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*In the next issue of
EDC Today:*

Technology Old and
New: Integrating Legacy
Systems with EDC

Vendors, Products, and Suppliers: A Consumers Guide to the EDC Marketplace – Part II

Welcome to our tenth issue! EDC Today is an independent publication about current information and issues in Electronic Data Capture (EDC) strategies and technologies for the Biotechnology and Pharmaceutical (biopharma) industry. Each month we examine topic areas related to EDC theory, technology, practice, or implementation.

Selecting a vendor is a critical process for biopharma companies. Biopharmas hoping to implement EDC systems have a range of options – from contracting the entire clinical trial data collection process to an Electronic Contract Research Organization (eCRO), to running the trial and collecting the data using an Application Service Provider (ASP), to performing the data collection process in-house. In this issue, we present several strategies for choosing among these options, as well as narrowing the choices of viable vendors in the growing marketplace.

Before beginning an in-depth discussion of the EDC marketplace, it may be useful to re-examine the material presented in Issue 9, which provided a marketplace overview. Biopharmas today can choose from one of three primary options for implementing EDC: contracting with eCROs, contracting with ASPs, or installing one or more products in-house.

For biopharmas, eCROs offer an important service: during the course of the clinical trial, they provide EDC systems for collecting and cleaning data and, at the conclusion of the trial, they deliver data to the sponsor, often in the format of SAS DataSetsTM. By partnering with an eCRO, sponsors are able to deflect some of the risk of running clinical trials using EDC, though at some financial and logistical cost.

ASPs are companies that provide hardware, servers, networks and network management, software and software management, help desk, maintenance, and other services for fixed monthly or annual fees. In effect, ASPs are a way to outsource computer systems and infrastructure. For biopharmas, ASPs offer software and hosting services that enable clinical data collection, and cleaning, and deliver cleaned data to sponsors. ASPs offer biopharmas the option of renting the hardware and software systems, as opposed to purchasing them.

The third option for sponsor companies involves bringing EDC products in-house. Sponsors choosing this option purchase both hardware (e.g., servers and networking devices) and software that

enable both the collection/cleaning of clinical data during the trial and potentially the production of SAS DataSetsTM at the trial's conclusion. Choosing to manage EDC systems in-house offers biopharmas greater freedom and flexibility, but with greater risk in absorbing the cost of the hardware infrastructure, and the risk associated with the longer-term viability of the software vendor they decide to use.

Each of these options carries notable risks and rewards. How does an organization decide which is best? One can compare the advantages of having a vendor host the EDC offering against the expense of providing an “in-house” EDC-web server. For example, keeping the software up to date, validated and in regulatory compliance, keeping the server secure from malicious attacks, and performing database back ups might be best done by the vendor. Furthermore, some vendors claim that overall study costs are more easily determined when the vendor hosts the EDC offering.

A “Quadrant In A Quadrant” Approach To Market Analysis

Since there are a large number of vendors (possibly as many as 70) in the EDC marketplace, it can be daunting for a biopharma to begin assessing vendors. A starting point was presented in Issue 9 – eCROs, ASPs, and “in-house” offerings. This market segmentation resulted from a top-down, quadrant-based approach devised by Dr. Mousley.

In this model, the company performing the analysis takes the two most important EDC criteria and divides the market up into four parts, called “quadrants.” Once a company selects which quadrant is most appropriate for them, a number of potential vendors are removed from consideration. For instance, if we estimate that there are 70 EDC vendors and we assume they are equally distributed in the quadrants, focusing on a single quadrant narrows the selection to roughly 16 vendors.

The analysis proceeds by taking the next two most important criteria, and further dividing the selected “quadrant” into four more parts. Hence the term “quadrant in a quadrant”. This model is a hierarchical top-down approach to selecting a vendor and relies on determining the most important decision-making criteria.

Since there are a large number of vendors and there will likely be vendor consolidations, a biopharma company may decide to select one or

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About EDC Management:

EDC Management was founded to assist biopharma companies plan, prepare for and implement Electronic Data Capture (EDC) strategies according to their data management goals and objectives. We do not sell or endorse any specific EDC software application or vendor.

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more backup vendors to their primary EDC vendor. If they do pursue backup vendors, selecting these vendors from the same quadrant will minimize process differences required to use the different vendor products. This means that companies will not have to re-engineer their processes in the event they need to switch to a backup vendor.

Furthermore, selecting the products from the same quadrant allows the biopharma to develop generic processes (and related SOPs) that are independent of the actual products.

As an example, consider a biopharma company that has chosen the following four vendor-selection criteria to be the most relevant to its business model:

1. Pricing (hosting) scheme: vendor or biopharma?
2. Set-up scheme: vendor or biopharma?
3. Legacy system (bridge) or standalone?
4. Thin or thick client?

Once the important criteria are identified, the vendor assessment team can divide the criteria into a series of quadrants for easier evaluation. For example, beginning with the first two criteria (pricing scheme and set-up scheme), we can create a set of four quadrants, each representing possible scheme combinations, and show examples of vendor products that fall within the scheme:

Table 1. Possible Pricing and Set-up Schemes

<p>Quadrant 1. Vendor Hosts, Vendor Setup</p> <p>Datatrak, CB Technologies, PhaseForward, PHT, Target Health, eResearch Technologies eData Entry (eRT eDE), etc.</p>	<p>Quadrant 2. Biopharma Hosts, Vendor Setup</p> <p>This is probably not a meaningful quadrant although some vendors such as eRT offer trial setup services on a contract basis.</p>
<p>Quadrant 3. Vendor Hosts, Biopharma Setup</p> <p>Datatrak, CB Technologies, PhaseForward, eRT eDE, etc.</p>	<p>Quadrant 4. Biopharma Hosts, Biopharma Setup</p> <p>Oracle RDC, PhaseForward, eRT eDE, Acumen, etc.</p>

At this level, a manageable list of choices has most often not yet emerged, as is the case here in our example. Supporting products from different quadrants at this level is difficult. Consider the problems of supporting an ASP product and an in-house licensed product with the same SOPs. It cannot be done smoothly, since a data transfer process from the ASP must be developed and supported, which likely is not needed at all for an in-house implementation of EDC.

The “quadrant in a quadrant” approach dictates that we apply the next two criteria (legacy vs. stand alone and thick vs. thin client) to the particular quadrant we have selected above. Let’s assume that we have selected Quadrant 1 (“Vendor Hosts, Vendor Setup”). Applying the next two criteria yields the following four sub-quadrants:

Table 2. Quadrant 1: Vendor Hosts, Vendor Setup

<p>1a. Legacy, Thin PhaseForward</p>	<p>1b. Standalone, Thin DataTrak, PHT, Target Health</p>
<p>1c. Legacy, Thick eRT eDE</p>	<p>1d. Standalone, Thick CB Technologies</p>

At this sub-quadrant level, the requirement for each of multiple products to be in the sub-quadrant is still desirable, but the impact on SOPs is less, and therefore the requirement is not as strong as the highest-level quadrant.

Thus, using this approach, our case study biopharma is able to wade through a dense pool of possible solutions in a stepwise fashion to arrive at a manageable list of products that will be appropriate for its specific goals.

Assessing Vendors: Secondary Factors

Once the top level decision has been made to partner with an eCRO or an ASP or to buy software and bring it in-house, biopharmas should perform an evaluation of potential vendors very carefully. The success of any approach is largely tied to the success and viability of the product vendor.

EDC vendors may offer competitive prices or cutting-edge technologies that look attractive, but selecting a vendor based on these criteria can be risky, as some of the companies may be unstable or at risk of failing. If all of an organization’s applications are integrated into a particular portal product and then the vendor goes out of business, for example, this could be disastrous. Colin Spink of IBM explains:

“With around 70 software providers in this area, making a long-term viable software choice is undoubtedly a challenge. Over the next five years the market will consolidate, resulting in both players and software products disappearing — potentially leaving your EDC implementation unsupported. Making the right software choice is key and requires understanding of not only the different products on the market, but also links back to an organization’s strategic deployment of the technology.”¹

Using Vendor Assessment Teams

Ideally, a designated assessment team should conduct vendor evaluations. Members of this team will need the following kinds of experience and expertise:

- A solid understanding of the requirements that the product must satisfy.
- A good overall knowledge of available technology options, especially those related to integrating legacy systems if necessary.
- The skills to evaluate a vendor’s market and financial position.
- Knowledge of the history of EDC in the biopharma industry.
- Familiarity with the investigators’ office environments, especially the existing and desired levels of IT staffing and experience.
- A thorough understanding of systems issues, including user interfaces, communication between systems, systems integration and implementation, and support for end users.
- The interviewing skills necessary to obtain information from vendors.
- An appreciation of the organization’s level of risk tolerance.
- An understanding of the organization’s long-term planning goals.
- Ability to organize and to communicate.

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Obviously, introducing a major new component to a system used by a large group of people with diverse backgrounds and requirements, is not a trivial project. Time will be needed to communicate the vendor selection team's mission, goals, expectations, and progress as the project goes on. Someone with excellent organizational and communication skills who is also readily familiar with clinical trials, EDC, and Clinical Data Management systems would obviously be an integrally valuable member of the vendor selection team.

Change, especially when it comes to the nature of someone's job, is a delicate proposition. It is vitally important to take all active measures to prevent or minimize the vendor selection project's chance of failure due to corporate politics, disaffected employee sabotage, and/or other non-technical factors. Having clear, credible, and frequent communication is just a start.

Once assembled, the vendor assessment team should approach vendor selection systematically. With so many criteria to consider, it may be useful to view the EDC marketplace not as one large unit, but as a collection of distinct segments. Market segmentation allows potential customers to distinguish among the various vendor offerings and/or solutions.

Segmentation can be taken a step further, to differentiation. A market segment might be thought of as a broad category and differentiation as subcategorizing. In the next section, we examine several different market segments, with emphasis on the potential significance to the buyer and/or end user.

Further EDC Marketplace Segmentation

Beyond the high-level segmentation that we have already discussed, biopharmas might want to consider additional market segments. These segments are presented in no particular order or rank, in part because different segments have differing values to different biopharmas. Ranking is an attribute of the end-user's and/or buyer's business requirements and of the perceived worth to the buyer.

Segment A: Vendor's experience, ability to provide service(s), and long term outlook

This segment focuses on the vendor's ability to deliver the product for the duration of the study.

- Vendor's experience, experience in years of clinical trials data management experience, number of clinical trials performed, number of New Drug Applications (NDAs) submitted, years of EDC trials experience, years of software development experience, years in business.
- Capitalization, financial stability, private versus publicly held firm; staffing, corporate life expectancy; product outlook and future development plans.
- Vendor markets an updated "full" legacy CDMS offering.

Many biopharmas grapple with the question of whether it is important that the EDC offering integrates with their existing CDMS. Certainly, there is an allure to an EDC offering that is built upon an existing CDMS product (e.g., Oracle RDC and eRT's eDE). If one already has a CDMS product, one might expect that incorporating EDC into a study will be easier. The development environment is familiar; the tables in the database are familiar. Designing one entry form for in-house entry and EDC use seems like a good idea. However, there are important potential problems to consider. For example, are these products as strong as those dedicated to EDC? Does their forms interface provide investigator friendly error checking? Like the many other criterion described here, the question of legacy systems can be answered only after a careful analysis of each biopharma's specific needs.

Segment B: Vendor's quality, documentation, training, validation, and testing materials

This segment focuses on the quality of the vendor offering. In particular, the product should be as defect-free as possible to insure user acceptance.

- User and vendor validation and operational qualification requirements.
- Customer support, training offerings and availability. Help desk availability, method of communications (e.g., phone and email) and languages spoken.
- Overall quality of the vendor's offering, "bug list", documentation, regulatory adherence, 21 CFR 11 statement, availability of test kits and scripts (and if ASP/CRO offering, auditable results), extent and nature of user help. It is important that the vendor have a defect tracking system in place, and procedures for making sure quality is assured.

Segment C: Architecture and feature set of the vendor's products and/or services

This segment focuses on the features of the product and the appropriateness of these features.

- Vendor markets an updated "full" legacy CDMS offering.
- Legacy system: integration, bridging, extension, or stand-alone.
- On-line data entry only versus on-line and off-line entry.
- Client software (Installed application, Browser and add-ins, Citrix and Terminal Server/Emulators). Extent of client versus server side scripting/processing.
- Development and/or scripting environments and tools.
- Security features - encryption and authentication.
- System customization support.
- Sustainable performance levels.
- System scalability.
- Product feature and implementation level listing.

Fulfilling one of the promises of EDC is predicated on being able to use it from any available, internet-connected personal computer. Unlike most software programs that must be installed on individual computers to run correctly, Web-based programs have varying levels of dependence on the local computer (i.e., the computer with which the end user accesses the Internet). "Thin client" programs are those that run solely within a browser and do not rely on anything specific to a user's computer configuration. On the other hand, a client with only a browser may not be able to support many desired EDC features and/or functions or may perform them badly. "Thick client" programs are those that need to use software locally to run correctly. In any event, programs that run on the Web server will need to be extensively validated.

If the vendor offering requires an installed client program, or downloads one or more browser add-in components, the issue of client system validation becomes more problematic. The less software loaded onto the client, the smaller amount of validation effort will be required. For thin client programs, validation of the Web-based program is not likely to be required on each and every client computer. Instead, only a representative computer might be used for validation purposes. In contrast, validation of all of the user's systems may be required for fat client programs. Simply put, the thicker the client, the more client validation, operational qualification, and support it requires.

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A related consideration is whether vendors offer off-line versus online-only data entry capability. EDC is expected to be most effective when entry and review is as real time as possible. Providing support for off-line entry runs contrary to this goal of real time activity. If the Internet connection at the EDC site(s) is not always available (this includes dial-up access by its very nature), being able to perform off-line data entry may be necessary. Off-line data entry raises additional questions about data security, safety (back up), and even more client system validation issues.

In addition to these considerations, several more questions should be addressed. For example:

- How easy is it to get the data to the statisticians and those putting together the FDA submission?
- Can items be auto encoded using a legacy system that has proven its business advantage over the years?
- How are central lab data managed?
- Are data transferable?
- Are data archivable?
- What if the vendor fails (goes out of business) or is bought out/taken over during a study?
- Does the sponsor have (or can they get) the resources needed to run the EDC offering in-house?

Segment D: “Usability” of the vendor’s products and/or services

This segment focuses on usability of the product. The emphasis here is on user-friendliness as opposed to software quality.

- User acceptance, Investigator friendliness/acceptance (to date.)
- Additional offerings/product features, support, services, partnerships (e.g., project management, training certification.)

When shopping for vendors, it is very important not to place too much value or emphasis on any one performance benchmark. Vendors naturally like to publish benchmarks that make their offering look the best. Sometimes it is difficult to compare one vendor’s measurement against that of another vendor. The industry seems focused on “page turn rate” – the speed at which the EDC end-user perceives the “next eCRF page” appearing on their monitor/screen. On the basis of investigator feedback, this performance measure seems to be particularly important. However, measurements of performance surpass just page-turn rate. They should also include data cleanliness, time from last patient completion to database lock, data entry system development time, report generation, case report form (CRF) printing, if supported (usually to PDF), and others.

Wading through the Choices: Multi-Criteria Decision Making (MCDM)

When assessing vendors, it is critical to identify and rank which features are necessary. One obvious way to approach this is to list functions that any currently used CDMS offers and, after pruning and adding to this list based on the suitability of these functions in an EDC environment, get group consensus from team members who provide input on the relative importance of each function. An unbiased approach to determining a

function’s “criticality” is essential. Furthermore, the listed functionality may need a detailed description so that each team member understands its scope. An example might be that Adverse Event auto-encoding against the COSTART or MedDRA dictionary is required and needs a user interface that allows the dictionary group to resolve terms that do not automatically encode.

When the criteria are more numerous or complex, a more systematic approach may be necessary. MCDM is a theoretical approach to making decisions in the presence of multiple, often conflicting, criteria.² Though MCDM problems vary in different contexts and industries, they share several key features:

- **Multiple criteria.** Multiple criteria often form a hierarchy, with some criteria assigned a greater value than others. Biopharmas may be able to rank the importance of different criteria based on the organization’s specific needs.
- **Conflict among criteria.** The greater the number of criteria, the more likely they will begin to conflict with one another. For biopharmas, the criteria of simple user interface may mean reduced number of data entry fields.
- **The hybrid nature of criteria.** As the number of criteria increases, they become increasingly difficult to directly compare with each other. For example, there may be a mixture of qualitative (user-friendliness) and quantitative (page turn rate) attributes, or a mixture of fixed (e.g., unit cost) and relative (e.g., field performance) attributes.
- **Uncertainty of criteria.** The value of certain criteria may be unknown due to the lack of data or incomplete information. For example, a biopharma may find “errors flagged per day” to be an important criteria, but different vendors may not track that exact data.
- **High volume of criteria.** After a thorough analysis of their needs, biopharmas may find they have many levels of criteria, each level with many more sub-criteria. It is not uncommon to manage a matrix containing hundreds of criteria and sub-criteria.²

In the experience of EDC Management, some of the basic points of MCDM are relevant to vendor selection. As demonstrated in the “Quadrant in a Quadrant” example, formulating a matrix of requirements (or criteria) with the alternatives (vendors’ ability to meet the requirements) is critical to the vendor selection process.

As suggested by the MCDM approach, the first step is to develop a statement of business model, requirements, and goals. This should include:

- Listing of lower level functional requirements
- Assessments of the types of clinical trials to be performed
- Existing Site Assessments / IT Levels
- Data Management Requirements
- Regulatory Requirements

Once the business requirements have been listed, an organization’s vendor assessment team should rank them according to importance and need. Next, the team should investigate which vendor products and/or services would fulfill the organization’s requirements, and score each vendor accordingly. Tallying the weighted scores should yield a variety of ranked solutions. Finally, the vendor assessment team can then select the optimal solution for their organization.

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Though MCDM offers a thoughtful and systematic approach to complex problems, MCDM assessments may not be conclusive. Rather than aiming at a single “best” answer, MCDM defines several possible solutions:

- **Ideal solution.** Ideal solutions to MCDM problems are those that exceed all desired criteria. Ideal solutions are very rare.
- **Non-dominated solutions.** Being “dominated” means being out-performed on one or more criteria. Therefore, a non-dominated solution occurs when no other solution is clearly better.
- **Preferred solutions.** If an MCDM analysis results in more than one non-dominated solution, the preferred solution is the best of these.
- **Satisfying solutions.** Satisfying solutions are those that at least meet – but not necessarily exceed – all criteria.²

When embarking on such a complex analysis, it is important for biopharmas to understand the possible results and adjust their expectations accordingly. Biopharmas may find an “Ideal” vendor, or they may find one that is only “Satisfying”.

Conclusion

Biopharmas are often motivated to adopt new processes and products by a desire to improve their financial standing. Currently there are over 70 EDC vendors, many of which produce immature products and have yet to become profitable. Though some vendors produce quality products, the outlook for many EDC products could conceivably be failure.

To start the vendor assessment program, the “quadrant in a quadrant” model can help biopharmas think about the important criteria for implementing EDC, and start to narrow the choices of viable vendors in the growing marketplace.

However, given the uncertain market, engaging in relationships with new vendors necessarily requires a certain amount of risk. Therefore, a thorough assessment of both specific business needs and level of risk tolerance is a critical first step to venturing into new vendor relationships.

With an ever-increasing number of options in the growing EDC marketplace, biopharmas are finding that a

Who's behind the research?

Our lead researcher, Kirk Mousley, PhD received BS and MS degrees in Electrical Engineering from MIT and a PhD in Computer Science from Lehigh University. He has been the President of Mousley Consulting, Inc. since its founding in 1993 and has directed the company's efforts in the areas of clinical database design, data editing/cleaning, document management, and submissions.

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systematic approach to vendor selection is necessary. MCDM, a powerful tool that has been useful in a range of other industries, may prove useful here as well.

Regardless of an organization's specific business needs or goals, selecting a vendor to meet those goals is a significant endeavor. Only through a deliberate process of needs assessment and vendor evaluation can biopharmas be confident that they are choosing the vendors, products, and services that push their business goals forward.

References:

¹ Spink, Colin. “Pharmaceutical Clinical Development: Electronic Data Capture (EDC) as a means for e-clinical trial success.” March, 2002. www.ibm.com.

² Manchester School of Management. *Introduction to Multi-Criteria Decision Making and the Evidential Reasoning Approach*. Available online at: <http://info.sm.umist.ac.uk/wp/Papers/wp0106.htm>

Additional Resources:

Waife & Associates, Inc. *The Waife & Associates EDC Report, 8th Edition*. <http://www.waife.com>

Available **EDC In Depth** Research Reports related to this issue:

10.1 "EDC Market Shakeout: Surviving the Wave of Change"

In the current market of 70+ EDC vendors, biopharmas face a candy store of potential technological solutions. However, it is important not to mix flavors – doing so would result in several solutions that are unable to integrate into a single, smooth business process. In this report, we describe the different market segments and help biopharmas determine which is optimal for their organization.

10.2 "EDC Hosting Models: Internal, External, and Everywhere In Between"

Biopharmas can choose from one of three primary licensing (or hosting) models: contracting with Electronic Contract Research Organizations (eCROs), contracting with Application Service Providers (ASPs), or installing one or more products in house. This report examines the risks and rewards associated with each option.

10.3 "EDC Service Levels: From Full-Service to Do-it-Yourself"

EDC service options run the spectrum from full-service CROs to out-of-the-box software suppliers. In this report, we present both the risks and rewards associated with particular types of EDC service providers. With this type of analysis, biopharma companies can select the best suited, most cost-effective, and least risky service options for their organization.

10.4 "EDC Vendor Assessment: Technical Considerations"

Evaluating potential vendors requires a solid understanding of the different technological nuances they provide. In this report, we provide a clear explanation of the divergent technological options available to new EDC customers, including: client software (Installed application, Browser and add-ins, Citrix and Terminal Server/Emulators); “on-line data entry only” versus “online and off-line entry”; and legacy integration, native/bridged, and stand-alone.

See back for order information.



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