

Portal Partnering: Connecting Pharma and CRO

By David Gwyn

The contract research market grew 13% in 2009, reaching \$23.5 billion, according to the Contract Research Annual Review 2010 report. As pharmaceutical and biotech firms look to cut costs and increase their R&D productivity, this growth will likely continue. But as these partnerships with contract research organizations (CRO) become more common, so too will the challenges of managing them. It will become essential for firms to establish collaborative communications with their partners and leverage workflows to help encourage communication and improve the efficiency of the working relationship. A partner portal, connecting the sponsor with the CRO, is an effective platform to achieve these goals.

A partner portal is a web-based application that allows a firm's partner to access resources shared between the two organizations. It is intended to bridge the gap between a sponsor's internal systems and those of the CRO. Information normally shared through repeated and redundant emails can now be accessed through a website where multiple pages categorize and organize the information.

Not only do partner portals provide a central location for staff from both organizations to communicate, they also enable the use of workflows to automate a lot of work that is currently being handled manually.

Workflows can be used throughout the clinical trial process, beginning as early as patient enrollment. Initial screenings through workflow-enabled reviews of inclusion and exclusion criteria provides a more scalable process for completing one of the most difficult activities of the clinical trial. A partner portal integrated with the Clinical Trial Management System (CTMS) pulls the enrollment data and reports progress on patient enrollment to the sponsor through a dashboard; a workflow generates alerts to inform key players when certain milestones are met. Once patient enrollment is complete, a workflow notifies the ERP system to ship clinical supplies to the appropriate sites, thus eliminating much of the work currently being done manually by monitors.

This approach can be extended by utilizing the partner portal as a common ground to facilitate communication between the sponsor, CRO, and investigators. Rather than sending documents through email, the sponsor utilizes workflows to send out documents for review and approval, such as the investigator brochure and other information on reporting procedures, staff training, and data collection. These approvals can even include digital signatures that are 21 CFR Part 11 compliant and self-provisioned – meaning no IT involvement is required to setup the signature process for a new investigator. Once approved, this content populates investigator sites that are created automatically by another workflow. Workflows are used to request missing information from investigators, such as their curriculum vitae and a 1572 form. By utilizing workflows to establish and enforce procedures within the partner portal, a sponsor can ensure that standard processes are followed by all of the individuals involved.

The partner portal can also help extend internal learning management processes to external partners. Once new procedures have been documented, notifications are sent to the people that need to review them, as identified by their training role. The workflow then tracks that those individuals have reviewed the material and records it for FDA audit and inspection purposes; it can even prompt the individual for their electronic or digital signature as proof that they've read the training material.

As the trial progresses, the partner portal can pull data from case reports forms in the CRO's clinical data management system, prompting a workflow to route the study for review and approval. The data can also feed dashboards that monitor certain metrics; reaching a specific level could trigger workflows that initiate a review. As patient satisfaction is measured, workflows triggered by reaching certain thresholds alert monitors or other study personnel to get involved and track the activities through completion.

Once the trial is completed, workflows can help gather content from the site by sending triggers to the clinical trial management system to make sure all elements are captured and stored where they belong. Workflows are also triggered to route data and the site itself for archival and/or deletion processes and automatic removal of external user credentials upon study closure.

The benefits of integrating workflows and portal solutions are many, including the obvious increase in collaborative communications and more efficient business execution. Measuring these benefits can be challenging, but the companies that have set up partner portals and begun to use workflows to establish and enforce standard processes for their partnerships most often measure ROI by a very tangible decrease in shipping costs. Workflow-based portal solutions also prompt a significant reduction in transaction processing time and turnaround time. And, most importantly, they trigger automatic communication and collaboration between partners in a way that wasn't possible before with disparate partner ecosystems.