Creating a Central Metrics Group

PHARMICA CONSULTING

ERIC LAKE

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Introduction

Thanks to a focus on productivity and cost reduction within the pharmaceutical industry, along with a prevalence of Six Sigma-inspired improvement efforts, metrics are on a lot of people's minds. In fact, one might argue that metrics are on too many people's minds. Consider a situation where you are collecting data in order to track cycle times for processes within your area of responsibility. At some point you're talking to a colleague about the idea of creating a handy dashboard to display all of your key metrics in one location. Your colleague, having some experience with dashboards, sends you a prototype of one she's working on in her department – and it contains much of the same data you have been painstakingly collecting over the last several months. Worse, there are discrepancies between your numbers and hers.

This story is undoubtedly all-too-familiar within many departments in clinical research and development, an area which has only recently begun to develop a true operations mindset. Most, if not all, managers of R&D departments recognize the criticality of collecting data and tracking the performance of their many processes. However, many of these efforts are disjointed, inefficient, and misguided. Conflicting reports, duplications of effort, and misapplied metrics plague many companies' attempts at making sound data-driven business decisions. The creation of a central metrics group can go a long way towards eliminating wasted effort and drastically increasing the value of an organization's data.

When is a Central Metrics Group Appropriate?

Before thinking about *how* to create a central metrics group, one must first ask *why* they should create one. Is it even necessary? The answer, of course, varies from situation to situation. Certainly all companies, regardless of industry, should adopt a continuous improvement mentality, meaning that metrics should be playing an important role in just about every business. A number of factors will help to decide whether or not a central group is appropriate. Company size is one, as larger companies will typically benefit more from such an arrangement by consolidating voluminous amounts of information and reducing duplications of effort. A company's technological maturity is another key factor as central metrics groups tend to rely heavily on an advanced technological infrastructure for the collection of data and dissemination of information. But perhaps the most important factor is the overall corporate strategy. The degree of commitment amongst top levels of the organization with regards to continuous improvement and their views on how it should be accomplished will ultimately be the deciding factor. Companies with a high level of commitment towards improvement will take the time to seriously consider whether or not a central group will work best for them. For many, the benefits of increased efficiency and consistent reporting of data will outweigh the bureaucratic headaches that come with setting up such a group.

Adding Value with Metrics

Too often, metrics are collected largely for the sake of collection. Alternatively, metrics are utilized by individual departments to "make their lives easier" (to keep tabs on things out of mere curiosity, for example) or measure against self-imposed yet meaningless targets. This often leads to localized optimization within the R&D value stream and a misalignment with other

departments and perhaps the organization as a whole. For example, many clinical operations groups focus on the cycle time from protocol approval to protocol first patient screened. In the long run, does it really matter how quickly one site begins enrolling patients? The critical measure the one that speaks to the flowing of data to the next step in the clinical development value stream - is when *all* sites *finish* enrolling.

The example given in the previous paragraph is also demonstrative of the "management by intuition" that seems to run rampant throughout the clinical R&D space. Having years of experience, while inarguably valuable, seems to be commonly used as a substitute for hard data as opposed to a supplement. The sooner that clinical departments recognize the fact that metrics can be used to validate intuition and unearth previously hidden trends and root causes, the better off their decision making will be.

Regardless of how a company structures its metrics "function", corporate vision should set the context for performance measurement1. Figure 1 shows one possible strategic management framework Such a framework assures that performance measures align from top to bottom, which in turn puts focus on metrics that show how well value flows through the value stream. A central metrics group can do a much better job of maintaining this type of framework than disparate entities can due to the coordination inherent in the structure of a central group. That is, it should be part of the central group's mission to keep metrics in alignment.

In order for a central metrics group to be effective, it must have a thorough understanding of both the business and basic analytical methods (in order to properly determine root causes of problems, etc). To this end, it is often worthwhile to create a group utilizing staff from a variety of areas, such as clinical, operations, data management and the like. Ultimately, the skill requirements will be based on the central group's scope, which needs to be defined early on. Will the group only handle late stage development processes, or everything from discovery through product launch? The next critical responsibility for the central metrics group is the definition of key performance indicators (KPIs). For any given process, there should only be a handful (no more than five or six), and more importantly they should speak to the true nature of performance in light of the higher level objectives. Therefore, an organization ultimately concerned with productivity should lean towards metrics on outputs (for example, patient visits processed) and resource allocation (for example, FTEs utilized), while an organization whose primary goal is to shorten time to market should focus on selecting key milestones that will help it manage its business from a speed standpoint. Ideally, the central group will work with members of the respective functional areas to define the KPIs (see Figure 2), thus keeping metrics in alignment while still satisfying the business' need for useful management reports at the operational level.

Defining KPIs requires a detailed understanding of not only the process at hand (having accurate process maps to work with is obviously helpful), but of the suppliers of the inputs (data) as well as the customers' requirements for the outputs (dictated by what they plan on *doing* with the information they get).

External Effectiveness	Internal Efficiency
Number of NDAs approved	Protocol approval to last patient in cycle time
Customer satisfaction (nternal or external)	Cost of a conducting a study
Percent of evaluable pa:ients versus total	Patient visits processed per FTE
Timeliness of deliverables	Last patient out to frozen file cycle time
Market share	Net Profit

Table 1 – Examples of Key Performance Indicators

Creating a Lean Metrics Reporting Process

A central metrics group can potentially have many different "customers" from all areas of the organization. Identifying critical-to-quality (CTQ) requirements for these customers is the first step in defining a data collection, analysis, and reporting process that satisfies customers' needs in the most efficient way possible. CTQs might center on the timeliness of the reports (how "real time" the data needs to be), the level of detail required (the patient visit level, for example), drill down capabilities (going from protocol level to visit level, for example), ease of use, and accessibility. Keeping the CTQs in mind, the group must then identify sources of data and evaluate the underlying system's ability to provide that data on a "just in time" basis. Where required KPI data is not available (or where the current system will not adequately support the new metrics process), a decision must be made to either implement a new system to collect the data or to alter or eliminate the KPI (keeping in mind that doing so may compromise the effectiveness of the metrics program).

Next, the methods for refreshing and distributing "standard" metrics reports must be determined. Typically, this will involve automation of data collection, the use of company intranets, and other tools that allow the ultimate customer to "pull" the reports whenever they need them. These "real time" reports and the expectations surrounding them must be carefully planned for early on to avoid customer frustration later.

Metrics reports are of little use, of course, if they are not accurate. It is therefore important to implement controls (mistake proofing) and checks (quality assurance) within the process to ensure accuracy of information. For example, using a clinical trial management system that makes users select inputs from drop down lists reduces the chance of data entry errors. Having the system prohibit the user from moving to the next screen before all required fields are filled in can greatly help in eliminating gaps in data. Automating queries of metrics data can also provide a systematic stability to the process. Meanwhile, a gate review system on data quality and whether or not the final report meets the CTQs will further reduce the chances of the customer being dissatisfied. Clearly, ensuring accuracy is one of the most important jobs of the central metrics group, and as such a significant amount of time should go into the planning, implementation, and continuous improvement of the metrics QA/QC processes.

One final distinction in the development of a metrics reporting process must be noted. The "standard" reports mentioned earlier refer to those reports that contain the agreed-to KPIs, have a standard design, and are simply refreshed on some recurring schedule as dictated by business needs. By contrast, users are also likely to request "ad hoc" reports from the central metrics group. While the general process for gathering and reporting of data will be largely similar, creating ad hoc reports is a far more resource-intensive task due to the (potentially large) volume of requests, difficulty in finding data, complexity of the requests, and a need for additional checks for quality. It is recommended that these types of requests by scrutinized by the central group to determine if there is legitimate business value in addressing them and if so how they should be prioritized.

Creating a Central Metrics Organization

Once the processes have been defined, work can begin on creating the organizational structure of the central metrics group. By identifying all tasks that make up the new processes, an estimate of required resources can be made. One uncertainty here is the volume of "ad hoc" requests that the group will need to support, which needs to be addressed with the group's executive sponsor ahead of time.

Next, determine if new job descriptions need to be created, or if tasks should be assigned as parts of existing job descriptions. Again, this will largely depend on the level of commitment and support from senior levels in the organization. It is critical that the proper amount of resources be dedicated to setting up the central group else it may be doomed to failure.

Once the job roles are made clear, and line and staff responsibilities identified, relationships between process owners and the central metrics function should be defined. For example, will the site management process owner be assigned one particular resource in the metrics group (the expert in that area), or will the group lead assign a resource based on availability? Clearly, the more flexible the group can be with its resources, the better it will be able to handle the flux of incoming work from different areas.

Another consideration in creating the new group is how process improvement projects will be identified and executed. Within a management framework such as Kelvin and Cross' Performance Pyramid mentioned earlier, the central metrics group will produce items of integrated financial and non-financial information that operating managers can use as a catalyst for process improvement[2]. How much involvement should the central group have in these process improvement efforts? While obviously a valuable resource for such activities, care must be taken to not overwhelm the central group and distract it from its core mission.

Lastly, the final organization chart needs to be created for the central metrics group so the structure and relationships are clear to both those internal and external to the group.

Organizational Change, Documentation, and Training

It is quite likely that the establishment of a central metrics group will be a radical shift for most R&D groups. Regardless of how much effort was put into creating the processes and structure of the group, if people aren't aware of the new group and how it will function (and, more importantly, benefit them), it will wither and die.

As usual, the best place to start is at the top, by gauging the level of executive support for the group. Is the effort being trumpeted by the highest levels of management as a showpiece of their effectiveness and innovation? Or has the green light been tentatively given with a "wait and see" attitude? The amount of "drum beating" – departmental communications, informational presentations, informal meetings with key personnel, etc. – required at the ground levels will be determined by the answers to these questions. If the answer's the former, it's likely that most people will get on board (whether they want to or not) without having to be pushed too hard; if the latter, then some serious consideration needs to be given to how the new group will be "marketed" to the larger organization. As mentioned earlier, showing people "what's in it for them" will make all the difference. If others within R&D can be convinced that they can get what they want when they want it, and with little or no effort on their part, the central metrics group will be on its way to organizational acceptance.

Having an idea of high-level support, the next step is to go about identifying all stakeholders and engaging the key ones in developing implementation plans and identifying potential obstacles. This not only gets additional buy-in from key stakeholders but can eliminate potentially serious problems before they have a chance to derail the new group. Developing and executing a communication plan is critical – who gets what information, how frequently, and in what form. People in the organization, especially key stakeholders, need to know what's happening at all times so they feel connected to the change and also so they can communicate back issues or concerns they may have. Again, the "voice of the customer" needs to be kept in the forefront of everyone's minds; the central group lead should be mainly concerned about adding value, and value is always defined by the customer.

Finally, training programs need to be developed, not only on the new processes but also on how to use the new reports. It cannot be assumed that all end users will automatically understand what they are supposed to do with the information that will be available to them. The end goal is to enable better business decisions, and all personnel need to be shown how the new reports (and indeed, the central metrics group as a whole) will help them reach this goal, and what limitations exist.

Implementation

Many promising initiatives fail in the implementation stage. Too often, everyone is so relieved that the solution is in place that they fail to support it when it counts - at rollout. The key issues at this stage involve managing the new process and workload, fielding questions and concerns, and tweaking the new process as needed. While this is largely the responsibility of the central group lead, having the support of key stakeholders (as discussed in the previous section) can be

extremely helpful in addressing any issues that arise while at the same time minimizing damage to the credibility of the new group.

Conclusion

This article has shown the high-level steps that need to be taken in the establishment of a central metrics group. The more detailed steps will of course depend on the answers to the high-level questions mentioned throughout this article. But perhaps the most important part of the whole process occurs in the beginning, at the point where the decision is made to undergo such an endeavor in the first place. As stated earlier, it is critical to maintain a top-to-bottom alignment of performance measures as strategic goals are linked to operations by translating aggregate market and financial goals into operational terms[3]. The drive to create a central metrics group should be based strictly on the need to make better, faster decisions within this context. The justification should be based on a business case which clearly states that the value in establishing a central metrics group far outweighs the costs. Even though pharmaceutical companies exist in an industry founded on science, they are businesses at heart need to be run as such.

Potential Benefits	Potential Risks
Increased efficiencies/reduced duplications	Increased bureaucracy
Use of common data sources	People may still create their own metrics
Consistent metrics "language"	Metrics group may become overwhelmed
Establishment of performance baselines	May be "overkill" in smaller companies
Better control over creation of new metrics	

Table 2 – Benefits and Risks of Establishing a Central Metrics Groups

There are many secondary benefits in setting up a central metrics group. Metrics always need to be "actionable", and meaningful KPIs can be used to create high-level scorecards and tactically manage studies or smaller processes. Creating baselines (on which to base future improvement efforts), establishing a repository for organizational knowledge, and identifying and communicating best practices are all crucial in further adding value to the organization. There is also the possibility of measuring the company against external benchmarks, but this author tends to agree with the comment by Womack and Jones, "To hell with your competitors, compete against *perfection* by identifying all activities that are *muda* [waste] and eliminating them."[4] Regardless of one's views toward benchmarking, it is clear that what data is available for comparison is selectively shared, due to either a desire to avoid giving away "too much" or a reluctance to spend money to participate in sharing of metrics via one of the existing benchmarking companies. In an ideal world, metrics "customers" would be able to get the exact information they need, exactly when they need it, and without errors. Note that these attributes closely reflect the lean concepts of value, flow, pull, and perfection that are sought after by all

companies, regardless of industry. Using these concepts will enhance the value of any central group, and bring order to the sometimes chaotic world of clinical R&D metrics.

For more information, please contact:

Eric Lake
Partner
PHARMICA Consulting
Eric.Lake@pharmicaconsulting.com **www.pharmicaconsulting.com**
973-945-4482

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