

Improving Efficiency in Clinical Development

How to Build and Manage an Environment of Continuous Improvement

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themselves and their organizations to tackle the changes that will be required to realize efficiency gains.



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The need to “do more with less” has become a cliché in clinical development. Everyone — from monitors in the field to vice presidents at headquarters — understands that the clinical-trial process is large and complicated, with many moving parts and plenty of processes that can result in delays and budget overruns. They also have known for years that the size and complexity of clinical programs have been increasing disproportionately faster than available resources.

Until recently, inefficiency in clinical development was taken for granted. But the need for, and ability to, change for the better is being driven by a convergence of increased scrutiny on the function and greatly improved methods for improving efficiency. This convergence has created an environment in which change, propelled by the need for continuous improvement, is becoming a way of life in clinical development.

Implementing Change

Throughout the years, clinical organizations have implemented change on an ad hoc basis, with varying degrees of success. Many organizations have significantly improved specific parts of the process, such as patient recruitment processes or management of clinical-trial data. But very few clinical organizations in the industry have positioned themselves to effectively manage in an environment of ongoing change that is forced by a commitment to continuous improvement of results. Following is an overview of the key things clinical leaders must consider to effectively manage their organizations in this era of continuous, comprehensive change in clinical development.

Most operational improvement experts will say any comprehensive approach to building efficiency requires reviewing (and often revamping) three key things: work processes, technologies, and organizational structures. Today’s clinical-development leader faces a seemingly endless and interdependent series of improvement needs in all three areas.

Process. Reducing the time and costs associated with closing a database and submitting study data requires improvements throughout the life cycle of a clinical trial — from study team planning to in-stream data analysis and management.

Technology. New, Web-based technologies such as EDC, CTMS, and systems to support site and study team training introduce a level of complexity to both technology and process management. To truly realize the promise of new technology solutions, clinical decision makers must take a systematic approach to selecting the right systems, redesigning processes so

that they are efficient and can mesh with new technologies, and executing effective training and rollout plans.

Organization. More and more, clinical-development organizations have the opportunity to identify and concentrate on core competencies and outsource all other activities. Organizing to capitalize on those competencies — and effectively manage partners to provide the rest — often requires fundamental changes to roles and responsibilities. Additionally, every process change and implementation of a new piece of technology has an organizational impact. Ensuring that these changes are adopted and become ingrained requires an unwavering vigilance toward refining organizational structures.

Change Management

Effective leadership in an environment rich with improvement initiatives requires a disciplined, consistent approach to managing change. Three areas are critical to effective change management.

Metrics. While most organizations have established robust metrics to measure their effectiveness in executing clinical trials, few have established a macrolevel mechanism for measuring the effectiveness of the multiple change initiatives undertaken in their organizations and assessing how the performance of each initiative affects the overall performance of the function.

Communication. As mentioned before, initiatives can have disparate impacts on an organization and other programs. Successful change-management programs foster communication among initiative leaders, leading to increased cooperation and accountability for results.

Visibility. Senior management requires a view across initiatives to understand progress, performance against metrics, and dependencies among initiatives.

Embracing Change

Overall, most clinical leaders deeply understand the need to improve efficiency. The next step is motivating themselves and their organizations to tackle the changes that will be required to realize efficiency gains. While the effort may seem large and imposing on the front end, the benefits can be great on the back end. One thing is certain; significant change is a way of life in clinical development and will remain at the forefront for years to come. The organization that better manages this change will quickly outpace its competitors, contributing directly to overall performance through reduced costs and improved efficiency in getting drugs to market. ■

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