

Full-Service EDC as an Alternative to Outsourcing

The lifeblood of the entire drug development process is information. Of that information, some of the most challenging, expensive, and unpredictable information to collect is the clinical data. Clinical data drives the need for collection of additional clinical data and all downstream functions of that data (e.g., clinical safety, clinical project management, data management, clinical trial financial administration, data analysis, data reporting, and regulatory interactions).

The rise of pharmaceutical development service companies has allowed many biotechnology and pharmaceutical businesses to operate in a "virtual" mode by outsourcing a wide variety of development functions to contract research organizations (CROs). These outsourced services span the entire pre-clinical development lifecycle, the regulatory process, clinical project management and clinical study execution, clinical financial administration, study analysis and reporting, and document and dossier submission.

Most sponsors describe their use of CROs as a strategic, rather than a tactical decision. However, most sponsors also view CROs as considerably more expensive than in-house resources¹ at a time when the pressure to reduce the cost of drug development has never been greater. Why does outsourcing remain so popular, and what are some viable alternatives?

The majority of companies turn to CROs to manage the vital but expensive clinical trial process because they don't believe they have the internal resources to manage it. A lot of time and effort goes into designing the scope of the study at the front end. The CRO then conducts the study under these pre-defined parameters and provides the company with the study answers at the end.

While this approach addresses a huge piece of the drug development process, it does have limitations. The sponsor company has little or no visibility into study results while the study is in progress. The cost and processes associated with change orders often inhibit creativity in the trial process. In addition, when paper is used, information like serious adverse effects and important safety trends are reported more slowly, which could impact the safety of study patients.

For these reasons, many companies employ the outsourcing model to some degree but few completely outsource development. They fall into two main categories:

- 1) Expense: Full outsourcing is expensive - i.e. sponsors may not be able to afford the out of pocket costs for outsourcing, the loss to time waiting for a CRO's scheduling, or the risk of third party limitations or errors slowing or even derailing the development process.

- 2) Control: The more directly a sponsor company participates in the development process, the more it learns about its product and its future prescribers, improving study design and execution.

Given the risks and benefits of outsourcing, the questions that every sponsor should consider are: *"Where should I outsource?" "Where should I insource?" and "Where should I invest in staffing rather than in services?"*

Clinical Data is the Logical Piece to Examine:

With the advancement of technology used in clinical trials, companies find that they can assume greater control of their studies without large increases in staff or technology investment. Cost savings alone can justify the investment for many companies, but the true value lies with increased safety combined with better, timelier information.

Companies find these remarkable results are a feature of how they capture and monitor clinical data, and especially when they implement electronic data capture. Does EDC actually allow a sponsor to do anything they just can't do with paper? Yes, absolutely. Consider the alternatives available to deal with the following requirements:

- ✓ *"I want to know in real time, how the patients tolerate a drug regimen before I increase the dose."*
- ✓ *"I need to know the precise enrollment statistics for all my sites."*
- ✓ *"I need to efficiently share safety information with the Drug Safety and Monitoring Board."*
- ✓ *"I need to provide Key Opinion Leaders with direct, real-time access to data."*
- ✓ *"I need to monitor efficacy and compliance data as close to real time as possible."*

What companies using well-designed EDC solutions discover is that they can run better trials in less time and at lower costs because they have greater visibility into trial information while it is being collected. There are fewer people involved so decision-making is greatly enhanced and timelines are shorter.

This means, for example, that if a company learns a new drug doesn't work well on women, but is exceptional for men halfway through a study, it can decide to change the focus of the study in real time and rapidly deploy the necessary changes. The sponsor gets better results more quickly.

EDC technology has been proven to facilitate both early and late development activities. It is particularly successful when the sponsor has real-time access to their data at any moment. In very early development, this helps sponsors to organize the results of all pre-clinical data. All the data can be collected and housed in a single, secure, and easily navigable location. They can be easily shared with any number of downstream users via Web portal technologies. They can be modified and changed as needed.

Another important aspect with EDC-based trials is the flexibility and ability to integrate with other systems and processes to improve results. A good example is how safety registries benefit from the integration of EDC along with interactive voice response systems to improve visibility of, and reaction to, adverse events.

Better EDC vendors will often act as an intermediary for Investigator Initiated Studies, handling the negotiation, study management, and data management with the investigator on behalf of a sponsor.

With the right EDC solution, sponsors can expect additional advantages, including:

- Sponsor controlled access to all study data in real time
- Full clinical trial management reports via the system or through a Web portal
- Grants administration and payment tracking reports via the Web portal
- Direct access to pooled data in support of writing the clinical study report
- The ability to more closely manage over-enrollment. This represents a potential cost savings of 5 to 10% of the study costs.
- Easy access to supporting information for SAE narratives (i.e. Conmeds and Medical History)
- Study personnel activity tracking via their log in into the system, and their data comments and queries
- Reconciliation of SAE's with the CRF database
- Sponsor defined data tables, plus safety, activity, and DSMB reports.
- Standardized output from studies in all phases allowing for easier pooling of data.
- Electronic CRF's directly from the system eliminating the need for scanning.
- Reduction in Data Management Resources

Full-Service EDC

Simply buying good technology doesn't magically 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 full-service EDC solutions that deliver technology expertise and clinical experience as a unified package.

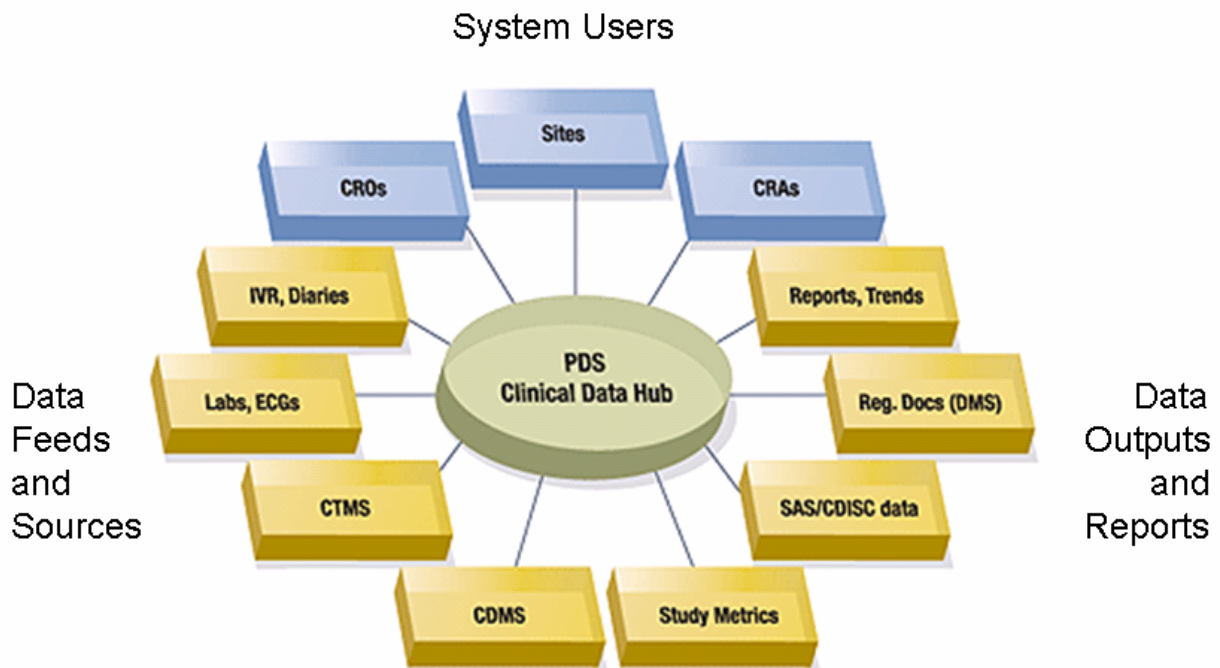
The full-service EDC approach combines expertise with cutting edge systems to yield better results while reducing the risk of new technology introduction. Tight integration of services and technology is key is to delivering a complete solution - otherwise sponsors can find themselves distracted with managing vendors.

Full-service EDC allows companies to precisely select the outsourced services they need from the best available vendor. Sponsors improve control and visibility of their study, yet ensure they have the right resources to manage the process with a combination of experienced outsourced services.

Full-service EDC is not about replacing people. It is about enhancing and augmenting what one person 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 enhanced. Therefore, it takes fewer people to manage the trial, and access to answers is much faster. Visibility into how things are going is much better, the ability to steer the trial is improved, reaction time is improved, costs are lower, and more.

The right EDC system makes all clinical trial information easily available to the sponsor and ensures ongoing trouble free system functionality, both at the sponsor's site and the study sites. With the clinical data at the fingertips of the sponsor, development services are more easily subcontracted and managed, if necessary. Thus, the system acts as a clinical data hub, which provides sponsors with greater discretion regarding which outside services may be required.



The winning combination surrounds the technology with the right people and processes that make it consistently successful. Full service EDC supplements your organization with the right people, if you don't already have them. For example, with the right technology, monitors can better plan their visits to the sites, focusing their visits on management issues, rather than just queries, and make better use of travel time.

Data Management

Outsourced data management services that augment an EDC-enhanced study can provide significant cost savings while still ensuring that the sponsor maintains control and visibility of the study. These data management services can include:

- Project management
- e-CRF preparation and initial edit checks creation
- e-CRF completion guidelines (if needed)
- Data management plan generation
- Non-logic consistency checks (Manual review and query generation)
- Manual query resolution
- Dictionaries, coding, and exception report approvals
- Coding guidelines
 - Manual coding
 - Review and approval of coding
- Data correction plan
- Final quality checks of study data

Using EDC, sponsors have more control over their clinical studies and better visibility into study data. Comprehensive services offerings such as full-service data management include staff supplementation that can save both time and money.

Conclusion

Full service EDC supplies the missing components that help many sponsors, large and small, to successfully transition to eclinical trials. Combining technological efficiency with experienced personnel ensures that sponsors get the information they need about their studies faster, and with better safety and control. This sourcing approach to managing clinical trials allows sponsors to strategically hire new talent, helping to extend the “virtual” nature of a company. It is not an all-or-nothing decision. It’s an intelligent decision that empowers the sponsor to put together the right combination of technology and services that most completely meets its needs.

About the Author:

Dr. William Claypool is chief executive officer and chairman of Phoenix Data Systems, joining the company in 2001. Previously, Dr. Claypool was responsible for global clinical drug development at SmithKlineBeecham, including clinical statistics and data management. He joined SmithKlineBeecham in 1991 and rose to senior vice president and director of worldwide clinical development and medical affairs in 1998. In this role, he established electronic data capture as the preferred platform for data management and also managed more than 34 regulatory filings and supported nearly two dozen pharmaceutical product launches.

ⁱ Vogel, John R. and Getz, Kenneth A., “Successful Outsourcing: Tracking the Evolving Use of Full-Service and Niche-Service CROs”, Applied Clinical Trials, June 2005