



Faster Study Start-Up and Reduced Costs through the Use of Clinical Document Exchange Portals

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Produced by Cambridge Healthtech Media Group Custom Publishing**

As pharmaceutical companies face intense financial pressures due to looming patent expirations on blockbuster drugs, weak drug pipelines and heightened competition, they are exploring strategies to improve operational efficiencies in clinical trials that will speed drugs to market. One of the more inefficient steps in the clinical trial process — study start-up (SSU) — has been carefully scrutinized; and although efforts to shave hours, days or weeks from clinical trial timelines have been somewhat successful,^{1,2} it still remains a bottleneck.

This whitepaper makes the case for web-based document management and exchange as a driver of greater efficiency in the SSU process for sites, sponsors and contract research organizations (CROs). Topics include:

- The current status of SSU practices
- The challenges of transitioning to a centralized, collaborative online environment
- Cost and efficiency benefits from the perspectives of both the investigative site and the sponsor or CRO



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Improving Document Exchange During Study Start-Up: Where to Begin?

On an industry-wide basis, clinical trials often fall behind their timelines from the very beginning — during protocol development, site selection and study start-up. Assessment of site feasibility, negotiation of contracts and budgets, planning for patient recruitment, legal reviews and approvals by institutional research boards (IRBs) and/or ethics committees all take considerable time and effort. Research suggests that each of these steps can cause delay, with contract and budget negotiations, and patient recruitment leading the pack. Contract and budget negotiations and approval are

responsible for 49% of study delays, followed by patient recruitment, which causes 41% of delays as seen in Chart 2 below.³

These tasks require document exchange, and inefficient document turnaround among stakeholders is often standard practice. The large number of documents that are typically exchanged during SSU are listed in Chart 1.

What is the realistic potential for time savings and efficiency in the SSU process with an online document exchange and management system? According to an online survey of 252 investigative sites conducted in March 2009 by Quintiles, a leading CRO, and IntraLinks, a provider of on-demand solutions for online document exchange, 67 percent of respondents report using unsecured email as the primary method of document exchange with sponsors during clinical trials.⁴ Sixteen percent of respondents still send documents via overnight mail, and seven percent fax their documents. One-quarter of the respondents working with paper-based methods of communication claim to spending more than three hours per week searching for documents, and 52 percent state that when traditional means are used, i.e., faxing, mailing or overnight courier, sponsors ask them to re-send documents once or twice a week.

For the investigative site, keeping track of a growing number of study start-up documents across multiple studies with multiple sponsors while ensuring the most recent versions are used is no small feat. This is especially true as data indicate that the same sites are performing greater numbers of studies that are increasingly complex.⁵

The importance of version control is highlighted in the FDA's analysis of 5400 audits conducted between 1977 and 1998 in which the most common deficiency was the informed consent process.⁶ Errors can easily occur when a protocol amendment necessitates a revised informed consent form (ICF) and new subjects at the site are consented using an older version. An online document management and exchange system ensures that the most current version is the one accessed by the site.

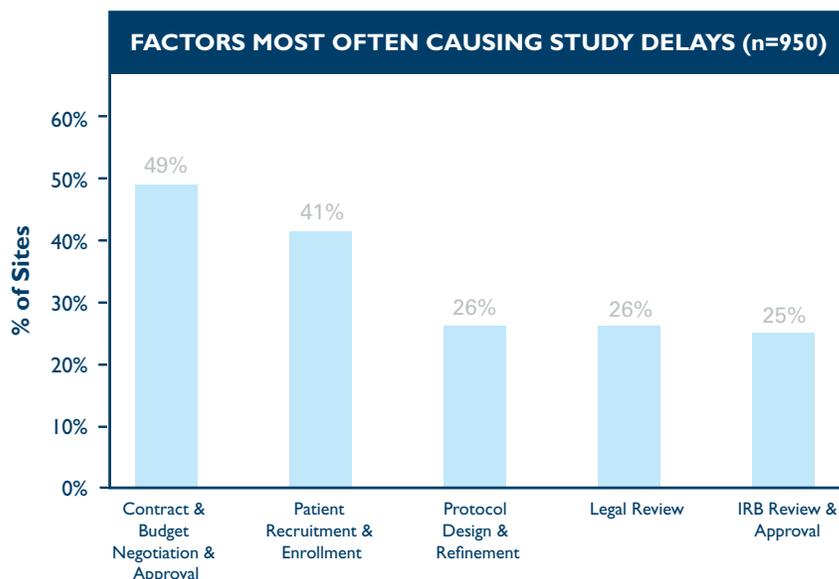
For the sponsor and CRO, tracking the status of study start-up documents for sites around the globe requires organization and tenacity. An online portal for site communication provides visibility into the status of sites' progress via reports generated directly from the system. Study teams can then be targeted in their follow-up activities with sites. Such reports also allow teams to easily provide updates for management to assess progress and trigger remedial action before timelines significantly veer off track.

Chart 1

Examples of Study Start-Up Documents

- Site feasibility survey forms
- Protocols
- Investigator brochures
- Site contracts
- Budget worksheets
- Patient recruitment plans
- Informed consent forms
- Advertising materials

Chart 2



Source: CenterWatch Survey 2009

Challenges of Moving SSU Online

An online document management system will represent a new process for some study teams, and as with any attempt to introduce new technology into an established process, there is an adoption curve.⁷ Users are typically comfortable with their current workflow or consider it the lesser of the evils, and any attempt to implement change is often met with resistance and annoyance. The same rocky technology adoption curve is expected with the introduction of a central portal for the exchange of SSU documents at the sponsor or the site levels, or possibly both. For each set of users, standard operating procedures (SOPs) for SSU activities are likely to have been in place for years, but despite this similarity, central portal adoption poses different challenges for the sites as compared to sponsors and CROs. This section explores those differences.

Site Challenges

Embracing new technology is expected to be the biggest challenge for sites on the road to widespread acceptance of communications portals as a tool for SSU.⁹ Sites continue to be overloaded with work from multiple sponsors, each with its own system for study start-up, communication, and ongoing clinical data collection. This reality tends to leave sites reluctant to learn yet another technology tool even though adoption of an online portal solution would mean all of a site's study documents could reside in one central location, and each staff member could quickly access them with one password.

New technology means the creation of new SOPs and a commitment to staff training. Many study coordinators at the site may rebuff efforts to engage in more training for an additional system, especially if they are already computer savvy, as they are likely to view this as a waste of time causing disruption to their efforts to stay current with their studies.

Training to use a web portal is minimal in comparison to learning expansive systems such as electronic data capture (EDC), clinical trial management systems (CTMS) or clinical data management systems (CDMS). Typically, training to use a central portal entails presentations at investigator meetings, online learning or use of DVDs. Training should take an hour or less, and should not be difficult for site personnel who are proficient in using the Internet. However, sponsors must plan for training throughout the entire study, not only at the beginning. New hires, delays in recruitment, or onboarding of rescue sites are all occasions that require training mid-study and site study coordinators could be reluctant to assume responsibility for training at that point. Given these parameters, on-demand training modules are ideal because they can be used at any time throughout the study, even if new site personnel come on board and need to use the system.

The importance of training cannot be overlooked.^{10,11} When sponsors fail to allot training time from qualified personnel, the responsibility usually falls to the colleagues at the sites or to the study monitor, taking time away from staff members' primary responsibilities. In order for the site to appreciate the benefits of an online document management and exchange system, training must be structured to meet the end users' needs, learning style and availability. If approached in this manner, widespread adoption of the system is possible.

The Cost of Study Start-Up Delays

Shortening the SSU enrollment timeframe can add significant value to the drug if the study is part of a registration package for regulatory approval. Consider the Earned Value (EV) analysis that was used to model a Phase III study of an antihypertensive scheduled to take two years and cost \$20 million dollars.⁸ Recruitment of 700 subjects was planned to be completed in 64 weeks, at a rate of approximately 11 subjects per week. Due to delays in study start-up, randomization fell to seven subjects per week in the first half of the study. EV analysis predicted that if the recruitment rate were maintained at that level, the study would run six months longer than planned and cost an extra \$1.3 million. An alternative for the sponsor at that point would be to initiate an expensive recruitment campaign, bringing the study in on time at a cost of several million dollars. Either way, delays in SSU incur greater losses during the endgame, particularly if the study is to be included in a new drug application.

Sponsor/CRO Challenges

In deciding whether to implement a hosted web portal to centralize document management and exchange among study participants, sponsors and CROs face numerous issues including: costs of the initial investment, the return on investment, whether the new system will integrate with the sponsor's or CRO's own web-based portal, ongoing training requirements for staff to ensure the proper use of the portal, and the need to generate new SOPs and establish new processes. This is a tall order for companies struggling to sustain pipelines in a very challenging economic and regulatory climate. It is this environment, however, in which forward thinkers can affect the most positive change. They attempt to move their organizations away from the less-than-optimal status quo, and toward the implementation of best practices to position them in front of, rather than at the tail end of, inevitable change. In the case of clinical trial technology, making the move requires several factors — buy-in from upper management, early adopters to champion the technology within the organization,¹² and commitment to process change and ongoing training for existing and new staff.

Investment in new technology is always a major consideration. In building a business case that supports the value of a web portal for clinical trial document management and exchange, weighing the financial investment of acquiring the technology and time and cost savings it will afford against the cost of continuing with inefficient current practices is essential. Also important is factoring in opportunity costs, such as those linked to burdening staff with maintaining a paper-based system or a less-than-optimal computer-based process for handling, retrieving and storing SSU documents. Lastly, as the EV analysis demonstrated (see sidebar), opportunity cost includes impact on submission timelines for any study on the critical path for a new drug application.

Worth noting as part of the comparison is that efficiencies linked to new technologies tend to be cumulative over time as end users become increasingly familiar with them through continued use across multiple studies. During this learning curve, costs are associated with changing SOPs and the internal processes needed to optimize the value of the new technology. Sponsors also incur costs in maintaining an internally built portal such as continuing investments in software upgrades, expanding collaboration capability among internal and external stakeholders, and implementation of standards, security and regulatory compliance. Many sponsors lack the resources to support this extensive effort internally, so their needs might be better served by transitioning to a central portal solution, which moves the burden of maintenance, integration of standards and support to the software vendor.

Optimizing Document Exchange: Key Elements for Successful Portal Implementation

Web-based portals that front a secure document repository and allow collaboration among participants are one technology option available to help streamline document exchange and facilitate process improvements. To make a significant impact on how internal and external stakeholders exchange documents during the study start-up process, a successful solution must be:

- Centralized
- Web-based
- User-friendly
- Cost-effective
- Secure

These features work together to optimize the exchange of documents that occur as clinical trials begin and throughout the conduct of the study.

Centralized

A central, sponsor-neutral portal serves as a single entry point to documents for all studies. A neutral third-party portal allows sites working on multiple studies with multiple sponsors to potentially have to access only one system to get to the information needed for any study in which they are participating. To gain access to all of his or her study documents across multiple studies in which they are participating, each user has a single credential. The portal becomes the single place of record for the latest versions of study documents such as investigator's brochures, ICF and protocol documents. Once the study begins, the portal can be used to rapidly disseminate study conduct-related information such as protocol amendments, updated ICFs, and adverse event information via "Dear Investigator" letters.

For sponsors and CROs, they gain cooperation and acceptance from sites that appreciate simplified access to documents across studies. Sponsors concerned with losing branding opportunities by switching to a third-party system often can have a private label splash page created to brand the study with a sponsor-specific message prior to entering the study page.

Web-based

With studies becoming increasingly global, a web-based portal is particularly compelling. A web-based solution ensures that everyone involved in managing the study has 24/7/365 access to the pertinent information needed to keep the study moving forward.

In order for a centralized portal with the features described above to provide access to studies of many sponsors, the simplest solution to use is known as Software as a Service (SaaS). This software deployment model is web-based, hosted and supported by a third-party provider. This means that the provider owns the infrastructure, maintains the software with periodic updates, including enhancements to security features, and serves a large customer base via a multilingual 24/7/365 help desk. This route requires no upfront capital investment on the part of the sponsor or CRO and may ultimately lower costs and accelerate timelines. In addition, this capability frees up the internal information technology (IT) departments at the sponsor or CRO for other purposes. When the software is owned and managed by a sponsor or CRO IT department, that organization bears the responsibility for ongoing maintenance, upgrades, security, training and support.

User-friendly

From the perspective of the end-users, or site personnel, the web portal must be a user-friendly technology that can be easily embraced in the transition from paper-based studies. With appropriate training and support, such as online tutorials, DVDs, presentations at investigator meetings, and a live help desk, sites will recognize the value and simplicity of having the ability to exchange the latest versions of study start-up documents quickly, easily and securely. Further, a new user should be able to complete online training in under an hour via self-paced training modules. And, at the completion of each, a short quiz can be made available to test the participant's comprehension of the material and then saved to maintain a record, providing the proof of training required for FDA 21 Code of Federal Regulations (CFR) Part 11-electronic records.

Cost-effective

From the sponsor's perspective, numerous fixed and variable costs are related to study start-up and the exchange of documents associated with it. The fixed costs are mostly personnel, whereas the variable expenses are tied to the cost of extra monitoring visits, time spent resolving queries, overnight courier fees, copying fees, and storage costs for paper documents. Although personnel costs appear to be fixed, if staff members no longer have to spend their time searching for SSU documents or turning them around, they can devote more time to other tasks such as recruitment and screening. Further, CRO project management and study monitor costs are often time-based rather than project-based, meaning that study delays use more of their time, and therefore, can drive up personnel costs. All of these costs and efficiencies to be gained must be considered in determining a true return on investment (ROI).

A simple place for a sponsor or CRO to start quantifying the ROI of implementing a web-based portal is the cost of overnight mail service. One CRO found that it saved about \$9,000 in overnight mail over a six-month period when using a web-based portal as an alternative for a study with 50 U.S. sites (see "Improving ROI and Timelines for Sponsors" — page 6). Additional savings to factor in when documents are sent online versus through the mail include the time needed to make copies and prepare labels. Delay is also reduced because information can be passed in near-real time, rather than losing days as documents move back and forth through the mail system. By using a web portal, these costs and the time lag involved in SSU document distribution and collection disappear. With contract and budget negotiations pegged as the slowest part of study start-up, these tasks, for example, could be completed more quickly as several hand-offs could be turned around in a single day as compared to several working days using an overnight courier service. The benefit is that sites can be activated and the drug shipped sooner, thus expediting patient enrollment.

Secure

A secure web-based repository and exchange system not only facilitates companies' efforts to comply with regulations for the creation, transmission, and retrieval of electronic documents, as described in 21 CFR Part 11*, but also provides security at three levels: system security, user access security and document security.

System security refers to adhering to the highest standards required to protect the sensitive information that is central to clinical studies. High standards are needed for systems or vendors to maintain SAS-70 Level II certifications and compliance with ISO 9000 standards.

User access security entails ensuring that the system has stringent user ID and password controls, and that different levels of user access and control in the web portal can be assigned to different study participants. All sites have access to the same version of the documents, and as individuals work with them, an audit trail is created detailing who reviewed them and when.

In addition to controlling document access at the user level, document security features should also be used. Document security options include: locking the document to prevent substituting earlier versions, prohibition from copying, printing or forwarding to unauthorized individuals, and watermarking, for additional security. These features give sponsors the confidence to freely share information among stakeholders.

*FDA 21 CFR Part 11 – Electronic Records; Electronic Signatures

Web Portals Are Ready to Deliver

Clinical trials are increasingly collaborative ventures among sponsors, CROs, sites, IRBs/ethics committees, clinical laboratories, and other providers that are becoming more global in nature. The general benefit of a web portal for secure document exchange is that it can streamline the secure and compliant flow of SSU documents for multiple studies among these participants. The following section presents evidence supporting this.

Sites Are Ready for Web Portals

It is widely acknowledged that in order for clinical trial technology to be successful and reach the desired return on investment, it must be accepted by the end user, or the investigative site. Results of a March 2009 survey of 252 investigative sites indicate that clinical trial technology is now routine at the site level, and sites are ready to embrace the web portal as a preferred communication tool.¹³ According to the survey, 80 percent report using some sort of online tool to manage study documents and more than two-thirds (68.5%) access their system at least once a week. More than 75 percent rate the ability to manage studies online as neutral or positive relative to paper-based management, and respondents cite time savings, better organization and easier communication with sponsors as top benefits. Of the 20 percent who have not yet used an online tool for management of study documents, 89 percent expressed a willingness to try one.

Table 1

BENEFITS OF MANAGING CLINICAL TRIAL DOCUMENTS WITH ONLINE TOOLS (n=950)	
Benefits	Response
Saves time	41%
Helps me better organize study-related information	22%
Makes it easier to communicate with sponsors	21%
Saves money	16%

Source: IntraLinks/Quintiles 2009

Respondents using a web portal today for document exchange were asked the biggest benefit. As shown in Table 1 on the left, 41 percent named time savings as the biggest benefit, followed by better organization of study-related information (22%), and easier communication with sponsors (21%).

Improving ROI and Timelines for Sponsors

With the near-universal acceptance of Internet applications in clinical trials, this is the time for sponsors to move toward an organized, centralized web portal designed to expedite communications among internal and external players during study start-up and conduct. By driving document management through a web portal, sponsors and CROs can cut weeks

from site recruitment and study start-up time with the potential for significant time savings and direct savings in operational expenses. If the typical Phase III study SSU duration is 22 weeks getting to “first subject-first visit” (FSFV),¹² with 35 days required to negotiate a clinical trial agreement (CTA) with independent sites, and 96 days to negotiate a CTA with an academic medical center,¹⁴ days if not weeks can be saved by using a web-based portal with repository and document exchange during the start-up phase, such as CTA registration.

Evidence of the time and cost savings that secure web-based document exchange can offer to sponsors and CROs is seen in four recent case studies conducted by Quintiles. The case studies tracked efficiency gains in SSU made by switching from a paper-based process to a centralized web portal system.

Results from one of the case studies — Study A, a U.S.-based study for a new indication, which enrolled at 50 centers and used one central IRB — highlighted the value of a centralized portal for document exchange. The two hours per site that Quintiles would spend on activities such as assembling documents and instructions, completing shipping labels for the site, and verifying receipt of documents, could be done in 10 minutes per site using the portal. This represents a 92 percent efficiency gain. In addition, by switching to the centralized portal, \$9,000 in courier costs were eliminated over a six-month period. Monitoring became more efficient because study supervisors were able to review documents electronically prior to onsite visits, and all documents were auditable, thereby generating fewer queries.

As additional validation of the portal’s value, Quintiles collected metrics on four Phase II and Phase III studies in which an online communication tool was used for SSU activities. All studies used U.S.-based sites. Results were compared to the CRO’s traditional methods, which took an average of 120 days for academic medical centers (AMCs) using local IRBs, and 30 days for private sites using a centralized IRB

to be ready for shipment of the study drug. In Study A described on the previous page, private sites were ready in 15 days, representing a 50 percent improvement over the usual time to enroll patients. In Study B, private sites were ready to start in 22 days and AMCs needed 97 days, representing 27 percent and 19 percent improvements, respectively. Additional results appear in Table 2 below.

Table 2

STUDY	SITES	TRADITIONAL METHOD (DAYS)	WEB-BASED COMMUNICATION (DAYS)	EFFICIENCY GAIN	TRADITIONAL METHOD (DAYS)	WEB-BASED COMMUNICATION (DAYS)	EFFICIENCY GAIN
		Private	Private	Private	AMC	AMC	AMC
A	50 private	30	15	50%	**	**	**
B	14 private; 1 AMC	30	22	27%	120	97	19%
C	29 private; 21 AMC	30	20	33%	120	91	24%
D	50 private	30	15	30%	**	**	**

Momentum for Portal Adoption Will Continue to Build

Source: Quintiles 2008

At a time when the clinical trials industry is transitioning away from paper-based trials and adopting technologies such as electronic data capture, electronic patient reported outcomes, and clinical trial management systems, users are ready to embrace technologies meant to streamline various pieces of the clinical development process. Much of the focus has been on compressing timelines once the trial is underway, but now the focus is shifting to incremental gains from the study start-up process.

A neutral web-based portal is key to improving document distribution, review and completion as well as facilitating communication among all parties, such as sponsors, CROs, sites, IRBs, laboratories and other providers. Using this approach, sponsors, for example, can achieve measurable gains by finalizing site contracts, and getting to FSFV more quickly. Keeping early site recruitment and activation on track is important to prevent studies from running over the projected timeline.

All of this happens by allowing study start-up documents to reside in a central repository, an important first step toward accelerating the many steps associated with study start-up. With the single log-on portal, study team members gain immediate access to the latest version of start-up documents as well as tracking capabilities for all of their studies. This eliminates the need for email, which provides limited security, as well as time-consuming tasks such as searching for the right document and/or version, making copies, and preparing packages for overnight delivery.

Going forward, as consolidation and globalization continue in the pharmaceutical industry, greater collaboration capabilities will become necessary to bring more efficiencies to clinical trial operations. This starts with a portal for accelerating the site evaluation and feasibility assessment process, drafting budget worksheets, contracts, and informed consent forms, completing Statement of Investigator Forms 1572, and other documents related to study start-up.

Research indicates that only about 10 percent of sites use a web portal as the primary method of communication for clinical studies. Although there is a long way to go before the web portal is the standard method of clinical trial communication, trends suggest this is likely to happen sooner, rather than later. It holds much promise for making meaningful gains in study start-up activities, as well as study conduct and study close-out processes.

Resources

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