Leading Change: Effectively Guiding the Organization through a Study Start-up Technology Transformation

Automating study start-up enables faster site activation, better collaboration with study partners, and more informed decision-making. The adoption of purpose-built study start-up technology, however, requires organizational buy-in and alignment. This paper examines common barriers to change and offers best practices to overcome them.

Introduction

Traditional methods used to manage study start-up – spreadsheets, emails, and file repositories – are slow and error-prone, resulting in costly delays for study teams. Research shows that missed start-up timelines can cost sponsors up to $2 million per month.[1]

The rise of precision medicine, global subject enrollment in response to COVID-19, and protocol complexities make it challenging to manage start-up processes manually in today's clinical trial climate. That's why sponsors and contract research organizations (CROs) are turning to technology specifically designed to manage the intricacies of study start-up, with adoption increasing in 2020.

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Deploying a new study start-up system requires careful coordination across multiple functional groups to ensure a successful launch and user adoption. Despite good intentions, the effort may stall if effective change management tactics aren't implemented. This white paper addresses common barriers to change and best practices for overcoming them. Insights from successful deployments at top 20 pharmaceutical companies support the recommended practices.

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[1] NCBI. Brianna M Krafcik, Gheorghe Doros, Mariana A Malikova. A single center analysis of factors influencing study start-up timelines in clinical trials. July 2017.

The Keys to Successful Adoption of New Study Start-up Technology

Executive leadership has approved the technology investment, budget has been secured, and the implementation project is beginning soon. What's next?

Buying and implementing software is just one element of a successful study start-up transformation program. Organizational factors can emerge as barriers to adoption. People can be resistant to change the ways they work, especially when they have been using the same tools for years.

Overcoming barriers at emerging and large global organizations involves change management – a collection of practices and techniques that enable people to do things differently.

Here are steps your organization can take to ensure successful adoption of the new study start-up technology:

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
Communicate effectively	Manage resistance to change	Coordinate execution	Make training and support a core of the project	Foster change at clinical research sites

UPFRONT TACTICS TO DRIVE SUCCESS

> Define a clear, compelling scope of change.

> Establish success metrics to measure progress.

> Gain executive support that aligns with strategies and goals. Demonstrating that the leadership team buys into the changes sets an example that others can follow. In some cases, an executive leader can serve as an internal champion who evangelizes the new approach and disseminates the message.

STEP 1 Communicating effectively

When undergoing a study start-up transformation initiative, communicating to users why the organization is investing in new technology secures their involvement early on and imparts they are key to achieving the goals and driving operational improvements. A successful rollout relies on tailored communications to a diverse group of stakeholders. New technologies can fail to gain traction because users are not aware of their existence. Or, if they are aware of the software, they aren't sure what it means to them or how to use it.

Conducting a stakeholder analysis to identify decision-makers and users is a key component of a well-managed launch program. A best practice is to group stakeholders by their expected uses of the system. For example, senior leadership will need to hear a different message—and cadence of messaging—than operational users such as study start-up managers and clinical trial assistants.

Initiating top-down communications with leadership first ensures that senior executives are not surprised by the announcement of the new study start-up solution. In some cases, face-to-face presentations are beneficial as they keep upper management informed about the project and its goals. After briefing the senior team, project leads can start a bottoms-up communication campaign to raise awareness among relevant people across the organization. This approach avoids a negative scenario where end users raise concerns about a system that their managers don't know about.

KEY TAKEAWAY
Create a communication blueprint that's tailored to various stakeholders.

Real-World Insights

A global top 20 pharma determined that a company-wide communication release was not appropriate for their new study start-up solution. Instead, they carefully crafted communications by functional area and adjusted the message to match stakeholder needs.

Even though messages are tailored to different audiences, they should still utilize consistent language. If resources permit, establishing a project-specific brand is a great practice to adopt. This might include formats, colors, and designs that stakeholders will associate with the study start-up initiative.

Timing of messages counts as well. A monthly newsletter to end users might start several months before the go-live date. Communication about configuration workshops and other critical pre-launch steps establish a baseline understanding of what functionality will be included in the initial deployment. As go-live approaches, communications should gradually raise awareness about what's happening and who will be affected.

CENTRALIZING INFORMATION

The global top 20 pharma found success by establishing a centralized place for project information. A dedicated intranet site gave employees a clear and reliable destination for news and practical guidance on the new technology. The company put significant effort into this aspect of their study start-up launch. The intranet site contained numerous sub-sections for different aspects of their Vault Clinical program.

STEP 2 Managing resistance to change

Forcing change on a top-down basis without consulting those who are affected produces sub-optimal results. Conversely, business users can become solution advocates rather than detractors if they feel their views are included in the project scope.

EVOLVING REQUIREMENTS
Early stakeholder input

ITERATIVE FEEDBACK
Making users aware of what's coming

LAUNCH
Training to instill confidence in end users

Stakeholder input is key. And, resistance to change may provide a strong context for soliciting feedback and achieving buy-in from system users. The best practice here involves engaging with business users early and often. Working with people throughout the evaluation, during solution mapping, and beyond, program leads can minimize resistance to change.

KEY TAKEAWAY
Early stakeholder input and iterative feedback, coupled with training, facilitate a smooth successful launch of study start-up technology.

Real-World Insights

WORKSHOPS IN ACTION

The global top 20 pharma conducted business process assessments around site activation to determine areas for improvement that would drive more efficient and effective site activation. After engaging with SMEs around business processes and technology, the project team developed and prioritized the solution's business requirements.

The global top 20 pharma found that early stakeholder engagement fostered a clear understanding of who would need to use the system and any process changes that needed to be implemented to achieve the goal of faster, streamlined study start-up. Subject matter experts (SMEs) across several functions participated in collaborative workshops to provide feedback, learn how the technology would affect ways of working, and develop a project roadmap. The program transformation team leveraged users' recommendations to make changes to proposed system capabilities, highlighting the commitment to listening and partnership.

STEP 3 Coordinating execution

An incremental introduction to new study start-up technology may be beneficial rather than a full-scale organizational rollout across all sites, countries, and studies. For example, it might be wise to start the implementation with site selection. Then, as users get comfortable with the solution for site selection, site essential document exchange and contract management can be implemented.

There must be adequate staffing, leadership support, and resources, or the execution will lag and likely fail. A best practice is to scope resource requirements and budgets as part of the total price of technology acquisition. Routine IT procurement may miss this step. Often, a software budget includes line items for licenses and services engagement, but not adoption execution and extensive training. This is a mistake to avoid.

THE SELECT STUDY APPROACH

Another approach to a phased rollout is launching the new technology to a select set of studies. Starting with a single study might be optimal. This way, people can use the system and issues can be resolved before rolling out on a global scale. An iterative feedback loop could take input from early users and factor it into modifications in the system before deploying to the entire organization.

KEY TAKEAWAY
Select an implementation approach that accounts for organizational culture, project goals, and timelines.

STEP 4 Making training and support a core of the project

The announcement of the go-live date, the launch itself, and the subsequent early usage period are all part of a continuous cycle of iteration. Users need to feel supported throughout each stage. Training prepares stakeholders to use the system and forms the foundation for a strong launch. Support helps keep them moving forward, even if they encounter technical issues with the solution.

An effective training program is based on a thorough understanding of the behaviors and skills that will help realize the system's business goals. This may involve mapping existing manual processes to workflows in the new application. For example, if the site feasibility assessment previously required a paper form, users must learn how to perform this task in the automated system. This approach ensures all users are confident they have the skills they need to be productive once the application goes live.

All companies that adopt study start-up technology should provide options for training delivery methods. A hybrid approach is often ideal. In-person classroom training can augment self-paced online tutorials. On-the-job coaching further reinforces key concepts. Technology vendors also typically offer customized, in-depth training programs that don't require a significant time investment from sponsors and CROs to prepare.

KEY TAKEAWAY
Comprehensive training across multiple methods and support tailored to stakeholder needs are essential to launch execution and ongoing success.

STEP 5 Fostering Successful Change at Clinical Research Sites

Implementing a study start-up system often requires change management strategies that impact sites, so it's important to include them in the technology launch plan too. Here are a few ways pharmaceutical organizations have addressed this.

A top 20 pharma developed a site launch plan that incorporated many best practices. They sent communications to site users early on informing them of the imminent process and technology changes so they could prepare. The communications emphasized the improvements in work processes and time savings with the new system.

THE VALUE OF A POWERPOINT

To ensure a seamless and simple transition, the top 20 pharma included a simple PowerPoint presentation sites could reference in all communications. Each site must acknowledge they received their account credentials and reviewed the PowerPoint.

Another top 20 pharma also sent a welcome email to sites informing them about the new technology. This initial email also included login credentials so sites could get hands-on right away. Site managers engaged with sites early in the deployment process to ensure they understood how to use the tool. Though the company didn't require formal site training, strong relationships between site managers and sites helped facilitate adoption of their new study start-up application.

An alternative practice, adopted by a fast-growing pharma company, involved sending sites targeted training videos and tip guides that covered topics such as budgeting, contracting, and site essential document collection so site users could familiarize themselves with the processes in the new tool.

KEY TAKEAWAY
Make it easy for sites to adopt new technology by enabling them with training materials.

Conclusion

Rolling out a new study start-up technology requires a thoughtful strategy and proper application of proven change management techniques. Overcoming organizational barriers is achievable by incorporating best practices that address the human and behavioral aspects of the change process. As leading pharmaceutical companies are demonstrating, strong adoption is possible by committing to methodical execution. The goals of the study start-up transformation need to align with organizational strategies and clear metrics must be established to measure performance. Training and support further encourage end user adoption. Armed with such practices, an organization can successfully improve trial quality and optimize clinical delivery.