Streamlining Clinical Study Design: Lessons Learned from the Pandemic

The pandemic drove changes in the way clinical trials are managed and increased momentum for the industry's shift toward digital clinical trials. Although the industry was committed to initiatives that enabled a more digital experience, many organizations considered that transition a long-term goal that lacked urgency. COVID-19 forced everyone to rethink study planning and execution.

Industry groups and regulators are still developing long-term approaches to digital trials but, in the meantime, organizations can apply early lessons learned to facilitate more streamlined study start-up and clinical trial methodology. Earlier this year, Amy Kisken, senior director for study startup at Bayer, shared four ways that sponsors and contract research organizations (CROs) can be more nimble and accelerate their development programs.

Facilitate change management discussions

Reassess processes and SOPs

Consider system validation and vendor qualification

Plan and invest in training

Facilitate change management discussions

Companies have learned that change management cannot be an afterthought, particularly as they've implemented digital methodologies. Clinical trials have seen three seismic shifts within the past two decades, according to Kisken, and some organizations have been caught off-guard.

First came the transition from paper-based methods to electronic data capture. The second big shift, still in its early stages, is the use of risk-based monitoring, which has yet to be optimized and standardized throughout the industry. The third and perhaps most paradigm-shifting change has been the industry's adoption of decentralized clinical trials.

Companies can adjust to these shifts with thorough change management and by facilitating deep-dive discussions. By using scenario-based questions they can assess concerns, identify processes to address them, and align stakeholders with new processes.

Assess concerns, identify processes to address them, and align stakeholders with new processes to facilitate change management.

For example, some organizations were uncomfortable that clinical research associates (CRAs) would never be on-site during the pandemic. Kisken noted that, if the concern was around data, they could communicate about their layered data review, implement a central data review team, or start targeted medical monitoring. If the concern was around site relationships, they could implement video calls and virtual tours.

"Asking these types of what-if questions can really help individuals identify self-imposed obstacles to adapting to this new reality," Kisken said.

Reassess processes and SOPs

Companies also learned they need to reassess their study-related processes and basic procedures. As cross-functional teams learned to cope with pandemic restrictions, some companies recognized that their standard operating procedures (SOPs) were written with the traditional clinical trial approach in mind.

For example, some had already transitioned to virtual site selection, but their site initiation process still involved an on-site component. As a result, they had to adapt those activities that were normally conducted in-person to a virtual environment and modify visit reports to ensure that any activities conducted remotely would be documented appropriately.

As Kisken pointed out, building flexibility into an SOP equips companies to respond to change and remain compliant. Along with SOPs, documentation requirements must be reviewed to ensure the faithful capture of all data, including digital data. In one example Kisken relayed, Bayer discovered a study template had not allotted sufficient space for the advanced digital signature. Although this was a minor detail, it caused significant issues and led to important process revisions.

Building flexibility into an SOP equips companies to respond to change and remain compliant.

— Amy Kisken, senior director for study startup, Bayer

Only when teams went back and examined the rationale for these signatures did they realize that several of them were not even legally required. The problem disappeared – and this may be the case for other clinical trial processes.

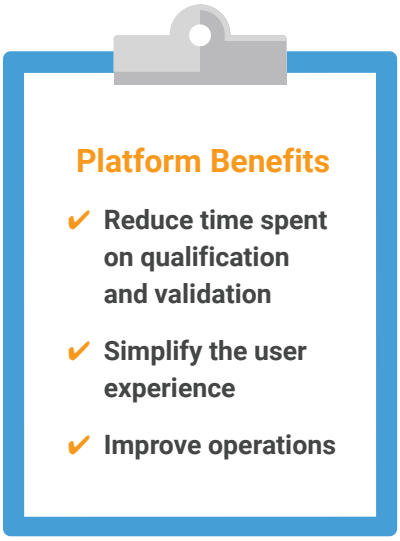
Consider system validation and vendor qualification

Challenges remain, however. A risk-based approach to validation still requires documentation, even when it is in electronic form, and not all study team members will be familiar with computer system validation requirements and related processes.

Raising organizational awareness about system development, and building out from that knowledge, will be crucial to preventing delays and ensuring that study teams are prepared during trial start-up. Another point to remember is that new technologies will result in the need to qualify new vendors, and teams will need to assess these needs and budget time for them.

By selecting platform solutions, Kisken noted, companies can reduce the amount of time they spend on qualification and validation and improve the user training experience by reducing the number of interfaces they need to be trained on.

The right technology solution can also improve ongoing operations. For example, during the first year of the pandemic, companies struggled to maintain even a basic level of oversight over various study countries and sites, particularly when pandemic waves affected different regions of the world at different times and severity levels. Even the simple task of knowing which sites were seeing patients and which sites were still recruiting them was extremely difficult to handle with paper-based records. Cloud-based systems allow granular data to be tracked so that teams can predict roadblocks, even during planning stages.



Plan and invest in training

As companies assess what they learned, there is real momentum for the industry to push forward with new processes and technologies and maintain the efficiencies gained during the pandemic.

Robust change management practices, and improvements in training and skill building, will be critical to advancing digital clinical development. Senior management and stakeholders put digitization plans into action alongside robust technologies to reduce investment costs and implementation timeframes.

The next few years promise to be exciting times in clinical development, and the industry faces vast opportunities. However, the rules, tools, and processes required for successful digital clinical trials are in flux and will remain that way for some time to come.

In the end, it is up to clinical trial sponsors to take full advantage of these opportunities by planning their digital strategies, and educating workers, not just in the "unit operations" of digital clinical development, but on the wealth of benefits it offers them and the patients they serve.