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Measurements, Metrics, and KPIs: Achieving a Balanced Scorecard

PEER REVIEWED | Jeff Kingsley, DO, MBA, CPI

[DOI: 10.14524/CR-16-0014]

Pharmaceutical, biotechnology, and medical device sponsors and contract research organizations (CROs) are hiring sites to do one thing: produce high-quality data. In pursuit of that single and seemingly simple goal, research sites have to do hundreds of things, including training highly competent researchers, recruiting numerous appropriately qualified research subjects, and managing complex nuances of the research protocol.

It's difficult enough to implement the processes and functions necessary to obtain high-quality data, but if you succeed in implementing the myriad policies and procedures needed, you will have only come half way to the goal.

A procedure is only valuable if it is producing the desired results, and if you are not measuring the results, you will have no idea if you are winning. Further, each procedure you add may have negative implications for your other procedures—these are the inevitable “unintended consequences.”

In such a research environment, key performance indicators (KPIs) are needed, and a tool known as a “balanced scorecard” is a must.

Why Measurements Matter

As clinical researchers, we know that in order to determine the safety and efficacy of an investigational product, medication, or device, we have to study it, and studying it means measuring it. We have to measure its safety against other medications or devices in its class, as well as its efficacy.

If we invent a new potential antibiotic in an existing class of safe and effective antibiotics, we have every reason to believe it will work. Yet we also accept that we positively cannot proceed without first studying this new potential antibiotic. We accept this as fundamental to the industry in which we work.

In our work life, we invent new processes to fix the ills of our businesses. These processes are designed well and should certainly work. However, all too often we implement processes and walk away. We often simply make the assumption that the processes will work. It is far too seldom that we take the time to then study the intervention, measure the results, and evaluate the effect on our other processes. It is equivalent in our clinical research world to considering matters of efficacy and side effect profiles. Too seldom do we pay attention to our own performance with the same rigor we apply in clinical research.

Interestingly, the simple act of measuring things improves the thing being measured, even in the absence of a meaningful intervention. This is equivalent to the placebo effect in our clinical research trials. This is known as the Hawthorne effect, and is sometimes explained as “what gets measured gets done,” going as far back as now famous experiments from the 1920s.¹ According to one description of the experiments, “By the time everything had been returned to the way it was before the changes had begun, productivity at the factory was at its highest level.”²

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LEARNING OBJECTIVE

After reading this article, participants should be able to design a balanced set of key performance indicators (KPIs) that maximize the participants' ability to achieve a strategic victory.

DISCLOSURES

Jeff Kingsley, DO, MBA, CPI:
Nothing to disclose

A Primer

A measurement is concrete, usually measures one thing, and tends to be quantitative. A metric describes qualities and requires a measurement of baseline characteristics. As an example, I can measure the amount of gas in my car and I can measure the distance I've traveled. The number of miles I've driven per gallon (MPG) of gas used is a metric, and is far more valuable than simply knowing the individual measurements that went into it. A key performance indicator (KPI) is the next improvement in measurement.

A KPI is a metric that is deemed to be a critical evaluation of the success of a process. There may be many measurements and metrics that are useful regarding that process, but there should only be one or two KPIs that provide a high-level, quick evaluation of the performance of that process. Is it doing well, or is it doing poorly?

You can think of a KPI as having your finger on your pulse. If during a normal part of your day your pulse is between 60 and 100, you're probably doing just fine. However, if your pulse (a KPI in healthcare) is outside that range, then it's time to dig deeper with more measurements and metrics to determine the cause. This is the same way you should measure the health of your organization.

A balanced scorecard is the collection of KPIs that look at the health of your organization from multiple different perspectives at the same time. Maintaining each of these KPIs within their desired range maximizes the health of your organization. (See Table 1 for a summary of terminology related to this article.)

It's important to note also that metrics, KPIs, and the components of your balanced scorecard can be either leading or lagging indicators. If your metric is a lagging indicator, it's providing you with information about what happened in the past without any remaining time to intervene and improve performance (leaving the opportunity to affect change in the future only). A leading indicator is a metric that is providing you with current data that are predictive of future outcomes.

Your leading indicators can provide you with an opportunity to intervene and impact performance before it is too late. Leading indicators give you the opportunity to affect change actively.

The balanced scorecard was a concept first discussed by Robert S. Kaplan and David P. Norton in *Harvard Business Review* in 1992.³ It's important to note that as you work to improve one metric, you can many times worsen others. For example, if a business is concerned only about its financial performance, it can achieve its financial targets at the expense of employee satisfaction and engagement along with the quality it's providing to its customers and many of its stakeholders. Similarly, it's easy to imagine achieving our operational measures at the expense of our financial performance.

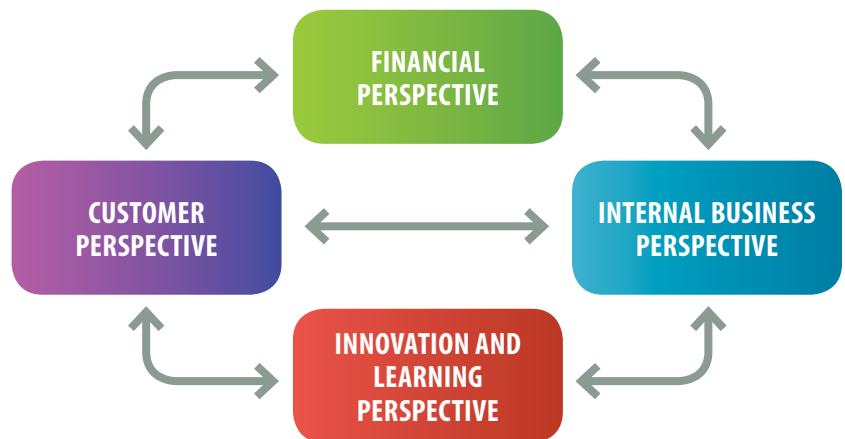
TABLE 1: The Terminology of Measurements, Metrics, and KPIs

Item	Description	Example
Measurement	Concrete, usually measures one thing, usually quantitative	Total number of research coordinators
Metric	Informs qualities because of a reference to a baseline state	Coordinator retention rate
Key performance indicator (KPI)	A metric considered critical to inform the success of a process or function	Coordinator satisfaction score
Balanced scorecard	A cluster of KPIs deemed to be the balancing point of ultimate success in the organization	Net profit margin Employee satisfaction % enrollment goal attainment % error rate
Lagging indicator	A metric that provides historical data and the ability to affect change in the future only	Net profit margin
Leading indicator	A metric that provides present data and the ability to affect change in the present condition	% error rate

Kaplan and Norton argued that a balanced scorecard consists of four distinct perspectives (see Figure 1 for a simplified visualization). These are the customer perspective, financial perspective, internal business perspective, and future perspective (innovation and learning). The balanced scorecard allows us to see when we're improving in one area at the expense of another, and it provides us with an ability to see where all of our important domains are maximized.

That Kaplan and Norton used four domains is irrelevant. Additionally, the four domains that they chose are less relevant than the domains that are pertinent specifically to any given industry (see Table 2 for some possibilities). For example, Southwest Airlines is renowned for putting its employees first, and certainly would list the employee perspective as one of its domains in a balanced scorecard.

FIGURE 1: Simplified Balanced Scorecard



All too often we implement processes and walk away. We often simply make the assumption that the processes will work. It is far too seldom that we take the time to then study the intervention, measure the results, and evaluate the effect on our other processes.

Suffice it to say that each business needs to choose which perspectives are most important in its unique case. Four balanced perspectives may be a good recommendation, but three or five would work just as well. Each of these perspectives should be tied directly to a mission-critical strategy of your organization.

A Few Words of Caution

First, just because we can measure something doesn't mean that we should. It's very easy to allow ourselves to begin measuring just about everything in our surroundings. Always ask yourself why you are measuring something. If the thing you're measuring is not directly linked to some mission-critical performance factor, consider stopping that measurement.

Measuring things takes time and effort from you and your team; be cautious not to focus that time and energy where there is little benefit. Determine in advance what your desired outcome is. What needs to be measured in order to monitor and improve performance on the desired outcome?

Sometimes, what really needs to be measured can be difficult. There's a tendency to measure what's easiest, and "the easy to measure drives out the hard, even when the latter is more important."⁴ The thing you really should be measuring may not be the easiest. If you have the capabilities to measure the right thing, always do so.

Second, always be wary of unintended consequences, since "human beings adjust behavior based upon the metrics they're held against."⁵ If the only thing you speak with your team about is

enrollment, your team members will likely pay more attention to enrollment numbers than they will to the quality of the data. You will also increase the likelihood of fraud at your site. Fraud is rare, but if all you focus on is enrollment, then the risk of fraud in your organization will be higher than an organization that focuses on quality. It's an unintended consequence of a narrow focus on enrollment.

A Site's Balanced Scorecard

Let's design a balanced scorecard for a research site.

1) WHAT ARE OUR MISSION-CRITICAL DOMAINS?

These domains need to take into account all stakeholders and the site's strategy. After choosing your domains, you should be able to confidently state that a balanced strategy to win in all the domains chosen maximizes your success. If you can still come up with a scenario where you can fail at your strategy, then consider whether you have chosen a balanced collection of domains.

2) WHAT ARE THE MOST SIGNIFICANT KPIS TO MEASURE WITHIN EACH DOMAIN?

To choose your KPIs, first consider what the functional areas touching this domain are in your operating model. Next, decide what result or outcome you wish to achieve in each area, and think about the activities or actions that drive that result. Finally, identify the measurements or metrics that let you know that the right activities are being performed, and that the right outcomes are resulting.

As stated at the beginning of this article, research sites are hired by sponsors and CROs to do one thing and one thing only—produce high-quality data. To produce data, sites need to recruit patients, and it is mission-critical that customers be served well. Therefore, the customer perspective should be part of the balanced scorecard, and should contain KPIs regarding enrollment numbers and data quality.

A sample KPI regarding enrollment numbers could be *percent of time achieving sponsor goal enrollment*, and a sample regarding the quality of the data would be the *percent error rate*. Now, the percent of time achieving sponsor goal is, by default, a lagging indicator, since you can only calculate that once goal enrollment was achieved. If the enrollment window closed prior to achieving goal enrollment, you no longer have any ability to intervene regarding that specific research trial.

TABLE 2: Possible Domains of Importance to a Business

Sample Domains	
Customer Domain	A site's customers are sponsors and CROs. What KPIs ensure these customers are satisfied? Better yet, what KPIs ensure that the customers are ecstatic with the site's services?
Internal Domain	How does one know that a business is functioning at its highest capability and in a fashion that ensures long-term success? This domain can be where the business leader focuses on his or her team, if the feeling is that an exceptional team is key to the business strategy.
Financial Domain	What KPIs ensure the maximum financial health of the business or business unit?
Vendor Domain	To be successful beyond research considerations, a site needs to provide exceptional service to the remaining medical community and to that community's patients. What should be focused on to ensure value is provided to this domain?
Innovation Domain	As the saying goes, "If you aren't growing, you're dying." Businesses need to continuously innovate and adapt to remain healthy. What should your organization be focusing on?

Your percent error rate, however, can be tracked in real time. That makes it a leading indicator, allowing you to intervene and improve the quality of the data within an existing research trial prior to that research trial ending. For example, if you see that your percent error rate is unacceptably high in a given research trial, that enables you to drill deeper into that trial and try to determine the reasons why. Are the error rates higher because of trial complexity? Is there confusion regarding interpretation of the protocol? Do the staff site members require retraining?

Additional KPIs pertinent to your customers could include *total enrollment % of goal across all studies*, *% sponsor repeat business*, or *customer satisfaction rate*. What is important is that you choose where you want to focus. You can't be all things to all people. How do you want to best serve your customers?

The financial domain is certainly necessary for a research site's balanced scorecard. Research is financially challenging for sites; ignoring this domain could be perilous. Repeat the process above to choose the KPIs you believe will maximize the financial health of your organization.

On the other hand, a research site only paying attention to its financial perspective can produce a very short-term view of performance. That site may immediately improve its gross revenue and net income by taking on as many trials as possible, and by processing as many patients as possible through those trials. That site may maintain a lean staff size to further enhance its financial profit, but it's reasonable to assume such a model would run the risks of increased error rates, lower subject satisfaction, and increased employee turnover due to the overly lean staff size. The long-term view of performance could therefore show that site's model as being ultimately flawed.

The internal perspective can't be ignored. It would include KPIs regarding employee engagement, payroll, or perhaps length of employment. If your business, for example, determines that your more senior research coordinators consistently produce higher quality data and higher levels of subject recruitment, then it would be reasonable to create a strategy for your business regarding methods to increase the number of senior research coordinators. Your KPIs regarding this strategy would fall into this internal perspective.

However, if you want to compete for research trials on cost, then perhaps you need to keep your payroll costs as low as possible, and should choose different KPIs to help guide you in achieving your strategy.

Now it's Your Turn

You need to do the work from here. All sites and all strategies are different. Therefore, site leaders cannot all use the same balanced scorecard and the same KPIs to achieve their strategies. You need to use the processes discussed to determine your balancing point, and how you will research your own outcomes to know with certainty that you are balancing your success.

The balanced scorecard allows you to bind your short-term activities to a longer view on performance. Once you've initiated a balanced scorecard in your organization, this scorecard will alter the foundations of how you run your business.

Your scorecard translates your mission, vision, and strategy into operational metrics. Your scorecard will alter what you speak about in your meetings. It will increase alignment throughout your organization, so that your entire team is rowing in the same direction at the same time. Your scorecard will affect business planning so that financial budgeting is in alignment with strategic goals. It will create a mechanism for continuous improvement and your organization will have improved levels of learning.⁶ You will have achieved the ability to research your own activities as well as your research investigational products, medications, and devices.

Conclusion

As clinical researchers, we measure things for a living, and yet as leaders of sites, small CROs, and small sponsor companies, we are amazingly poor at measuring our own behaviors. However, measuring our own behaviors is the only path to continuous improvement.

A balanced scorecard provides us with the capability to maintain a long-range review that integrates the perspectives most critical to long-term success. Focusing strongly on one perspective—and one perspective only—can produce outsized results for that perspective, but it's unacceptable to allow your other critical perspectives to suffer.

The ultimate win is achieved when you are able to maximize performance throughout your balanced scorecard. To do that, you need to push evenly in each of the domains you deem critical. As you improve one domain, others may slip a little in their optimal range. As you improve others, you may lose ground on your first; but remember the Hawthorne effect.

If we pay attention to all of our mission-critical perspectives, we will continue to make incremental improvements in each, and we will ensure that our end results are the healthiest they can possibly be.

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Strategies for Defining Key Performance Indicators in Research

PEER REVIEWED | Priti Sahai, MD | Rashmi Sahni, PhD

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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.¹

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.² 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.³

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

Priti Sahai, MD;
Rashmi Sahni, PhD;
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.”⁴ 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.⁵ 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.⁶

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.

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.

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."⁹ 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."⁷

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.

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.⁸ 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.¹⁰

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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Are Performance Metrics About Doing the Right Things or Simply Doing Things Right?

PEER REVIEWED | Linda Sullivan, MBA

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National Public Radio's (NPR) *This American Life* in 2010 told an eye-opening story of General Motor's (GM) awakening to Japanese competition that was storming the automobile industry in the early 1980s.¹ The story focused on well-worn facts, namely, that at the time, GM was producing cars of questionable quality and poor resale value, whereas Toyota was turning out highly reliable cars and ultimately stealing massive market share (GM's market share fell from 77% in 1980 to 45% in 2009).²

The NPR tale tells of a culture of faster, faster, faster at GM plants, with little emphasis on quality, whereas the Japanese plants adopted the reverse philosophy—making quality its hallmark. Time and cost were critical factors for the Japanese automaker, and they were meticulously measured and scrutinized, but quality was never sacrificed to meet those benchmarks.

To the astonishment of American executives and workers sent to Japan to learn the Toyota way, Japanese line workers were able to stop the line at any time to prevent a problem from happening, or to immediately fix one that had just happened. The one cardinal rule in GM plants was to NEVER stop the line, ever. Doing so would likely result in a firing, because after all, poorly made cars would be fixed in the rework area. Interestingly, Toyota plants did not have a rework area—one wasn't needed. Moreover, Japanese cars were produced faster and at lower cost.

This story could be a parable for the current status of metrics in the clinical trials sector, an industry in need of transformation³ and a re-imagining of how success should be defined and measured in an effort to improve study quality. In keeping with that theme, this article describes how stakeholders are changing how they do things for

better execution of the many steps that produce quality clinical trials, as measured by standardized performance metrics.

This article also discusses the direction that regulatory agencies are taking to encourage greater risk mitigation and management techniques from the beginning of clinical trials to improve operations. Ultimately, what follows asks the question: Are we simply using performance metrics to determine if we are doing things right (according to the plan), or are we using metrics to improve the plan—doing the right things—from the beginning?

Critical Success Factors

Performance metrics based on standardized definitions are new to the world of clinical trials. Stakeholders have long maintained company-specific metrics, such as the percentage of clinical trials within a program meeting enrollment targets or the amount of time needed to lock a database, but in the interest of better study execution, industry-wide, standardized definitions are required. Such definitions have been lacking, making industrywide research difficult and creating confusion when different stakeholders attempting to collaborate have dissimilar definitions for similar functions.

The Tufts Center for the Study of Drug Development (CSDD) recognized this problem nearly two decades ago, when it presented findings from a workshop on the importance of using standardized performance metrics across the industry to benchmark productivity and motivate excellence among staff.⁴ In its report, the center also noted that metrics are most effective when they help stakeholders look at the “big picture” and the overall trends, which is a departure from the continual practice

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LEARNING OBJECTIVE

After reading this article, participants should be able to describe how to use a structured approach to determine the right metrics for improving clinical trial planning and execution.

DISCLOSURES

Linda Sullivan, MBA:
Nothing to disclose

of focusing on one particular metric or a group of metrics that may not lead to better performance.

Looking at the big picture, or more specifically, aligning performance metrics with critical success factors and key performance questions (KPQs) is the next horizon. This approach is fundamental to how the Metrics Champion Consortium (MCC), an industry group founded in 2006, operates. MCC brings stakeholders together to define standardized performance metrics, and helps identify what to measure and how to use those measurements to drive process improvement and mitigate risk, all by measuring the right things. This is a major departure from “measuring things right”—in check box fashion—simply because that is how it has always been done.

To start, MCC considers the concept of the critical success factor as the foundation, referring to what an organization must do to achieve desired outcomes and ensure successful competitive performance. Massachusetts Institute of Technology’s Sloan School of Management is credited with developing this strategic approach in the late 1970s to help organizations seriously consider what is needed to improve operations. In a classic article in the *Harvard Business Review*, John Rockart describes the need for a critical success factor, as without it, executives are generally overwhelmed with data that are of little use in making critical management decisions.⁵

For the clinical trials industry, there are numerous critical success factors that focus on measuring the right things (see sidebar). One example is the expectation that all studies will have more than 85% of sites enrolling more than one subject (see Table 1). Once the critical success factor is determined, KPQs that align with organizational roles and responsibilities—such as those at the executive, program, and study team levels—can be developed. KPQs should provide insights about factors in a process that help users achieve success, processes, and/or data that need to be managed to ensure success, and recognize problem areas that need to be improved or fixed. Good KPQs include time, quality, and cost/efficiency performance aspects, and provide information to make decisions.

Specifically, at the executive level, a KPQ might be: What portion of studies within each program has 15% or more of sites enrolling fewer than two subjects? Table 1 shows other examples of KPQs for this critical success factor, along with metrics designed to answer them.

The metrics for this critical success factor and others were developed by MCC, which offers an array of peer-vetted, standardized performance metrics for clinical trials, laboratory, and imaging. Importantly, these metrics reflect what stakeholders want to measure, namely factors related to time, cost, and quality. Much like the automobile parable, however, stakeholders tend to

Critical Success Factor

“...the limited number of areas in which results, if they are satisfactory, will ensure successful competitive performance for the organization. They are the few key areas where ‘things must go right’ for the business to flourish. If results in these areas are not adequate, the organization’s efforts for the period will be less than desired.”

—John Rockart⁵

overemphasize time-related metrics at the expense of quality, which often results in increased risk for rework as a clinical trial unfolds.

In the clinical trials sector, rapid drafting of the study protocol is a good example of a task where satisfying time-related metrics is highly valued. The protocol development team is rewarded for completing the protocol by a specified time, but does the protocol meet a set of quality requirements? When organizations do not assess protocol quality during the development phase, it is difficult to know. Furthermore, not including a quality measurement sends a message to the protocol development team that quality is not important.

With this scenario, it is not surprising that protocols often need rework, possibly amendments, within 30 days of completion. There is also an increased risk for an expanded timeline and budget. Mitigating or avoiding this situation—doing the right thing—may involve crafting a critical success factor that acknowledges the level of complexity of today’s protocols.

By comparison, relying mostly on time-related metrics—doing things right—may show that monitors are behind schedule in completing study reports, but this approach is unlikely to address why they are behind. It could be the fault of a challenging protocol, which may be better detected by quality metrics used from the start. This is a key consideration, given that Tufts CSDD research shows that protocols, the basis of clinical trials, are increasingly complex.

In a typical Phase III study, Tufts CSDD found that the total number of endpoints rose to 13 in the 2011–15 timeframe as compared to just seven a

Critical Success Factors that Focus on the Right Things

- ➔ All studies have more than 85% of sites enrolling more than one subject
- ➔ Develop a quality protocol in a timely manner
- ➔ Use quality sites that deliver clean data in a timely manner while following GCP compliance regulations
- ➔ Ensure that sites have drugs and other clinical supplies onsite when needed
- ➔ Collect/Analyze safety and endpoint data required for submission
- ➔ Monitor and respond to subject safety events in a compliant manner

Source: Metrics Champion Consortium

TABLE 1: Key Performance Questions (KPQs) and Metrics at Different Levels

Critical Success Factor: All studies have more than 85% of sites enrolling more than one subject		
Organizational Level	KPQs	Metrics that Answer the KPQs
Executive	What portion of studies within each program has 15% or more of sites enrolling fewer than two subjects?	Percentage of studies where 15% or more sites consent fewer than two subjects/program
Program	What portion of sites from each study in the program has enrolled fewer than two subjects?	Percentage of sites in each study that have consented fewer than two subjects
Study Team	What portion of sites in the study has enrolled fewer than two subjects?	Percentage of sites in the study that has not consented at least two subjects

Stakeholders are changing how they do things for better execution of the many steps that produce quality clinical trials, as measured by standardized performance metrics.

decade earlier. Similarly, the total number of procedures jumped to 163, up from 97 in the 2001–05 time period.⁶ With this big change, amendments are mounting up, and are costly.

Research indicates that sponsors implement at least one substantial global amendment for nearly 60% of all clinical trial protocols, which tends to reduce the number of patients enrolled. However, the tactic also extends clinical trial durations and costs to the point of averaging \$141,000 for a Phase II study and \$535,000 for Phase III.⁷ The high cost of quickly made protocols plus subsequent amendments highlights the importance of seeking balance among time, cost, and quality metrics, all in an effort to influence performance and avoid rework.

Emphasis on Quality and Regulatory Influence

The emphasis on doing the right thing aligns well with industry efforts and guidance from regulatory agencies. In the past few years, agencies have released guidances and regulations focusing on ways to be more strategic about study planning and execution. Much of this effort encourages stakeholders to focus on quality from the beginning of clinical trials, rather than relegating it to a costly afterthought.

Interest in quality metrics started gaining traction several years ago, with input from MCC and from the Clinical Trials Transformation Initiative (CTTI), a collaboration between the U.S. Food and Drug Administration (FDA), Duke University, and multiple member organizations. CTTI launched its first Quality by Design workshop in 2011, with the intent of incorporating quality and risk management principles into clinical trials, similar to what had already become standard practice in other areas of drug development.⁸ In particular, there was a strong focus on becoming proactive regarding the objectives of a clinical trial and the defining factors critical to meeting those objectives. This entailed gathering the right data, so stakeholders could take action to prevent or mitigate risks that could negatively impact study execution.

In 2013, the concept of assessing and mitigating risk was further advanced when the industry group TransCelerate Biopharma Inc. released the Risk Assessment and Categorization Tool (RACT).⁹ The RACT framework provides organizations with a standardized means of assessing project- and protocol-level risk and quality before conducting studies.

Building on the RACT framework, MCC has taken a particularly comprehensive view of quality metrics as key to avoiding or mitigating risk. The MCC Risk Assessment & Mitigation Management Tool provides an approach for risk assessment, risk mitigation, and issue management.¹⁰ Figure 1 details MCC's risk management process, which starts with conducting a protocol assessment, followed by gathering data for risk identification.

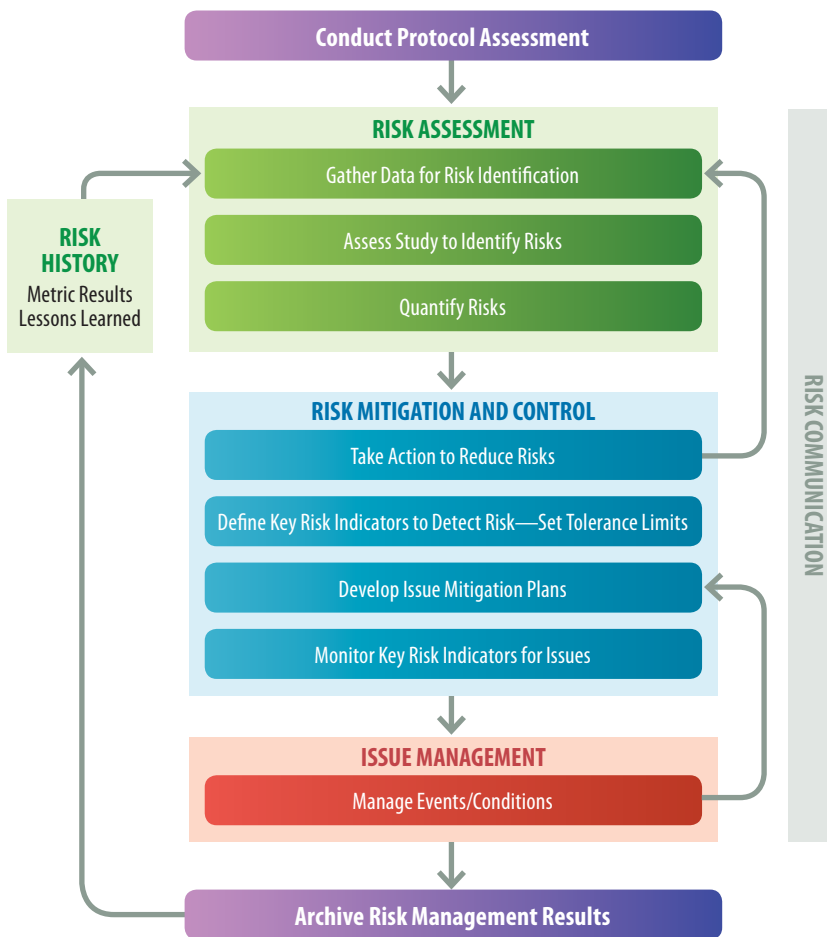
This MCC framework is rooted in a 2013 Reflection Paper from the European Medicines Agency (EMA).¹¹ In that document, the EMA describes the necessity of incorporating risk-based quality management at a very early stage in a clinical trial. Also, protocol design, use of technology, and other issues are deemed particularly important to mitigating risk. In that same year, FDA released its guidance on risk-based monitoring, stating that sponsors should be prospective in understanding the risks that could affect data collection and performance of critical processes, and in identifying critical data and processes.¹²

The next horizon is happening in November 2016, when the International Conference on Harmonization (ICH) E6(R2) guideline is expected to be released.¹³ It is intended to replace the widely used R1 guideline implemented in 1997, which is commonly known as the Guideline for Good Clinical Practice (GCP). The intent of R2 is to keep pace with the changing scale and complexity of clinical trials, and to ensure greater use of technology to modernize approaches toward clinical trial design, conduct, management, oversight, and documentation to enhance human subject protection and data quality.

R2 will include many changes, with Section 5—Quality Management—particularly noteworthy. It stresses the sponsor's responsibility to ensure operational feasibility, avoidance of unnecessarily complex protocols, and efficient design of clinical trials.¹⁴ It also states that the quality management system should use a risk-based approach. For example, risk mitigation activities may be incorporated into protocol design and implementation, and into monitoring plans.

With the implementation of R2, the clinical trials sector is expanding its interest beyond quality metrics to include risk indicators, and eventually, to predictive indicators. The new guideline will have far-reaching consequences, as risk management processes will become the core of clinical trial operations.

FIGURE 1: Metrics Champion Consortium Risk Management Model



Source: Metrics Champion Consortium (2015), adapted from EMA Reflection paper on risk-based quality management in clinical trials (EMA/269011/2013)

Doing the Right Things

Making improvements to clinical trial operations is all about asking the right questions. Is the protocol feasible? How do we select quality sites that can produce clean data? These are critical success factors for helping stakeholders look at the big picture, and if properly addressed, they help ensure better clinical trial execution.

For too long, the industry has repeated older processes, which tended to focus on measuring speed of operations while reining in costs. It has largely been a box-checking exercise to determine if stakeholders were doing things right (according to the plan), without considering if they were doing the right things.

Because data continue to show that transformative action is needed, a newer approach is gaining traction—one built on a structure of critical success factors followed by key performance questions and metrics that answer them. This methodology is being supported by regulatory influence, all in an effort to move the needle toward process improvement and less rework, saving time and dollars, while improving study quality.

The high cost of quickly made protocols plus subsequent amendments highlights the importance of seeking balance among time, cost, and quality metrics, all in an effort to influence performance and avoid rework.

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The Evolving World of Metrics

OPEN BOOK TEST

This test expires on August 31, 2017

(original release date: 8/1/2016)

Measurements, Metrics, and KPIs: Achieving a Balanced Scorecard

- Per the article, metrics matter because of which of the following:
 - The Hawthorne effect
 - Improving one process will frequently make a second process worse
 - Measuring things is fun
 - Leading indicators give us the ability to affect change in the present condition
 - 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only
- Per the article, a “balanced scorecard” for a research site can be defined as:
 - A cluster of key performance indicators (KPIs) where profit is balanced with employee needs
 - A group of four KPIs prescribed by Kaplan and Norton in 1992
 - The collection of KPIs that look at the health of your organization from multiple different perspectives at the same time
 - A group of metrics that provide present data and the ability to affect change in the present condition
- A lagging indicator is:
 - A metric that provides present data and the ability to affect change in the present condition
 - A metric that takes a long time to calculate, but is critical to the overall study success
 - A metric that provides historical data and the ability to affect change in the future only
 - A metric considered critical to inform the success of a process or function
- Which of the following are considered examples of metrics?
 - Coordinator retention rate
 - Revenue per year
 - Miles per gallon
 - % error rate
 - 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only
- Which of the following is an example of a leading indicator?
 - Miles per gallon
 - Net profit margin
 - % error rate
 - % enrollment goal attainment
- Besides the capture of evidence of improvements gained in particular areas at the expense of others, what other “ability” does a balanced scorecard allow?
 - The ability to see where all of our important domains are maximized
 - The ability to place our customers’ needs above all other needs
 - The ability to affect change in the present condition
 - The ability to measure metrics that are difficult to measure
- According to Kaplan and Norton, the “domains” of a balanced scorecard are:
 - The different addresses where research activities are performed
 - Of little importance because they are different from business to business
 - Financial, internal, customer, and innovation and learning perspectives
 - The different perspectives of your business that you feel are mission critical
- The unintended consequences of holding people accountable to metrics can include which of the following:
 - Unethical behavior because enrollment is the only critical metric
 - Financial failure because quality is the only critical metric
 - Employee longevity because employee satisfaction is the only critical metric
 - Improved quality outcomes because profitability is the only critical metric
 - 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only
- Which of the following is the best strategy to follow when choosing KPIs to measure within each domain?
 - Measure the metrics that are the easiest to measure in the area
 - Identify metrics that let you know the right outcomes are resulting from the right activities
 - Measure the same metrics that the other sites do in our industry
 - Measure as many metrics as possible across the entire business model
- Benefits of a balanced scorecard include:
 - Increasing alignment throughout your organization
 - Increasing alignment of financial budgeting with strategic goals
 - Increasing focus on employee needs over those of financial performance
 - Creation of a mechanism for continuous improvement
 - 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only

Strategies for Defining Key Performance Indicators in Research

- An increase in demand for KPIs in research can be attributed to:
 - Marketing campaigns
 - More contracts and agreements
 - New regulations and scrutiny
 - Mounting social pressure
- An effective KPI program can potentially:
 - Increase clinical trial costs
 - Optimize clinical trial processes
 - Extend the clinical trial duration
 - Elevate risks of doing studies
- A KPI is a type of metric that takes into account which of the following?
 - Opinions
 - Business values
 - Context
 - Strategies
 - 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only

Find the most current online test at www.acrpnet.org/homestudy, including any revisions made after publication of this issue of *Clinical Researcher*.

- 14.** It is challenging to develop an effective KPI program because:
1. One can't just copy KPIs defined by others
 2. Sponsor requirements need to be assessed
 3. Standard processes and designs already exist
 4. A vast variety of trials and departments exists
- A. 1, 2, and 3 only C. 1, 3, and 4 only
B. 1, 2, and 4 only D. 2, 3, and 4 only
- 15.** A holistic KPI portfolio is characterized by:
1. Composite and interconnected metrics
 2. The ability to monitor ongoing processes
 3. An unlimited number of metrics
 4. A variety of subjective inputs
- A. 1 and 2 only C. 2 and 3 only
B. 1 and 4 only D. 3 and 4 only
- 16.** Which of the following are best practices for identifying successful KPIs?
1. Identifying a program's objectives
 2. Monitoring each and every metric
 3. Identifying how results will be communicated
 4. Maintaining a constant focus on catching deviations
- A. 1 and 3 only C. 2 and 3 only
B. 1 and 4 only D. 2 and 4 only
- 17.** While capturing and tracking metrics in research, it is important to:
- A. Create more Excel templates
 - B. Use interoperable systems
 - C. Employ additional staff
 - D. Get feedback from patients
- 18.** Why do sites often fail to realize the benefits of their KPI programs?
1. Research site staff don't put in the required effort
 2. Absence of timely communication
 3. Carelessness or nonchalant attitude
 4. Failure to implement findings
- A. 1 and 2 only C. 2 and 4 only
B. 1 and 3 only D. 3 and 4 only
- 19.** For the best results, when should a performance metrics program be established?
- A. In the design phase of a clinical study
 - B. When randomized controlled trials are in progress
 - C. When a new treatment works well
 - D. While selecting patient populations
- 20.** One of the five major "Collect-Share-Use" goals noted in the *Federal Health IT Strategic Plan 2015–2020* is:
- A. Sharing electronic health information in the public domain
 - B. Advancing research, scientific knowledge, and innovation
 - C. Banning the use of health IT products
 - D. Promoting quantity over healthcare quality
- Are Performance Metrics About Doing the Right Things or Simply Doing Things Right?**
- 21.** A lack of standardized performance metric definitions can:
1. Make industrywide research difficult
 2. Create confusion for collaborating stakeholders
 3. Enable industry benchmarking
 4. Improve stakeholder communication
- A. 1 and 2 only C. 2 and 4 only
B. 1 and 3 only D. 3 and 4 only
- 22.** According to the Metrics Champion Consortium, an approach that results in measuring the right things includes aligning which of the following?
1. Critical success factors
 2. Key performance questions
 3. Performance metrics
 4. Risk indicators
- A. 1, 2, and 3 only C. 1, 3, and 4 only
B. 1, 2, and 4 only D. 2, 3, and 4 only
- 23.** When aligned with critical success factors and key performance questions, what do metrics provide?
- A. Valuable insights
 - B. Uncategorized information
 - C. Worthless data ranges
 - D. Unverifiable opinions
- 24.** According to John Rockart, the few key areas where "things must go right" for a business to flourish refers to:
- A. Performance targets
 - B. Critical success factors
 - C. Key performance indicators
 - D. Key performance questions
- 25.** Key performance questions should align with which of the following?
- A. Executive-level roles and responsibilities only
 - B. Program-level roles and responsibilities only
 - C. Organizational roles and responsibilities
 - D. Study team-level roles and responsibilities only
- 26.** Key performance questions should provide insight about:
1. Factors that help you achieve success
 2. Processes that need to be managed to ensure success
 3. Areas considered unimportant to achieving success
 4. Problem areas that need to be improved or fixed
- A. 1, 2, and 3 only C. 1, 3, and 4 only
B. 1, 2, and 4 only D. 2, 3, and 4 only
- 27.** Key performance questions should include which of the following aspects of performance?
1. Time
 2. Quality
 3. Color
 4. Cost
- A. 1, 2, and 3 only C. 1, 3, and 4 only
B. 1, 2, and 4 only D. 2, 3, and 4 only
- 28.** Which of the following is a result of using a combination of time, cost, and quality metrics?
- A. Decreased rework
 - B. Some increase in rework
 - C. No change in rework
 - D. Substantial increase in rework
- 29.** Which of the following are components of a risk management model?
1. Risk assessment
 2. Recruitment
 3. Risk control
 4. Issue management
- A. 1, 2, and 3 only C. 1, 3, and 4 only
B. 1, 2, and 4 only D. 2, 3, and 4 only
- 30.** The ICH E6(R2) guideline will emphasize the sponsor's responsibility to do which of the following?
1. Ensure operational feasibility
 2. Avoid unnecessarily complex protocols
 3. Design efficient clinical trials
 4. Monitor all datapoints
- A. 1, 2, and 3 only C. 1, 3, and 4 only
B. 1, 2, and 4 only D. 2, 3, and 4 only