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In the next issue of  
**EDC Today:**

Implementing  
Site-Friendly EDC

### 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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## Buy vs. Build: Exploring EDC Technologies

*EDC Today is an independent publication on current information and issues in Electronic Data Capture (EDC) strategies and technologies for the Biotechnology and Pharmaceutical (biopharma) industry. Each month we examine topics related to EDC theory, technology, practice, or implementation.*

*To assist organizations making the transition from paper-based clinical trials to EDC-facilitated trials, our fourth issue examines many of the options available for creating and implementing EDC systems. In particular, we address the fundamental decision biopharma companies must make regarding EDC – to buy or build? Plus we provide an overview of some common technologies used to create EDC applications.*

When shifting to an electronic environment, biopharma companies must make strategic decisions about how to implement EDC. To make the best decision, these companies should have a basic understanding of the array of technological options at their disposal.

When looking to the marketplace for possible solutions, biopharma companies must evaluate conflicting information offered by vendors, and sort out the marketing material from the technical material. Although off-the-shelf software for EDC applications has improved significantly in recent years, no leader stands out in this field, making the decision even more difficult for those companies searching for a commercial solution.

In addition, the options offered by the fast-changing marketplace have blurred the distinction between the choice to build or to buy – offering several ‘in-between’ approaches that many companies will adopt.

Two of the most recent technological advances, information portals and Extensible Markup Language (XML), are worth serious investigation. Portal technologies can improve understanding

and workplace productivity by allowing users to access all software applications from a single place on their computer. XML is especially useful for integrating legacy systems and databases, as it includes definitions of data allowing disparate systems to figure out how to use the data. Biopharma companies considering making the transition to EDC should familiarize themselves with the various types of portal technologies and their potential benefits, and should consider using XML.

### EDC Systems: Buy, Build, or Both

One of the most important decisions organizations must make when transitioning to EDC is whether to buy commercially available (off-the-shelf) systems or to create their own systems.

Traditionally, biopharma companies have been faced with similar buy vs. build decisions around such systems as data entry and management, adverse event reporting, study management, project management, and so forth. However, since EDC involves more esoteric technologies than traditional in-house programming, many companies will find it far more challenging to build.

In the past, some biopharma companies have opted to build custom software for EDC operations. They chose this option for two reasons: 1) existing software did not offer the features they desired; and 2) they felt that they would gain a competitive advantage with software tailored to their specific operations. Recently however, improvements in commercially available software have prompted more companies to purchase software rather than build their own.

Among the recent improvements that software vendors have begun to provide are systems with built-in electronic audit trails and encryption protocols. Many vendors claim their systems are compliant with the FDA



regulation 21 CFR 11, which details conditions upon which the FDA will consider electronic records and signatures equivalent to paper records and handwritten signatures. Although they do not endorse any vendor or product, the FDA has posted a list of these vendors on its Web site (www.fda.gov).

As off-the-shelf software becomes more sophisticated, companies have moved to buying over building, realizing that they can save time and money by customizing an off-the-shelf software application. To date, no clear software leader has emerged. This is not because the technology is insufficient, but rather because vendors have had difficulty predicting and customizing all of the broad range of clinical trial options and processes.

In today's market, a pure, start-to-finish build of an EDC system by a biopharma company is unusual, although some contract research organizations (CROs) and larger biopharmas have done it. However, a pure buy is also unusual because the available products almost always need to be customized for a particular company's needs. Within the two main options of "build" or "buy," the market offers approaches that combine aspects of both and blur distinctions between them:

- An organization might decide to build, but to implement that construction on a framework of portal software purchased from a vendor.
- An organization might decide to buy, but to lease computers and software through an Applications Service Provider (ASP).

Biopharma companies must thoroughly analyze their business goals and needs before choosing to buy or build an EDC system.

**Some fundamental points to consider when debating buy vs. build:**

- Ideally, purchasing off-the-shelf software is less expensive than hiring programmers to write customized programs. However, the more customization a product requires to meet an organization's needs, the less this is true. The same applies to a product's potential deployment difficulties or incompatibilities with existing infrastructure.
- Generally, purchasing and implementing an off-the-shelf software application should be faster than building from scratch.
- If the organization's focus is not, or should not be, software development, then minimizing the in-house programming is important.
- An organization should consider the motivation and job satisfaction of its IT staff when making this decision. Unless their career interests lie closer to the application domain than software development, an in-house programming staff may find customizing and working with off-the-shelf software less professionally satisfying than creating original programs.

When building an application, starting with a commercially available portal product for the framework provides a huge head start. These portals, also called access portals or enterprise information portals (EIPs), are electronic infrastructure upon which a company's databases, archives, files, e-mail, Web browser, and other applications can run smoothly. Access portals are especially useful for integrating older, legacy systems with new systems.

Building systems on a portal framework requires a sophisticated IT staff performing integration, support, and validation functions. The approach demands a somewhat different set of skills from those of software developers for new applications, but those skills are no less important. The greater number of customizations and integrations of systems (especially legacy systems) that are required, the more skilled the IT staff needs to be.

When deciding not to build, some organizations opt for ASPs rather than buy computers and systems outright. ASPs are partners 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.

In their book, *Building Corporate Portals Using XML*, Clive Finkelstein and Peter Aiken, predict the growing importance of ASPs:

"This is a radical move that will transform desktop computing as we know it. It will provide ubiquitous computing through the Internet and the intranet. And with a move to wider bandwidths on the Internet – with higher data rates available also through wireless computing via PDAs or mobile phones that access the Internet for email and browsing – we will soon be able to work not just from the office, but from anywhere. In a few short years these ASPs will become Information Utilities for the future."<sup>1</sup>

Biopharma companies must consider certain issues when choosing the ASP option. For example, the ASP will have physical control of the data much as a CRO does, but how the sponsor accesses that data – whether the sponsor will have real-time access, for example – will be negotiated as part of the service level agreement (SLA). Even though low-level details will be handled by the ASP provider, sponsors will still need in-house IT staff to understand and monitor the remotely controlled database(s) and applications. Finally, it is important to remember that ultimately the responsibility for the integrity of the data lies with the sponsor. Hardware and software outsourced through an ASP must still be validated. Because the vendor who originally created them should have heavily tested the hardware and software, the sponsor should not have to repeat those tests. Instead, documentation of the design-level validation and testing should be available. However, sponsors do need to undertake and document functional level testing.

(continued on page 3)

This includes identifying and documenting the effects of any known limitations or problems relevant to the sponsor's study. In addition, validation requires a detailed audit of the ASP.

## A Closer Look at EDC Systems Technology

Whether building, buying, or choosing an in-between option, biopharma companies benefit from gaining an understanding of some of the fundamental technologies used to create EDC systems. One of the biggest challenges in creating an EDC system is how to tie a company's old and new databases and software together into one easy-to-use package. The technological "cyber glue" used to bind these components together are called access portals or enterprise information portals (EIPs). These portals are frequently created with a Web-based programming language called XML.

It is often difficult for some of the systems used within an organization to communicate and share information with other systems. The programs in each system can be connected and have the capability to communicate with each other, but their programming language often uses different terms to refer to the same data that needs to be shared. In *Building Corporate Portals Using XML*, Finkelstein and Aiken offer the following analogy about why it is difficult for dissimilar programs and databases to communicate with each other:

"Every country is now interconnected in a vast, global telephone network. We are now able to telephone anywhere in the world. We can phone a number, and the telephone assigned to that number would ring in Russia, or China, or in Outer Mongolia. But when it is answered, we may not understand the person at the other end. They may speak a different language. So we can be connected, but what is said has no meaning. We cannot share information."<sup>1</sup>

To communicate successfully with each other, such dissimilar programs need a kind of dictionary that translates one language into another. Traditionally, that translation has been provided by Electronic Data Interchange (EDI) technology. EDI has been widely used for business-to-business commerce for years. However, EDI is complex, expensive, and generally out of the reach of small companies, especially biotech or pharmaceutical startups struggling to bring their first product to market.

XML is a new Internet technology that offers a simpler, less expensive, and effective way to translate languages between different databases and systems, both inside and outside an organization. XML creates common definitions of data – termed "metadata" – that can be shared and used by all systems. Not only does XML provide a bridge between different systems, it also provides the means to convert data and files into Hypertext Markup Language (HTML) so they can be viewed using Web browsers.

With XML, legacy databases and files can be integrated into new systems more readily. In addition, software programs throughout an organization can more easily coordinate activities. Given these capabilities, XML gives smaller companies the technical power that was once available only to larger companies through EDI. In fact, because of its accuracy and cost effectiveness, many larger companies use XML-based technology as well.

While an EDC application need not be part of a portal, portal technology can provide user friendliness and additional information and support to EDC application users. In much the same way that Internet portals, such as Yahoo! or AltaVista, are gateways to Web content, access portals are browser-based systems that give users a single point of access to an organization's data and software applications from their desktops.

Choosing among the portals available on the market can be a daunting task for an organization. In his 2002 article "A Better Understanding of the Enterprise Information Portal Market," technology analyst Jean-Sébastien Mercy offers the following assessment:

"...most vendors have embraced the EIP market whole-heartedly. As this is a relatively new trend, for the moment, the best way to differentiate solutions is by looking at each vendor's origins. However, these differences will fade as products develop and as the market matures. Therefore, while some vendors are trying to cover the panoply of functionalities required to meet enterprise needs, others are concentrating on very specific functionalities in order to gain ground on a market segment that will eventually be abandoned by victors of the first round."<sup>2</sup>

### Mercy also identifies the following types of portal vendors, based on the particular approach or technology emphasized in their products:

- **Infrastructure vendors** such as IBM, BEA, Oracle, Sybase, and Microsoft have developed portal applications based entirely on their Web application server and database technologies.
- Because portals facilitate information access with programs similar to a search engines, **search/categorization vendors** such as Autonomy, Arisem, and Verity have developed portals that rely heavily on their search, categorization, and indexing technologies.
- **Content management solution vendors** such as Documentum, Interwoven, iManage, InStranet, and OpenText have also joined the portal market because document or information management is also a key element of any portal.

(continued on page 4)



To date, biopharma companies have made effective use of content management solutions, and this trend is likely to continue. A number of larger pharmaceutical companies have built document repositories based on Documentum; other vendors, such as OpenText, have also begun to gain market share by offering similar capabilities at lower prices. In addition, vendors are enhancing their content management solutions by adding support for XML documents and for integration with publishing systems for regulatory submissions. (Examples include Liquent CoreDossier, CDC Solutions EZSubs, ArborText Epic Editor.) Content management solution vendors view portals as a natural extension of content management, and they already have an established presence in the biopharma industry.

Looking forward, biopharma companies will continue to adopt additional tools and methods for effective use and management of their many existing databases. Widespread adoption of Knowledge Management (KM) and the systems that support these activities is expected in all large corporations, including biopharma enterprises. KM is a collection of approaches – including organizational psychology, creative indexing and access to databases, and design of collaboration applications and infrastructure – that show signs of becoming an independent discipline for effective use of corporate information and knowledge development.

All three categories of vendors have a stake in the advancement of KM. The search/categorization vendors offer the newest approach while the infrastructure vendors have provided collaboration tools with varying degrees of success (for example, IBM NetMeeting, IBM Lotus Notes). Vendors offering portals from the Web infrastructure and search/categorization perspectives will be attractive to those companies that already have positive experience with those technologies or that see the value in developing KM tools and techniques to complement content management.

A broad range of features can be included in a portal depending on an organization's needs, and portal vendors continue to debate the features and functionality that should be contained within their products. The ability to add features, content, and functions as an organization's needs evolve is important.

**“When Shopping for a portal product, having a ‘wish list’ in hand will help to navigate through the portal market.”**

**One vendor, Citrix Systems, Inc., suggests that a portal should contain the following features at a minimum:**

- **Personalization**, which can be implemented by individual end users or organizations, based on their needs.
- **Aggregation of information from disparate sources**, which reduces the number of places that users have to look for needed content.
- **Presentation-layer design and management** for easy navigation.
- **A search function** that provides access to multiple data repositories and document types.
- **A collaboration feature** that allows users to work together on specific projects or tasks.
- **A content management function** that allows users to modify or add content to the portal according to evolving needs.<sup>3</sup>

Wish lists should be made in consultation with personnel who will use or maintain the portal, including the system developer, other IT staff, data managers, and investigators. In addition, the list should contain all the portal features an organization requires, especially those specific to planned clinical trials. Finally, the list should be prioritized, meaning it should indicate which features could be added most easily by in-house IT staff.

**Benefits of Portals and XML Technology**

The primary value of portals for developing/integrating an EDC system is that portals provide a programming platform for creating and integrating the application. An XML-defined view of clinical databases – an important new way to build the underlying infrastructure for the portal – may simplify and enhance the integration of an EDC application. Also, data sets produced from such an EDC system are more easily coordinated with data standards, which helps produce data sets that are more submission-ready.

A portal can be a valuable tool for collecting access to a number of systems and tools in one “desktop” working environment. Integrating e-mail and other communications tools into the portal can increase the effectiveness of clinical workers. Likewise, having access from this portal desktop to key content and associated workflow introduces many potential advantages.

*(continued on page 5)*



Because of its ability to tie together disparate systems and databases, XML-based portal technology also facilitates integrating older, legacy systems into an organization's new EDC system. It is important for biopharma companies to remember that their legacy systems are not exempt from the FDA rules on electronic records, particularly audit trail and validation requirements. Portal technology can make validating legacy systems easier and can provide security tokens that can be used for audit trails.

Building an EDC system in conjunction with an information portal is one approach to an integrated EDC application. Since portals and XML technology are likely to have a greater presence in the future of all database environments, including biopharma companies, this approach is worth considering today.

*Finkelstein, Clive and Aiken, Peter. XML and Corporate Portals. "Building Corporate Portals Using XML." McGraw-Hill, September 1999.*

<sup>2</sup> *Mercy, Jean-Sébastien. "A Better Understanding of the Enterprise Information Portal Market." [www.owendo.com](http://www.owendo.com), 2002.*

<sup>3</sup> *Citrix Systems, Inc. "Enabling the Virtual Workplace With an Access portal." [www.citrix.com](http://www.citrix.com), 2002.*

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## 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.

**Karl Mousley** received his BS in Mechanical Engineering from Rose-Hulman Institute of Technology and a MS in Computer Science from Villanova University. He has been a senior member of the technical staff at Mousley Consulting, Inc. since 1993. Among his significant accomplishments are the investigation, evaluation, and implementation of new computer technologies for clinical data management systems and developing strategic plans for integrating these technologies into current systems. He has extensive experience preparing Standard Operating Procedures (SOPs).

**Robert Pearsall** received his BS in Electrical Engineering from MIT and his MS in Nuclear Engineering/Biomedical Instrumentation from The Ohio State University. He is Senior Consultant and Vice President for Business Development at Mousley Consulting, Inc. He has been involved with a variety of clinical data system projects for biopharma, including data management systems, electronic data capture (EDC), electronic submissions, validation compliance, and knowledge management. He was team leader and design architect for pilot projects in FDA/CBER electronic submissions.

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To buy or to build – this is one of the most fundamental decisions an organization must make when transitioning to EDC systems. This detailed report explores the pros and cons of each approach and offers some alternatives that combine aspects of both.

### "EDC and the Alphabet Soup: IIS, NT, UNIX, APACHE, ASP, CF, HTML, XML, CSS, DHTML, CGI, JS, SOAP, DAO, and CITRIX"

When learning about EDC technology, the uninitiated are sure to face confusing jargon and bewildering acronyms. By defining and explaining some of the most common EDC-related terms, this report separates the critical concepts of EDC from the jungle of technical language.

### "EDC Needs Cyber Glue: Tying the New and the Old Together — XML, Portals, and Workflow"

Extensible markup language (XML) brings dissimilar databases and other software applications into one smoothly running EDC system. XML-based portals provide users with a gateway to all of an organizations data, software, and other information. In this report, we explain how XML and portal technologies can improve workflow within a biopharma company.

### "Legacy Systems: Bridging the Past with the Present"

For biopharma companies moving into the electronic environment, two major challenges arise from legacy systems: integrating legacy systems into current operations and bringing legacy systems into compliance with FDA regulations on electronic record-keeping. This report explores options for integrating legacy systems, especially from a data management perspective.

See back for order information.



## edc **today**

Issue No. 4



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