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In the next issue of
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Portals, and How They Can Make EDC Work Better

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 twelfth issue takes a closer look at information portals, one of the more recent web-centric technological advances. Portal technology can improve understanding of the workings and goals of the clinical trial and workplace productivity by allowing clinical workers to access all software applications and clinical trials information from a single place on their computer. Biopharma companies considering making the transition to EDC should familiarize themselves with the various types of portal technologies and their potential benefits.

Definition of a Clinical Research Portal

Since “Portals” are a relatively new web-centric technology and a fairly new technological concept, it is important to understand just what is meant by the word. For our purposes, a Clinical Research (and perhaps EDC-integrated) Portal is an Internet Web site that provides a person with a single location and login for all the information and applications needed to perform their work over the course of a clinical trial. Such a portal might be called an “access” portal.

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. This means that all study materials (such as the clinical Protocol, applicable SOPs, guidelines, instructions, and forms) can be located at the Portal.

Furthermore, a portal can restrict access to materials to those clinical workers that have a need for them. Many portal products, such as ClinPort, provide an integrated security environment. Not only is there a single login, but also access privileges to documents and applications can be administered from a central location.

Another aspect to a portal is the facilitation of communication. A portal can provide a structured “meeting place” or ad hoc forum for clinical workers to discuss issues uncovered during a clinical trial. A portal can offer directory services, allowing a worker to find an appropriate contact (be it e-mail, postal address, or e-mail address.) Portals can also provide messaging with an audit trail which helps provide compliance with 21 CFR 11.

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In addition to study materials, all study related “tools” (such as the EDC, study agent tracking, and SAE systems along with monitoring reports) could be located in one place — at the portal. With an integrated security framework, security tokens can be passed to these tools so that additional logins can be minimized.

A broad range of features can be included in a portal depending on an organization’s needs. 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.

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.¹

When shopping for a portal product, having a list of business requirements in hand will help to sort out the vendors in the portal market. The list of business requirements should be made in consultation with all of the people that will use or maintain the portal, including clinical research associates, clinical data managers, study site investigators and their personnel, patients, the system developer, and other IT staff. Additionally, 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 must be present and which features can be optional.⁴ For more on how to choose and acquire a portal, refer back to [EDC Today™](#), Issue 4, “Buy vs. Build: Exploring EDC Technologies”.

Collaboration and Portals

Another difficult to “pin-down” technical term used frequently in the context of portals is “Collaboration”. Software vendors offer a myriad of “examples” but the definition seems elusive. At minimum, it is the ability to share documents and information. One way in which collaboration differs from process management, which one might view as SOP directed or “scripted” work, is that it is inherently ad hoc. Nathaniel Palmer states in “Portals and Collaboration” that a portal should allow its users to “dynamically form teams without the restriction of geography, organizational hierarchy, or even corporate boundaries.”² Palmer further notes:

“Whereas processes are necessarily scripted and defined when automated with software, collaboration is fluid and requires facilitation, not control. Most organizations view the portal as a means for sharing work, not enforcing rules and rigor. A common application of portals is the ability to create and share a workspace, often short-lived and self-managed, while incorporating resources and online information.”²

This sharing of documents and information can be achieved in a large number of ways. A clinical research portal might provide a “workspace” and allow empowered “workgroup” members access and ability to share documents. It might do a lot more, or a lot less. A fresh perspective to consider: A Clinical Research Associate’s (CRA’s) work is driven more often by externalities than by factors inside their workplace (i.e., their employing biopharma.) Day to day, they might be more likely to be concerned with their investigator’s enrollment status and ongoing collection of data for “active” patients than they are with the review of proposed new SOP on training. They might wonder why it is more difficult to share information with an investigator as opposed to a co-worker down the hall and wonder which is more important and has a larger impact on their productivity.

However, Palmer sums up his position by stating, “The fluidity of collaboration, the liquidity of information - these are the new factors of competitive advantage.”²

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Applications of a Portal to a Clinical Trial

How then can the capabilities of portal technology be applied to a clinical trial? Table 1 shows a number of functionalities that a portal might support and describes who and how such functionality might be useful within the scope of conducting a clinical trial.

Table 1. Portal Functionalities and Their Potential Impact³

Functionality	Who and How It Helps
Assist in investigator or patient recruitment (and/or ties to patient registries)	Biopharmas can find and retain qualified and motivated study sites and investigators. Biopharmas and investigators can locate or draw in patients that meet study entrance criteria.
Provide incentives for participation (e.g., training, educational programs)	All participants can benefit from training and educational programs as well as materials that explain or demonstrate study-related concepts and procedures.
Organize and run events (perhaps in a manner similar to using “Net Meeting” for all personnel working on a study)	The ability to bring together a geographically diverse group quickly, and with “visual” enhancement, offer study participants a meeting place that allows them to “show and tell” what they are doing or want to do. Perhaps Investigator Meetings, now costly and logistically complex, could be conducted within the digital environment.
Facilitate coordination/communication in all stages of a trial	A bulletin board, guestbook or electronic forum can be made available to clinical workers for the purpose of communicating study-related information. The portal might also support directory services to allow one clinical worker to locate and communicate with an appropriate colleague, and provide messaging with audit trail capabilities.
Share Study Materials and Data	A document and data repository containing information about the study could be made available to clinical workers on a controlled access basis. Getting answers quickly to their questions will help all clinical workers.
Allow priority messaging for critical items (e.g., Serious Adverse Event Reporting)	All participants can benefit from improved communications, and support for priority communications, such as critical Serious Adverse Event reporting.
Provide training	Training and training materials can be presented in the portal. Training might consist of a streamed video, a “walk through” demonstration of “how to” use a particular system found in the portal (e.g., EDC system), as well as more mundane (but time proven) tools such as user manuals.
Provide site and individual skills assessment (and qualification/certification)	In addition to training, skills assessment and qualification can be done using “computer assisted” methodology and FDA “mandated” documentation could be generated automatically.
Provide customized content and “style” to each participant (e.g., selected study materials, language and allows handling of cultural differences)	One benefit of the “access control” mechanism used by portals is that it readily supports “customization” of content presented to each portal visitor. For the clinical worker this means all information important to them can be arranged within the browser to suit their evolving personal needs and tastes. Language barriers can be overcome in a limited way.
Establishes a link between sponsor and investigators	No longer will the study monitor or CRA that is the site’s designated contact be the sole communication pathway between sponsor and investigators. While the sponsor may not desire investigator-to-investigator contact, such contact might be beneficial in the interest of science.
Maintain community of participants after study conclusion	A more intangible benefit to all involved is being able to maintain links with others, others that have become “team members” with valuable experience to offer. “Post mortem” evaluations may also be more fruitful as team members can be polled for their impressions and other input.
Quantities of Web host statistics for data mining (or for process improvement purposes)	The sponsor can use the statistics generated by the web host to continuously improve the portal’s offerings.

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Support for Integration of Legacy or Auxiliary Systems

A significant portion of the “real bang for the buck” offered by portal technology might well be the support for integration of legacy or auxiliary systems and the repositioning or realigning of these systems so they are in direct contact with the clinical workers they are intended to support.

Building systems on a portal framework requires a sophisticated in-house 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.⁴

The potential benefit, however, makes integration of legacy and auxiliary systems worth considering. For detailed descriptions of legacy and auxiliary systems, please see *EDC Today*TM, Issue 11, “Technology Old and New: Integrating Legacy Systems with EDC”.

Portals can be used to integrate any or all “auxiliary systems” and make them more effective by “pushing” them out to their “users”. Table 2 lists some auxiliary systems and some of the potential benefits of placing them within a portal.

Table 2. Benefits of Including Auxiliary Systems Within a Portal

Auxiliary System	Impact of a Portal on Clinical Workers
Assay Samples/Results Tracking Management	Assay sample tracking information and the results of the assay can be made available to Study Site Personnel looking for sample status (e.g., location) and results. Study monitors and CRAs can track samples and view results as they become available. Samples that are missing might be traced or even redrawn if required.
Serious AE Reporting and SAE Reconciliation	Since reporting Serious Adverse Events (SAE) needs to be performed on an expedited basis, the process can be streamlined by having access to the SAE data entry system pushed out to the investigator site. Sponsors would complete the reporting process (i.e., inform the FDA) when alerted by the SAE system of a new incident.
Patient Randomization and Study Agent Accounting/Tracking	As patients are enrolled, the investigative site could access the portal in order to request study agent shipment for the new patients. If integrated with a randomization process, the shipment of the appropriate study agent (i.e., placebo or “drug”) can be almost completely automated.
Investigator/Site Accounting/Tracking	Investigators could maintain their own contact information, helping a sponsor keep up-to-date. Investigator payment history and other site-related information might also be made available.
Patient Tracking	As patients are enrolled, the portal can make patient tracking status information available to all clinical workers involved with the study. Project managers can determine very quickly how trials are progressing and quickly identify problem sites.
Ad-hoc and Study Monitoring Reports	Study Monitoring reports can be used to present a big picture view of the study progress. Ad-hoc and other reports can be made available, possibly using the entirety of the data (both clinical and tracking) to aid in efficiently running clinical trials.

Conclusion

A portal can be a valuable means for accessing and integrating a number of systems and tools in one “desktop” working environment for the clinical worker. Integrating e-mail and other communications tools into the portal can increase the effectiveness of clinical workers. Likewise, having access to important documents and needed data from the clinical worker’s desktop introduces many potential advantages.

Because of its ability to tie together disparate systems and databases, portal technology also facilitates the integrating of 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.

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

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References:

- ¹ Citrix Systems, Inc. "Enabling the Virtual Workplace With an Access Portal." www.citrix.com. 2002.
- ² Nathaniel Palmer, "Portals and Collaboration", e-doc volume 17 Issue 1, January/February 2003 pp. 12-14.
- ³ CTC2, "CTC2 vs. Physician Portals and e-Hubs" www.ctc2.net 2003.
- ⁴ *EDC Today*TM, Issue 4, "Buy vs. Build: Exploring EDC Technologies".

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).



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