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Five Steps for Improving Processes in Clinical Trials

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Nobody would accuse the clinical research enterprise of being a paragon of efficient processes. It's not that we don't want our processes to be efficient; it's just that the work needs to get done, no matter how inefficient the current processes are. After an initial burst of enthusiasm, process improvement projects seem to lose steam and then are quietly set aside for more pressing priorities.

The good news is that there is a proven, five-step process for improving business processes. This article will provide an introduction to the five steps, using risk-based monitoring (RBM) as an illustrative example.

But first, let's define what we mean by "process." In essence, a process is a standardized series of steps taken to achieve a goal. Processes simplify, streamline and regulate our activities. Formal processes are known as procedures ("standard operating procedures (SOPs)"), with well-documented steps. In our business, procedures are frequently designed to comply with governmental regulations and guidelines. Informal processes, on the other hand, just seem to exist as customary practices that are passed along by word of mouth, along with the forms and other artifacts of the process.

The Japanese method of kaizen (continuous improvement) is not limited to incremental changes. Sometimes, major changes are required to fix an obsolete or broken process. RBM, for example, requires major changes that cannot be implemented in tiny steps. Successful organizations must therefore be able to make major process improvements.

The five basic steps to significantly improve a process are: (1) map, (2) analyze, (3) redesign, (4) assign resources, and (5) implement improvements. Only after completing the first four steps can we productively move on to the fifth step, in which a process is actually improved.

1. Map the current process

Process mapping involves sketching the process to be improved, identifying the core objectives, and clarifying critical roles and decision points, as well as deliverables and timing. Like everything else in clinical research, this isn't as simple as it sounds. Numerous tools can be used for mapping, such as flowcharting, cause-and-effect diagrams, control charts, gap analysis, and "blue skying" (i.e., ignoring preconceived notions). The project team should select its tools based on the nature and complexity of the project, the experience of team members, and the culture of the organization. It's best to stick with a consistent set of tools.

In our RBM example, we could "blue sky" a statement of objectives. Assuming there is no tradition of 100% source document verification (SDV), what exactly are we trying to accomplish? Is our goal to reduce cost, improve quality, or something else? What are the problems with 100% (or any other percent) SDV? How will RBM affect the field monitoring staff? What are the costs and benefits to the sites, especially if remote monitoring is anticipated?

2. Analyze the process

Utilizing the flowchart, cause and effect diagram, or any other tool that was used in the previous step, process analysis relies on the application of basic investigational tools, such

as Five Whys and Five Hows, or something more sophisticated like Root Cause Analysis (RCA) or Failure Modes Effect Analysis (FMEA). Regardless of the tool used, the most important questions will be about quality, cost and timelines, and the tradeoffs between them: Why are we doing this? What is causing the pain points? How are we spending our time? Can we improve quality *and* reduce costs? Answers to these questions will be needed in the subsequent steps.

For RBM, a simple tool like Five Whys and Five Hows can be very effective in analyzing the current and proposed future processes. Although examples of the Five Why's/How's frequently show the questions cascading from each other, a useful model can also contain separate, standalone why/how questions, for example: Why have we historically performed 100% SDV? Why has the FDA called for a more efficient clinical monitoring process? Why is RBM seen as an attractive alternative? How will RBM really improve data integrity? Why should we embrace this change?

3. Redesign the process

Central to redesign is the notion of eliminating problems. The first principle of process redesign is to work with people directly impacted by and responsible for the process itself, which is especially important when multiple organizations are involved. A key word is "impacted," a much broader concept than "responsible party." Involving all the impacted parties provides the opportunity for everyone to understand what the process is meant to do, what problems it is meant to solve, and what benefits are to be achieved. It not only clarifies ownership of the process but also prevents the all-too-common case of a new process that does not smoothly mesh with existing processes. In addition, it minimizes the chance that a responsible party will not lend the support needed to complete the project.

A new RCA or FMEA analysis should be performed for the proposed, new process.

When part of the process is outsourced, redesign can be complicated by conflicting priorities, disparate SOPs and cultures, etc. What happens if a service provider is replaced? Will the process be imposed on the new provider, or will the service provider's part of the process be treated as a black box?

The second principle of process redesign is that the new process must actually work. For example, how does moving to RBM affect field monitors, their assignment to sites, and the way their visits are scheduled? Will the company's data management systems support the necessary analyses? Will the sampling algorithms be so complex that nobody actually understands them or knows how to adjust them if the results are suboptimal? What does "suboptimal" even mean? If a process improvement complicates, rather than simplifies a process, implementation will require extra care.

4. Assign resources

Many process improvement projects fail because of unrealistic expectations as to achievable results or the time and resources required to accomplish those results. The team must identify and obtain the necessary people, computing resources, funds for consultants, etc., *for the duration of the project*.

In our RBM example, the new process will not just impact field monitors. Resources from the data management, information technology, training and human resources functions will also be needed. An advisory council of research sites might be useful.

5. Implement improvements

The project part of a process improvement project moves into high gear during the implementation phase. All the normal project management requirements apply, especially the need for strong management support to overcome institutional inertia.

Without stakeholder buy-in, process improvement projects are destined to fail or be implemented in a half-hearted manner. Experienced personnel have probably seen process improvement projects and other management initiatives come and go, so why divert resources from pressing priorities into yet another waste of time?

Institutional patience with process improvement projects is limited, so it is best to start showing a positive contribution as soon as possible. A pilot program can be helpful in major or controversial process improvement projects, especially when stakeholders or management are a bit skeptical.

Above all, when implementing a process improvement project, it is critical to consider the cultures of all the organizations involved. In our RBM example, how did the field monitoring staff react to the move from paper to electronic case report forms? What is the attitude of the quality management department toward statistical quality control? How much authority is delegated to managers of subsidiaries, regions or therapeutic areas?

The process of improving processes is not rocket science, but does require a systematic approach and commitment to follow the five steps outlined above.

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