

# Strategies for Defining Key Performance Indicators in Research

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Few people would argue that clinical research provides value with respect to gaining a better understanding of diseases, driving innovation, identifying novel therapies, and improving quality of patient care. Recent years have seen steady growth and significant changes in the clinical research domain. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), the pharmaceutical industry has invested more than half a trillion dollars in research and development since 2000, and more than 5,000 drugs are in development in the United States alone.<sup>1</sup>

With growth and change comes additional complexity. Protocols now have an increasing number of touchpoints and data variables; as of 2012, a typical protocol averages 13 endpoints and 167 procedures.<sup>2</sup> Studies are under more scrutiny than ever before, and there are an increasing number of regulations with which researchers need to comply to avoid receiving, for example, Warning Letters or Form 483 findings from U.S. Food and Drug Administration audits and inspections.<sup>3</sup>

The new regulations and scrutiny have resulted in an increased demand for approaches and solutions that improve efficiency without compromising quality. Key performance indicators (KPIs) that bridge the gap between strategies and results are integral to ensuring efficiency. While sponsors and contract research organizations (CROs) have made targeted efforts to establish KPI programs that help optimize clinical trial processes, costs, and timelines, the efforts at research sites have largely been sporadic and unsystematic.

This paper discusses strategies and best practices for developing a program at research sites that enables an organization to monitor research processes and outcomes in an efficient and effective manner. Using particular examples, this paper demonstrates that even as research site staff learn

to carefully review KPI portfolios established by sponsors and CROs, they need to define and leverage context-specific KPI targets.

## The Growing Importance of Effective Monitoring

There is a growing interest in KPIs, with many organizations either having implemented them already, or struggling now to implement them, or being keenly interested in doing so, but unsure how to proceed. Even with increasing awareness regarding metrics and KPIs, unanswered questions abound at these sites: What metrics should one measure? What KPIs would have significant impact on clinical research? What should one do after collecting the measurements?

No matter where a site stands with respect to KPIs, it is first important to understand the basics.

By definition, a metric is a standard of measurement, which may or may not involve a value (e.g., while accrual metrics involve numbers and absolute value, compliance metrics only indicate quality). Collecting metrics is only a starting point of a KPI program, as every metric is not necessarily a KPI; but what exactly is a KPI?

### LEARNING OBJECTIVE

After reading this article, participants should be able to recall a few strategies for identifying relevant KPIs in research, and to use them for developing a KPI program that benefits a particular research site.

### DISCLOSURES

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*Nothing to disclose*

A KPI is a type of metric that takes into account business values, context, and strategies. As Wayne Eckerson puts it, a KPI “is a metric that embeds performance targets so organizations can chart progress toward goals.”<sup>4</sup> In other words, a KPI is a composite metric that is tied to targets and that indicates how an organization is performing relative to a specific objective.

For instance, if a site wants to improve accrual of patients in its clinical trials program, it can record the number of enrollments daily, monthly, or annually, whereby it obtains a metric. However, on its own, this metric doesn’t give a sense of whether accrual targets were achieved, or how the site is performing over time.

On the other hand, if the site has its targets, but doesn’t have the measurements that are required to give it a full picture, it is still no closer to monitoring its performance. A KPI, unlike a metric, would track screen failures and withdrawals, and check how accruals change over time.

A holistic KPI portfolio, involving composite and interconnected metrics, helps in leveraging measurements and monitoring ongoing processes for improving multiple facets of a clinical research program, including administrative, financial, clinical, and others.

## So, What KPIs are Right for Me?

When initiating a KPI program, research sites often measure the wrong things—or end up measuring too much or too little—to be really effective. However, if site staff consider what KPIs are right for them seriously, they will be on the right track. Why? Because when it comes to KPIs, one size does not fit all, which is what makes finding the “right” approach a challenging process.

There is no standard way of developing a KPI program, and while site staff can learn from colleagues at other sites, they can’t just copy what another site did without investigating whether it’s right for their own particular needs. “What KPIs are right for me” does not mean that a site should ignore KPI portfolios developed by sponsors and CROs, or develop KPIs that correspond to subjective opinions. On the contrary, relevant KPIs for sites often align well with sponsor requirements, and are based on objective data.

“For me,” however, is a call to make KPIs more context specific, and a reminder that the “one size fits all” approach does not work across sites.

Indeed, a single KPI program often doesn’t work across different types of trials, departments, and indications—even within the same organization.

Given the variety of disciplines, processes, and study designs associated with clinical research, it is important to have a holistic KPI program that takes into account different types of research and organizational goals. Furthermore, the staff of research sites need to look beyond their walls to ensure that their KPIs are aligned with the needs and goals of other stakeholders in the clinical research process, such as sponsors and CROs.

The overarching goal of all parties is to ensure optimal performance throughout the clinical trial process; to do this in an effective manner, the goal should be incorporated throughout the process, and not just upheld by specific entities or at specific time points.<sup>5</sup> Instead of seeking a magical number of metrics or attempting to create a list of universally useful KPIs, it is best to focus on strategies and considerations for designing a KPI program that works for an individual site today, but continues to evolve as the site’s goals change over time.

## Identifying Relevant KPIs

Determining relevant KPIs requires strategic planning and considerable effort. It is often tempting to select metrics that are the easiest to measure, but if they aren’t the right ones for a specific site, precious time and effort will be spent on setting up a KPI program that doesn’t yield results. As Abraham Lincoln famously said, “If I had eight hours to chop down a tree, I’d spend six hours sharpening my ax.”

While there is support for the theory that measuring something provides motivation to make it better, there is also evidence to support that “every metric, whether it is used explicitly to influence behavior, to evaluate future strategies, or simply to take stock, will affect actions and decisions,” and the end result may not be what an organization had hoped for.<sup>6</sup>

Picking up on the earlier example of accruals in a clinical trials program, let’s say a site defined a KPI to track study enrollments across its entire research portfolio, and that it started showing a positive upward trend. Well, one may conclude that the KPI worked, and that the site is reaching its overall goal. Unfortunately, this is not entirely true.

The success of the KPI depends on what the site’s overall goal was—if it was to simply increase the number of enrollments, then yes, the KPI worked.

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any KPI based upon time to activation would not be accurate or reliable. It is important, therefore, to make sure that site staff not only identify all of the KPIs to be used, but also provide accurate definitions for all to ensure clarity in communication and decision making.

Once KPIs have been identified, the logical next step is to figure out how the metrics will be captured and tracked. Many organizations have a clinical trial management system that captures critical data in a more consistent and reliable manner. In addition, sites may need to collate these data with data from other systems such as the electronic health record, institutional review board (IRB), or financial systems at the sites. While implementing these systems, organizations should take into account the adaptability of systems for capturing key metrics that will assist them in tracking their KPIs, and in being interoperable with other systems.

### Utilizing Your KPI Program—A Continuous Process of Learning

It is not unusual to come across sites where staff have put a tremendous amount of thought and effort into identifying relevant KPIs and gathering accurate data, and yet they failed to realize benefits from the entire process. Launching a KPI program deceptively gives stakeholders the sense that capturing and monitoring the metrics is automatically going to help improve performance. Usually the failure to realize benefits can be traced back to a lack of planning in how to act upon the results from monitoring KPIs.

Figure 1 depicts how multiple components work together in the design of a holistic KPI program. The interconnected cycles indicate the significance of timely communication and implementation of findings.

Results of the information collected from the KPI program should be visible to all relevant stakeholders. It is equally important to rapidly implement findings from constant monitoring of KPIs. Through the timely implementation of findings, one can continue to validate one's discoveries and incorporate improvements into a continuous process of learning.

Meanwhile, what exactly does timely implementation of KPIs look like and what are its outcomes? Mark Donaghy provides valuable advice on when to incorporate performance metrics in a research program: "Performance metrics are the project management version of the data and analysis in a longitudinal clinical study. ...Performance metrics programs produce the best results when established in the design phase of a clinical study. Application of the Deming Cycle (Plan - Do - Check - Act) encourages a planned, systematic, and explicit alignment of study endpoints with objectivity in performance data collection and analysis."<sup>9</sup> Donaghy reminds us

**TABLE 1: Dos and Don'ts for Identifying Successful KPIs**

Do	Don't
✓ Identify the program's objectives before developing KPIs.	✗ Start with a consideration of metrics that are easy to track, but which may have no correlation to the overall objectives.
✓ Identify who will consume the results and how they will be communicated.	✗ Focus only on catching deviations, but rather look for information that will help to plan and avoid issues.*
✓ Be proactive in planning how the KPIs will be utilized to fulfil the program's objectives. This will ensure that the metrics are validated for effectiveness well before an organization collects and monitors more of the same.	✗ Monitor each and every metric, as it can create a lot of "noise" and become resource intensive; instead, focus on a select few that tie to the overall program goals.

\* Joy Baker suggests that "best indicators assist in problem solving and lead to preventive actions (e.g., prevention of patient falls) rather than corrective actions after an incident or episode has occurred."<sup>7</sup>

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However, if it was to increase the number of accruals (subjects who have completed or are completing a study) in order to have more successful study outcomes, then the site should also be tracking the numbers of consent withdrawals, screen failures, dropouts, and other early terminations to know whether there is an actual increase in accruals.

Table 1 summarizes some key dos and don'ts to keep in mind while identifying relevant KPIs.

### Gathering Accurate Data

Even though there is no simple formula for determining relevant KPIs, experts recommend selecting KPIs based on data and variables that can be measured objectively and avoiding signals that are based on subjective qualifiers.<sup>8</sup> Besides realizing that KPIs are important to manage a more effective clinical research program, most sites should also recognize the need to have defined processes and accurate systems to obtain the data to support an effective monitoring program.

Having identified what one wants to measure, the next important step is to define the KPIs, including identifying sources of information. What makes the need to define KPIs critical is that often the data being monitored are in multiple systems, which are not harmonized in terms of their meaning or are not being collected in a consistent manner.

For example, it is not unusual to have many different interpretations applied to an "active" trial, or variations in how individuals or departments define the date that their trial became "active." If there is no standard way of interpreting this, then

**FIGURE 1: An Effective KPI Program – A Continuous Process of Learning**



of the importance of building a performance metrics program before undertaking any major activity within a clinical trial.

The significance of measurement and monitoring of KPIs can be further demonstrated with concrete examples. It is well acknowledged that site staff want to track turnaround times in their study activation process. For instance, sites might want to measure the time to IRB approval or time to contract execution. In such cases, having a single number with an upward or downward trend isn't entirely helpful, unless there is an analysis associated with it and an appropriate plan for action.

Only analysis can shed light on the data that have been tracked. An organization, for example, might find out that the time to approval is increasing because of an influx of a large number of trials at the site, which would necessitate looking at the staff allocation ratio and improving it. Alternatively, an organization might learn that the increasing timeframe is due to numerous back-and-forth messages and incomplete submission packages, which, in turn, would call for action in improving the process for submission.

Another likely explanation is that the overall number is skewed because of a specific process instituted for early-phase studies, which would call for a closer look at that new process. Having the information available at one's fingertips helps identify the exact problem area and takes the guesswork out of it. Furthermore, timely action and ongoing monitoring of KPIs ensure that the learning process can continue to occur, and that an organization can show improvement in weeks and months rather than in years.

## Conclusion: The Big Picture

Finally, it is important to remember that developing a KPI program is not a strategy unique to the research community. "Advancing research, scientific knowledge, and innovation," was specifically called out as one of the five major "Collect-Share-Use" goals in the *Federal Health IT Strategic Plan 2015-2020* released by the U.S. Office of the National Coordinator for Health Information Technology as part of the Health Information Technology for Economic and Clinical Health (HITECH) Act.<sup>10</sup>

Interestingly, the HITECH plan's other four goals, emphasizing the need for healthcare organizations to develop a holistic plan that integrates clinical and research perspectives, also have a direct or indirect links to clinical research. By incorporating KPIs that not only improve sites' financial and operational performance in clinical research programs, but also attend to clinical outcomes and research programs' integration with point of care, healthcare organizations will truly begin to realize the potential of translational research, and ultimately bridge the divide from bench to bedside.

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