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Reengineer Your Clinical Research Site Processes

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Decentralized trials, technology and remote monitoring are rapidly evolving. Site staff shortages demand a search for efficiency and flexibility even as sponsors rethink their criteria for site selection. It is no longer realistic for even the best sites to continue business as usual.

Even successful organizations can improve, especially when the world is changing around them. In fact, many successful organizations are successful because they are good at improvement. Successful organizations can outgrow old processes that have come to impede further growth.

Identify Your Critical Processes

The process of improving processes is called "process reengineering." Using a process Gino Wickman identified in his book *Traction,* we started the process at our small sites by looking at the patient/study participant experience. Two critical processes became apparent: patient recruitment and patient care. We then identified four critical supporting processes: marketing and business development, regulatory compliance, invoicing/accounting and human resources. Every clinical research site shares these critical processes but they may look at them differently. They may also consider other processes to be critical. For example, next year we may add quality and risk management to our critical processes.

Assign Process Owners

Assign an owner to each process. The owner is not necessarily someone who manages the people who perform activities in the process. The owner of the regulatory compliance process could, for example, be a senior regulatory specialist with a special interest in and aptitude for overseeing the process. Also involve people who can help reengineer the process or who are responsible for performing activities in the process.

Focus on the Biggest Problems

We started by listing the processes in the order that a patient experiences them. By conducting a "walk through" of our processes for patient recruitment and patient care, we were able to physically identify the bottlenecks and areas where excessive time seemed to be spent. We listed and described these processes in a simple Microsoft Word document, but you could easy map them graphically as well.

Describe the current main steps in each process and the flows between them. For maximum flexibility, arranging stickies on a wall or a whiteboard might be helpful. Then transfer the process description into a flowchart document, possibly using "swim lanes" for different functional roles. Microsoft Visio is a popular tool for flowcharting.

Later, if necessary, create a flowchart for the activities within certain main steps. Keep in mind that the objective is not to create pretty flowcharts; it is to help the reengineering team visualize the process.

Once the most problematic steps are identified — the ones that subvert quality, timeliness, efficiency or flexibility — start digging deeper. Review trends over time — which metrics have gone downhill or not kept up as you have grown? Examine the metrics of other sites, and even other industries, to identify weak areas.

One problematic step we found occurred when patients responded to an ad campaign. Phone tag often lasted for days. We addressed this bottleneck by first sending a text message asking for a good time to talk. With this simple change, the recruitment specialist saved time and scheduled visits increased by 13 percent.

Discuss ways to improve the identified steps. Keep in mind that the most junior person in the room might be the expert or have novel ideas, since their thinking is not entrenched in "the way it's always been done." Someone else might have relevant insights from an entirely different industry. Do not be surprised if the discussion escalates into a vigorous debate. Different people have different attitudes toward change itself. Most changes will affect different people differently. For example, a change might increase one person's workload while decreasing someone else's status. Drive the discussion by repeatedly asking "why." It should take only a few "whys" to discover the real reasons for a process step being done the current way or why someone objects to a change.

After the team has achieved a good shared understanding of a process, its issues and some options for improvement, take another look at the process with a blank slate. Ask the team, "If we were to build this process from the ground up with no regard for the current process, what would it look like?"

Your familiarity with current processes and their problems can help you think of ideas for improvement. However, it can also constrain your creativity. Look outside the clinical research industry for ideas on how similar problems have been solved. For example, how do popular restaurants process diners (patients) to their tables (exam rooms)? How do they handle diners (patients) when a table (exam room) is unavailable? In our case, a customer service expert from a tactical gear company taught us how to build trust in the first few minutes of a telephone call with a patient by asking about their dogs or kids — almost everyone has a story to share — and, thereby, establish a personal connection. You can also learn about innovations and best practices by reading articles, attending conferences and sharing ideas with other sites, as well as from study sponsors, CROs and solution providers.

Document the New Processes

Create a processes folder on a shared drive. In that folder, create a separate folder for each process. In these folders, house process descriptions. A flow chart and a three- to six-page text document should be adequate to describe a process without it becoming too cumbersome or going into such minute detail that it reduces flexibility. Too much detail will make the people performing the activities feel like they are robots with no leeway to exercise their expertise.

Include a task list for each process owner that lists their process oversight tasks that occur daily, weekly, monthly or even annually. For example, the patient care task list may include checking daily on the status of monitor queries, checking weekly that a principal investigator has signed all lab reports, checking monthly for expired lab kits, and checking annually that standard operating procedures are consistent with the actual process and updating them if necessary.

Include forms, checklists and other documents used in the process. For example, our marketing and business development process folder contains our info sheet for business development, a list of studies that we can print or email to referring physicians and reference material on business development. Our recruitment process folder includes short study descriptions for enrolling studies, inclusion/exclusion checklists to cover when pre-screening a patient and current consent forms that can be sent to patients for review prior to their visit.

Implement the New Processes

You can implement some changes before others. Some personnel may be more comfortable with parts of the old processes, so ensure that everyone consistently adopts them. Resistance can reveal process defects and ambiguities to address. Use metrics to confirm that the new processes are actually superior to the old ones.

Continue Improvement

Tackle one or two processes at a time and cycle through them on a regular schedule (e.g., annually). It is not necessary to update every part of a process at the same time; focus on the most problematic step(s) and come back to the others in the next cycle. Some processes will require more patience than others because they are more complex, the upgrades are more difficult or expensive, the way to improve them is less clear, day-to-day tasks are more pressing or the people are more resistant. The most important goal is to establish a culture of continuous improvement that increases quality, timeliness, efficiency and flexibility over time.

Resources

Dane E. "Reconsidering the Trade-off between Expertise and Flexibility: A Cognitive Entrenchment Perspective," *Acad. Manag. Rev.* 35 (2010), 579–603. 10.5465/amr.2010.53502832.

Grant, A., *Think again: The Power of Knowing What You Don't Know* (Viking, 2010).

Wickman, G., *Traction: Get a Grip on Your Business* (BenBella Books, 2011).

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