource, using best in class vendors for EDC execution can add real value to the equation. As with any outsourcing contract or license agreement, ensure that you implement strong vendor management and communication to drive the success of your results and a mutually rewarding relationship.

Conclusion
Data management, EDC, and even clinical trials are not generally considered to be core competencies that a pharmaceutical or device company must master to be competitive. The prime directive is to determine the efficacy and safety of a potential compound or device—safely, quickly, and efficiently—and get it approved. The right course for any company is the best match for the available resources.

Both EDC vendors and CROs are fairly flexible (some would say indiscriminate) about partnering with each other. However, if a sponsor desires a technology that is appealing with an outsourcing partner that they feel is right, both parties will only gain if they make it work for you. If someone says they can’t work with one of your selections – choose another someone. It probably says more about their own abilities than your selection.

Unless you’re a large company – Pharmaceutical, Biotech, or CRO – the expertise and scale required to run EDC probably doesn’t make financial or business sense to bring it in-house. Even if you work in one of these companies, it’s a matter of focus and will to make technology transfer work for you if you choose to make EDC a key area in which to invest your resources.

If you don’t fit this description, then you should be certain to realistically assess what it will likely take to bring EDC in house and balance that with the intended benefits. For many companies, Functional Outsourcing represents the best way to meet your timeline and budget, with a minimum of risk and a maximum of control.