

FIVE STEPS to Better Clinical Performance



Performance Measurement & Management

FIVE STEPS TO BETTER CLINICAL PERFORMANCE

Common barriers to clinical development effectiveness can be found in every organization.

Building an effective clinical development process may appear to be an impossible dream. There seems to be no easy path to solving what recent research has identified as the top issues and challenges confronting clinical management:

- Timely decision making.
- Patient recruitment.
- Cost reduction.
- Effective initiative management.
- Solving the productivity crisis.
- Better scorekeeping.

These pains are caused by operational disconnects or even barriers that appear, in some mix, in every organization we have seen.

Through experience and research, we have identified five specific capabilities needed to bridge the disconnects and remove the barriers:

- Establishing priorities and aligning the organization around the clinical development strategy.
- Solid, cross-functional performance metrics.
- Strategy translated into actions through clear linkages.
- An effective management toolkit, including on-the-fly analysis across multiple data sources.
- Strategic management.

As it turns out, developing these capabilities directly solve clinical performance pains.

Addressing those barriers will help drive clinical performance.

FIVE STEPS TO BETTER CLINICAL PERFORMANCE

Clinical development effectiveness is largely about translating strategy into action.



These five capabilities build on each other. Once you have clearly articulated the clinical development strategy based on corporate objectives, you then need to establish performance indicators. The next step entails linking everyone's actions back to that strategic intent, and so on.

FIVE STEPS TO BETTER CLINICAL PERFORMANCE

Strategy is more about what we stop doing than what we start doing.

Step 1

Set strategic priorities for clinical development

Step 1 calls for capturing the existing corporate strategy, cascading it for clinical development and documenting it in a new way called a “strategy map.” The strategy map is the “secret sauce” that is a requirement for all great clinical performance solutions.

Drs. Kaplan and Norton frequently quote a Fortune magazine article revealing that 90% of strategies fail—not because they are weak, but merely because they are not executed! Given such a high failure rate, the most important gain for your organization will come through the execution of your existing strategy—not through devising a better strategy.

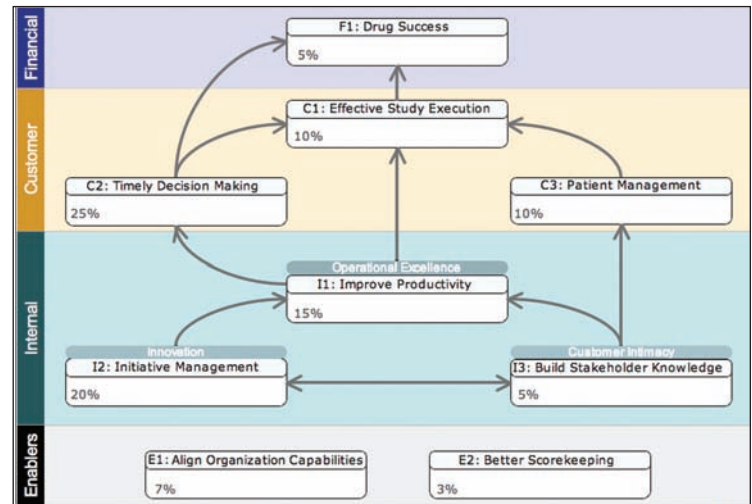
Do not allow your clinical performance project to get sidetracked into

another “strategic planning” activity. Take whatever strategy your organization is actually using and capture that. (After using the clinical development effectiveness methods for six months, you will have enough information to have an informed strategic planning discussion.)

Much has been written about building strategy maps, including *Strategy Mapping* by Drs. Kaplan and Norton (a must-read). A strategy map describes what the organization needs to do to be successful. It includes a limited number of key strategic objectives, an explanation of how they work together for success and an indication of their relative strategic importance for the coming year.

In building a simple map, the senior team can create alignment across their areas and an overall game plan, without committing to specific actions, performance levels or ownership. The strategy map becomes a risk-free tool to engage the leadership team in agreements about the way forward.

As the organization learns and needs to refine its strategy or direction, the strategy map becomes the tool used to discuss, model, capture and communicate those changes.



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Get the performance monitoring processes working first and fast.

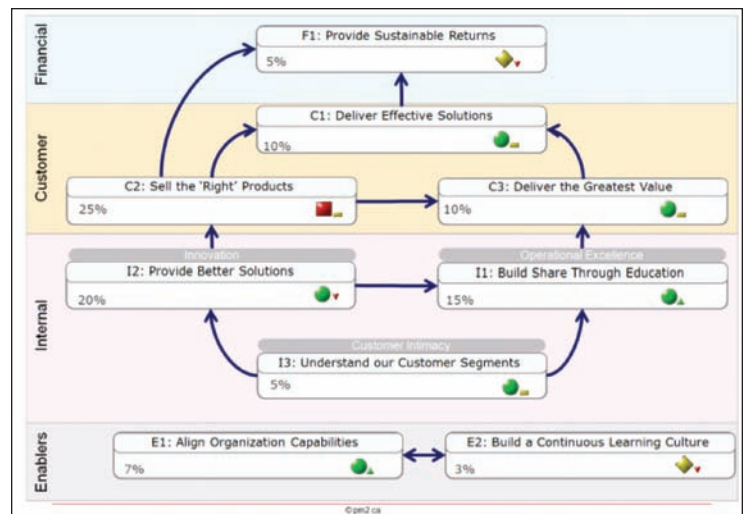
Step 2

Establish performance indicators

Great performance management solutions start off with indicators—not measures.

What is an indicator? Think of the “check engine” light on your car dashboard. It is just an indicator that lets you know a key system is not performing. Then you need diagnostic tools and an expert to perform an analysis and recommend what action to take. This step builds the indicator, Step 3 builds the diagnostic measures, and Step 4 builds the diagnostic tools.

In clinical development, one of our clients uses “patient recruitment efficiency” as an indicator of CRO performance. It is not precisely accurate, but does provide some insight into the ability of the partner to identify the best sites, and effectively recruit patients and manage trials.



By using indicators, not measures, a number of benefits can be realized:

- Better breadth of performance coverage with fewer indicators, because a single indicator provides wide coverage, e.g., fast patient recruitment might be impacted by better site selection, management and the ability to market to potential patients through a wide range of channels.
- Ability to start using the performance monitoring portion right away. There are *always* indicators in the organization that can immediately be used in the scorecard. Like the dashboard in your car, you can start using this dashboard as soon as it is created, even before the diagnostic tools are completely in place.

It is important to select indicators *after* you have built the strategy map. Without a clear understanding of the strategy and priorities, it is impossible to select the right indicators or level of detail required.

FIVE STEPS TO BETTER CLINICAL PERFORMANCE

Translating strategy into action is the single most important step in clinical development effectiveness.

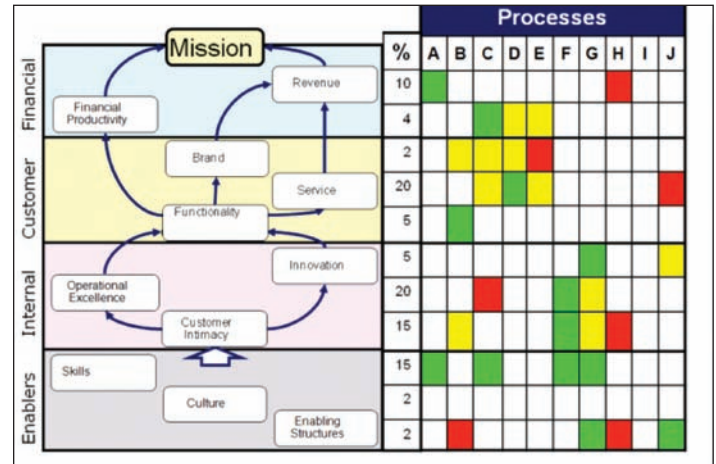
Step 3

Link actions to strategies

The goal of clinical performance programs is translating strategy into action. We need a way to take the big-picture strategic intent and convert it into what we do day-to-day—the processes and projects we work on.

In this third step, the team should produce a short list of core processes, identify which ones are critical to each strategic objective on the strategy map and then rank the processes' ability to support that objective.

This will allow the organization to identify the strategic impact of each process. Processes that have a high weighting but provide poor support are performance risks for the organization.

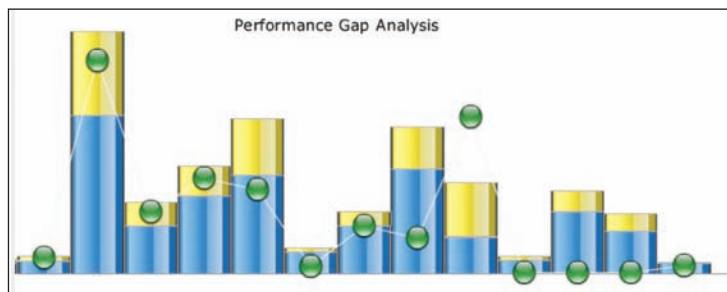


Likewise, all significant projects should also be ranked based on their impact in improving the performance around each strategic objective.

Ideally, projects will provide support around the identified weaknesses in the processes; if not, the organization has a misalignment between the projects and strategic need.

It is not unusual to find that 40% to 60% of existing projects do not link to any strategic objectives. Those projects should be stopped right away, so as not to divert resources from the things that will help execute the strategy.

By the end of Step 3, the team will have a rough-cut risk-analysis illustrating the “execution gap”—the gap between what the strategy calls for and the capabilities of existing processes and projects.



In this illustrative chart, the team can clearly see the risk profile by strategic objective.

FIVE STEPS TO BETTER CLINICAL PERFORMANCE

Effective toolkits must support ever changing analysis and reporting requirements and clearly define who needs to do what.

Step 4

Build the management toolkit

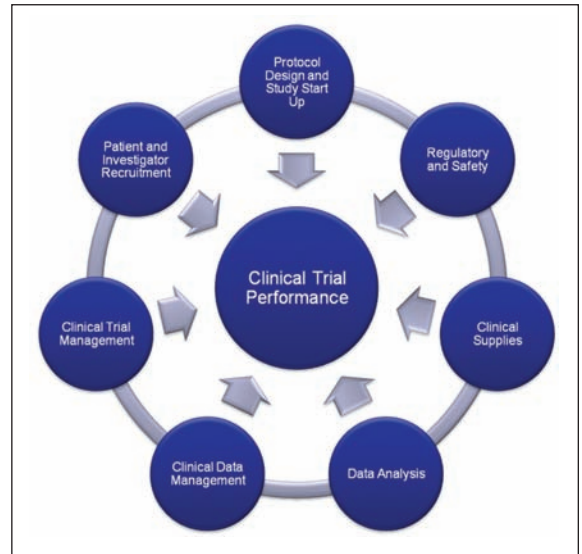
The toolkit we are describing here is a combination of data harvesting and comparison software applications. The clinical operations team needs to be able to quickly form and test hypotheses that might explain the performance. Experience has proven there is a small number of analyses and reports that are always important, but beneath that thin layer of consistency, there is a myriad of ever changing reporting needs.

The only constants are the underlying transaction systems and data sources. The trick is to build a toolkit that can grab any data from any of those sources, at any time, and provide the connection points between them. For example, we may have a question about our costs against budget for a specific clinical trial. On an ad-hoc basis, we may want to look at the trial progress globally, or at all trials being run in a certain therapeutic area ... or any combination.

Specific tools, like business intelligence (BI), scorecards, dashboards and mobile access, overlay the better management practices and enable the effective alignment of strategy to daily activities.

In addition, clear lines of accountability and authority need to be drawn. Departments, teams and individuals must understand what they are expected to do and how that will contribute to success.

The planning process is also often enhanced in order to become more driver-based and agile to respond to the ongoing changes in demand and market conditions.



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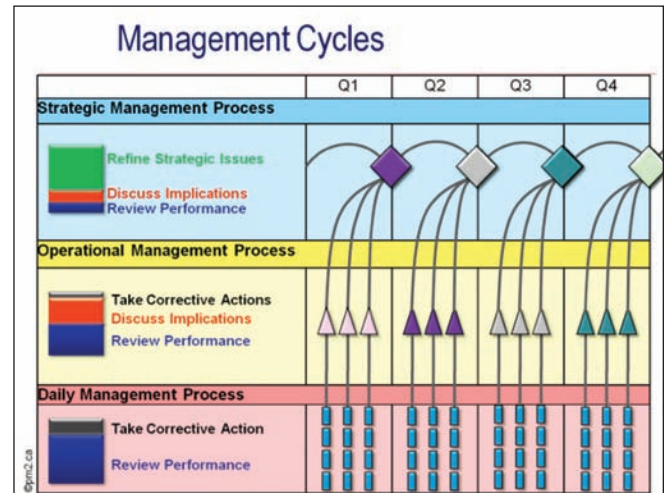
Think of your golf swing—changing how you manage will affect the value you get from these tools.

Step 5

Manage strategically

Building all these tools, but not adjusting how we manage, is a bit like buying a new set of golf clubs and not changing your swing. The fifth phase focuses on how to use these tools to generate order-of-magnitude performance improvements. A combination of specific tasks, processes and meetings will be required, plus a collection of capabilities, capacity and frameworks.

What is “strategic” management? Central to this is the addition of a new type of quarterly management meeting—a strategic management process—where the strategy map and weighting are reviewed to ensure that they are constantly tracking the best way forward for the organization.



Based on the work done in Steps 3 and 4, the organization can begin linking the strategy down to the team or individual level by assigning accountability for each supporting process and project, which in turn is linked to each strategic objective.

The information infrastructure must mirror how management thinks:

- Strategic tools to support prioritization.
- Operational tools to underpin the operational issues.
- Diagnostic tools to begin modeling solutions.
- Analytic tools to understand specific actions to be taken.



*Create a rapid pilot—
and quickly roll it out
for the rest of the
organization to
make better.*

The big secret: Do it FAST!

It is important to get this program into the hands of the organization as soon as possible. Two bad things happen if you spend too much time before the organization starts using the tools:

1. The organization begins to feel the clinical performance program is becoming a tool to punish them for their “red” indicators.
2. The team begins to think that they have the right answer and becomes reluctant to change, regardless of the organization’s feedback.

Keep it simple—do it fast. Build a pilot system in a very compressed time with a team of a dozen people, quickly release the pilot... and then spend the next six months making it better and better!

Here is the problem this approach solves: no matter how many people you put on the team, you will have access to only a tiny portion of your organization’s wisdom. They will miss critical aspects of your organization’s success.

A useful trick to create a great performance management solution is to “rough it in” first. Use the team to create a working pilot and then quickly release it to the organization with the knowledge that the entire organization will have great ideas around making it better. And, by contributing to it, they will take strong ownership of the clinical performance solution.

Think of building a new house. The scorecard team members are just building the overall frame. The organization’s job is to add the walls and do all the finish work.

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The pm² approach to rapid results

pm² recommends addressing five distinctly different tasks that provide the foundations, tools and capabilities for more effective clinical processes.



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We usually accomplish each of these steps in one day, and the entire pilot is completed in a single business week. In a few cases, though, the culture and tempo of the organization may spread this process over five weeks—or five months. In principle, it should be significantly faster than one would first think. Typically it takes about 17 weeks to take this pilot into full production mode.

Remember that the key to success is—like framing a house—to build the whole structure’s framework quickly in order to make it self-supporting. If you pause too long between any of the steps, the entire program fails as the organization begins to “tweak” elements before the overall structure is built and understood

About Brett Knowles and pm2

Brett Knowles, founding partner of Performance Measurement and Management (pm2), is a long-time thought leader in performance measurement and an advisor to the IBM Cognos Innovation Center for Performance Management. His credentials include over 3,000 scorecards, planning and ABM implementations, including many in the life sciences and healthcare industries.

He co-founded the first BSC application and served as a vice president working for Drs. Kaplan and Norton at the Balanced Scorecard Collaborative. Brett's clients have won three Hall of Fame awards from Drs. Kaplan and Norton and have been profiled in all of their recent best-selling books, as well as in *Harvard Business Review*, *Forbes* and *Fortune* magazines and several business books.

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