Development, Implementation, and Validation of a Capacity Management System

Martin D. Hynes III, PhD

Robert D. Swarts

Nicole R. Egli

Jeanette M. Colonna
Lilly Research Laboratories, Eli Lilly and Company, Lilly Corporate Center, Indianapolis, Indiana

Organizational capacity management remains a significant tactic in reducing drug development cycle times and cost. The implementation of a project management system from the German software company, SAP, and supporting business processes was a significant step forward in our journey toward an enhanced capacity management system. However, it became apparent that a supplemental tool was needed to schedule resources and provide more detail on resource type. To achieve an effective capacity management process, each of the functions must have a robust capacity model with supporting tools in place. This article describes how a functional capacity model was constructed and utilized for ongoing capacity management. In addition, it describes how that model has been validated with data from the project time entry system. Finally, this article outlines the roles and responsibilities of various groups involved in the capacity management system. When the linkages between the groups are leveraged along with the capacity model and supporting information technology tool, it results in a capacity management process that allows for optimal project resourcing.

Key Words
Capacity management; Capacity modeling; Project management; Portfolio management; Resource utilization

Correspondence Address
Martin D. Hynes III, Product Research and Development, Lilly Research Laboratories, Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285 (e-mail: mdh@lilly.com).

INTRODUCTION

Changing technological, economic, and political realities exert increasing pressure on the pharmaceutical industry to improve resource utilization and productivity dramatically. Industry analysis shows that while development costs and time to approval have risen, the probability of technical success in many cases is declining (1). Such business realities lead to fewer approvals in the face of mounting research and development (R&D) cost (2). These trends are not sustainable for the pharmaceutical industry.

One essential response to the rising cost of drug development is the implementation of advanced capacity management tools and processes. Used effectively, these tools and business processes can minimize waste and maximize the use of existing scientific talent by ensuring deployment of critical skill sets to the highest value projects at the correct time and in the appropriate quantities. These more advanced tools also enable scenario planning to optimize complex portfolio-wide resourcing decisions over an extended future period.

Eli Lilly and Company is engaged in the process of leveraging state-of-the-art capacity management tools, technology, and theory to drive rigorous resource utilization and decision-making processes. The first step in the journey involved a companywide implementation of an enterprise system purchased from the German software company, SAP, that integrates project systems, human resources, and valuation and control components in 2001 (3). With this system, the central cross-functional project management organization was able to integrate project plans across the global R&D organizations for new molecules with direct expenses and human resource requirements. Thus, for the first time, planned resource demand versus supply was able to be measured at a high level for all functional organizations engaged in new drug development activities.

The decision to implement an SAP-integrated enterprise system was in large part due to the anticipated benefits derived from such functionality. As expected, a number of benefits were derived from this implementation, including providing integrated and visible project information to the organization from one source and better defined accountability for project management and functions. Additional implementation benefits included monitoring and reforecasting of business plans in a timely manner; validated lists of project deliverables that are tied to functional capacity models; and a current business plan that includes eight quarter rolling forecast based on project cost (3). For the first time, the global R&D organization was able to compare planned versus actual hours worked on all drug development projects for the entire drug development portfolio as well as view project schedules. Once these benefits had been realized, the next steps in our capacity management journey were planned.

Given that not all resources are fungible, the functions executing project work required an even greater degree of granular data than provided by SAP. In particular, the functional organization wanted the ability to

1. Identify the specific skill sets (eg, analytical chemists, pharmaceutical scientists, etc.) that become available when projects are terminated.
2. Provide quarter-by-quarter forecasts of project resource demand and resources available by skill set.
3. Run simulations to assess various project/resource combinations to determine optimal resource usage for the portfolio of compounds under development.

In light of these requirements, additional business process and supporting tools were developed.

METHODS

CAPACITY MODEL DEVELOPMENT

The Pharmaceutical Product Research and Development (PPR&D) group within Lilly Research Laboratories undertook the creation of a detailed, robust, and flexible capacity model. PPR&D comprises nine functional areas, including early-phase development, late-phase development, analytical characterization, engineering, biopharmaceutics, reference standards, raw materials, business and quality operations, and technical support. Each functional area has unique capacity requirements that needed to be understood prior to being rolled up into an integrated model capable of showing cross-functional resource requirements at each phase of product development.

As a starting point, actual time entry project data from the corporate SAP system were collected from employees at the component level on a monthly basis and clarified across five categories: project hours, multiproject hours, noncompound support, quality activities, and "human resource" events such as vacation or illness. Capacity planners for each one of the functions, in partnership with functional line management, analyzed the data to establish a set of standard project tasks with clearly defined deliverables, resources, and durations. This then permitted the identification of slots of capacity based on functional area tasks and the skill sets of scientific personnel needed to support various drug development projects. Separate capacity models were thus established for each functional area within the PPR&D group. They were assembled into an integrated model capable of showing early-phase and late-phase resource requirements within each PPR&D functional area. Other functional areas within the global R&D organizations (eg, toxicology and regulatory) have developed and validated their own capacity models and tools. The accuracy of the PPR&D model was confirmed by a comparison of actual versus planned hours.

CAPACITY TOOL DEVELOPMENT

With an accurate, integrated capacity model in hand, the next step involved developing technology to support and extend new capacity management capabilities. The option of expanding the SAP functionality was considered but subsequently eliminated due to the complexity of implementation, cost, and timelines involved. Organizational priorities required rapid implementation, integration within the existing SAP infrastructure, low maintenance, and moderate costs. In addition, management wanted to be able to plan by activity-based resource usage, schedule projects, provide flexible reporting with good visualization capabilities, and support scenario planning.

The decision was made to engage an outside vendor to design and develop a custom system to support the capacity management business process. Advanced Process Combinatorics (APC) of West Lafayette, Indiana, was selected on the basis of its proven expertise with capacity modeling in the pharmaceutical industry, its record of successful past projects, and its highly interactive consulting model. APC is known to build a close working relationship with its customers throughout the consulting engagement, permitting an iterative development process. The time frame from concept to completion could be measured in months yet still guarantee full integration with local tools as well as the possibility of expanding the functionality in future.

ROLES AND RESPONSIBILITIES

The establishment of a capacity model, tool, and business process has required several distinct groups to work together to coordinate business processes, project information, and deliverables. Project managers, capacity planners, financial representatives, human resource managers, and employees each have unique roles and responsibilities to execute within the new business process and supporting tool system.

In the first phase of project planning, project managers drive the development of a project plan, project schedule, and project structure in SAP and estimate durations for each deliverable. On management approval, this becomes the baseline plan. Capacity planners for each function within PPR&D provide initial resource estimates for the planned project with indicated duration. These estimates are validated by the capacity planners based on a comparison of planned versus actual time entry data in SAP. Resource or duration estimates for the identified project may be adjusted periodically by the capacity planner and project manager, respectively, as required by shifting demand. A financial representative participates on the project team as needed to ensure that planned investments are in line with project and portfolio strategies. The financial representative also develops a long-range investment valuation. Human resource managers establish organization structures within SAP, create specific job requisitions, and work proactively with line management to identify staffing strategies (both internal and external) to maintain sustainable growth rates.

As projects progress to the second phase of project maintenance and control, the project managers closely monitor both time and cost data. They retain accountability for overall project delivery and must notify the governance committee if forecasts exceed planned tolerance limits. Meanwhile, the capacity planners manage functional capacity in conjunction with line management to ensure adequate resources for the delivery of project milestones, reforecasting resource information as needed. The financial representative maps the operational plans to the project strategies and provides a balanced scorecard report for the project. Human resources managers assist employees and management in the creation of robust performance management plans, which may involve the redesign of work processes, organizational change, training, and staffing adjustments. In this phase, employees are responsible for achieving their deliverables, reporting their project time, and notifying others if anything in the plan changes.

During the final phase of project closeout, it is the responsibility of the project manager to notify appropriate personnel of the project termination, to develop termination plans in SAP, and to lock the project structure on actual completion. Capacity planners provide ongoing resource and duration estimates for the remaining deliverables of the project and work with line management to transition resources optimally to other projects. The financial representative forecasts and communicates closeout expenses and ensures that third-party financial obligations are met. Human resource managers may help facilitate the transition of qualified employees to other projects or areas of unmet business needs, support employees during transition, and work with capacity planners and line management to identify any changes to organization structure or staffing strategy needed prior to the next project start-up. Employees may need to provide information related to their remaining deliverables and then complete those in a timely fashion. Increasingly, employees are being required to exhibit both breadth and depth of knowledge, as well as flexibility in adapting to changing business needs and project assignments.

RESULTS

VALIDATION OF THE CAPACITY MODEL

Once the capacity model was built, its accuracy was then assessed to ensure that it was not only accurate but also predictive of project resource demand. This was done by comparing planned versus actual hours worked on given drug development projects. The plan-versus-actual data are summarized in Figure 1. As can be seen, there is a high degree of correlation between planned versus actual project hours with a few notable exceptions. Those exceptions shown in the figure were closely examined to understand if these differences were the result of poor planning, technical issues, or a lack of a predictive capacity model. The detailed examination of these outliers shows that there was in all cases a technical or business explanation for why there was a significant difference between planned versus actual hours. An additional step in validation was to compare the total head count in the component with that projected by the capacity model. As can be seen in Figure 2, there was a high degree of alignment with the model projecting 476 people on board versus an actual head count of 488. This discrepancy of 12 people is a very small percentage of the total.

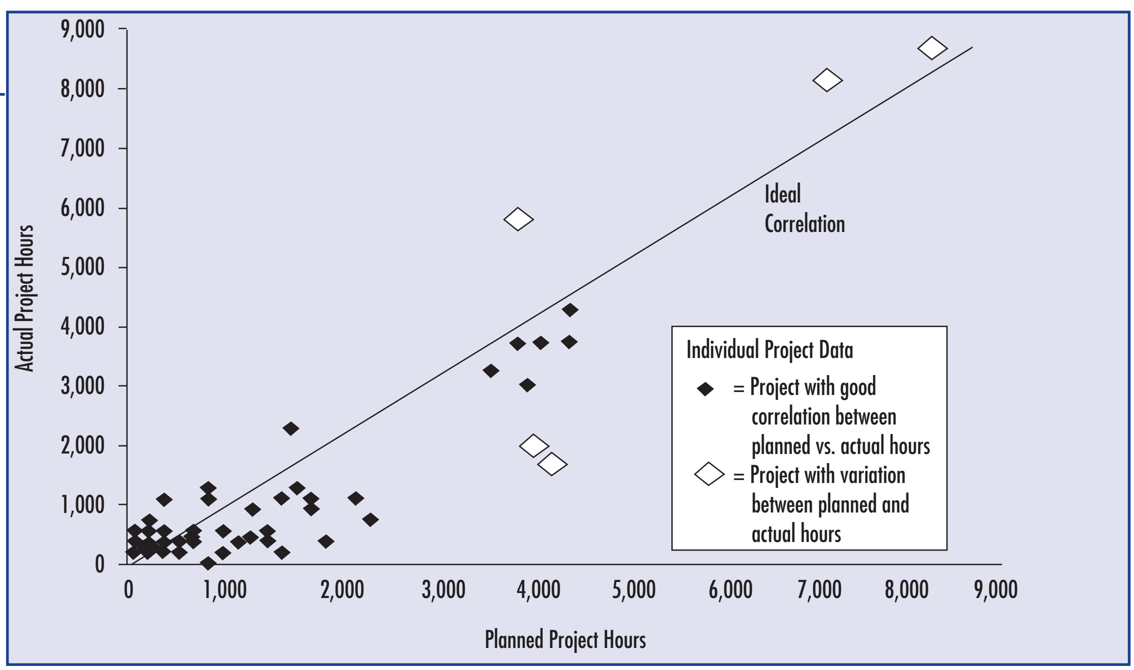
CAPACITY TOOL

APC in collaboration with Lilly capacity managers designed, developed, tested, and rapidly deployed a functional capacity tool called STAR (Scheduling Tool for Allocating Resources). STAR met all the functionality requirements established at the beginning of the project as evidenced by its ability to perform activity-based planning; flexible reporting by individuals and groups; graphical output of resource usage versus time; exportation of capacity plans and project status to Excel spreadsheets; full integration with existing corporate tools; and an architecture supportive of future enhancements. In addition, functional capacity data can be owned and easily maintained by the capacity planners and other users via their personal computers.

Drug development project managers enter planned timelines and milestones for each project into SAP. As the project progresses, actual project costs and employee time entry data are entered into the system as well. Both planned and actual information flows into STAR from SAP (see Figure 3), where it is integrated to continue to validate the capacity model as well as support functional capacity management and

FIGURE 1

Correlation between planned project hours and actual project hours worked by PPR&D employees.



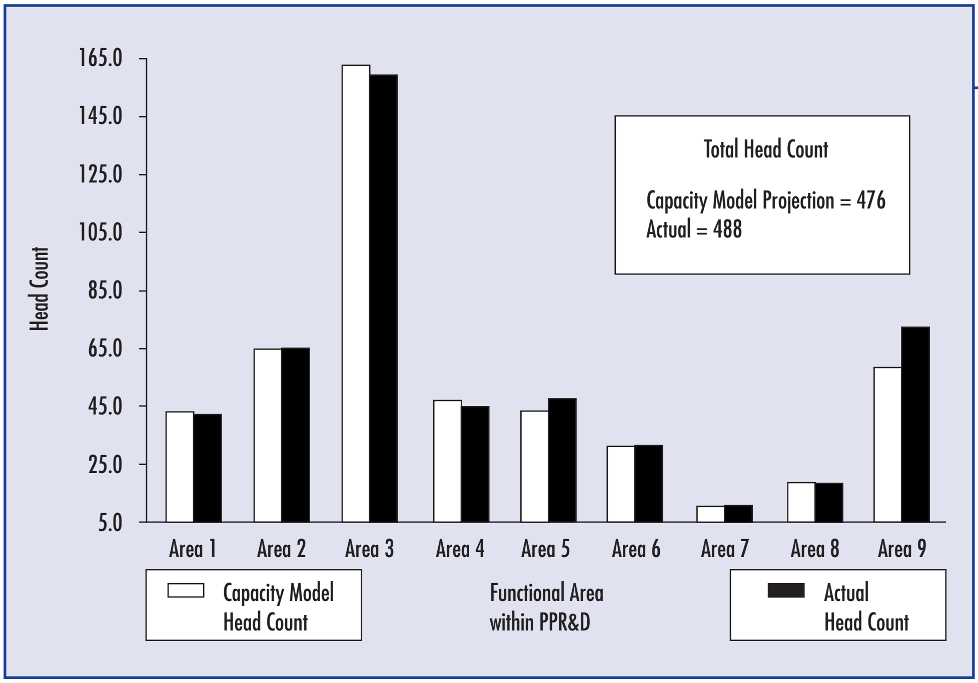


FIGURE 2

Validation of the PPR&D capacity model: actual total functional head count versus head count projected by the capacity model.

local reporting. This local report is in addition to the data from the SAP system that include plan versus actual reports of time or costs (Figure 4), project milestone reports, portfolio demand reports, and project demand reports. In addition to its reporting functionality, STAR can be used to optimize scheduling or to generate reports on demand by activity, by resource, or by project. An example of this is shown in Figure 5, which shows the demand for formulation scientists for a portfolio of projects overtime time.

CONCLUSION

Prior to the development and implementation of the PPR&D capacity model, it was generally assumed that all development projects were unique. The establishment of the capacity model, with the help of STAR, has established consistent deliverables for drug development projects across the component. It has clarified the personnel and skill sets needed in different functional areas to support product development across the life cycle, making it possible to identi-

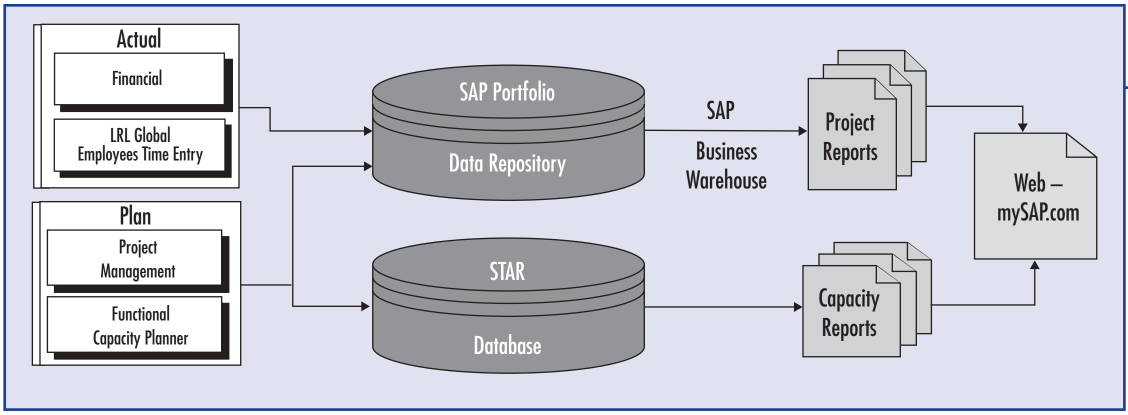
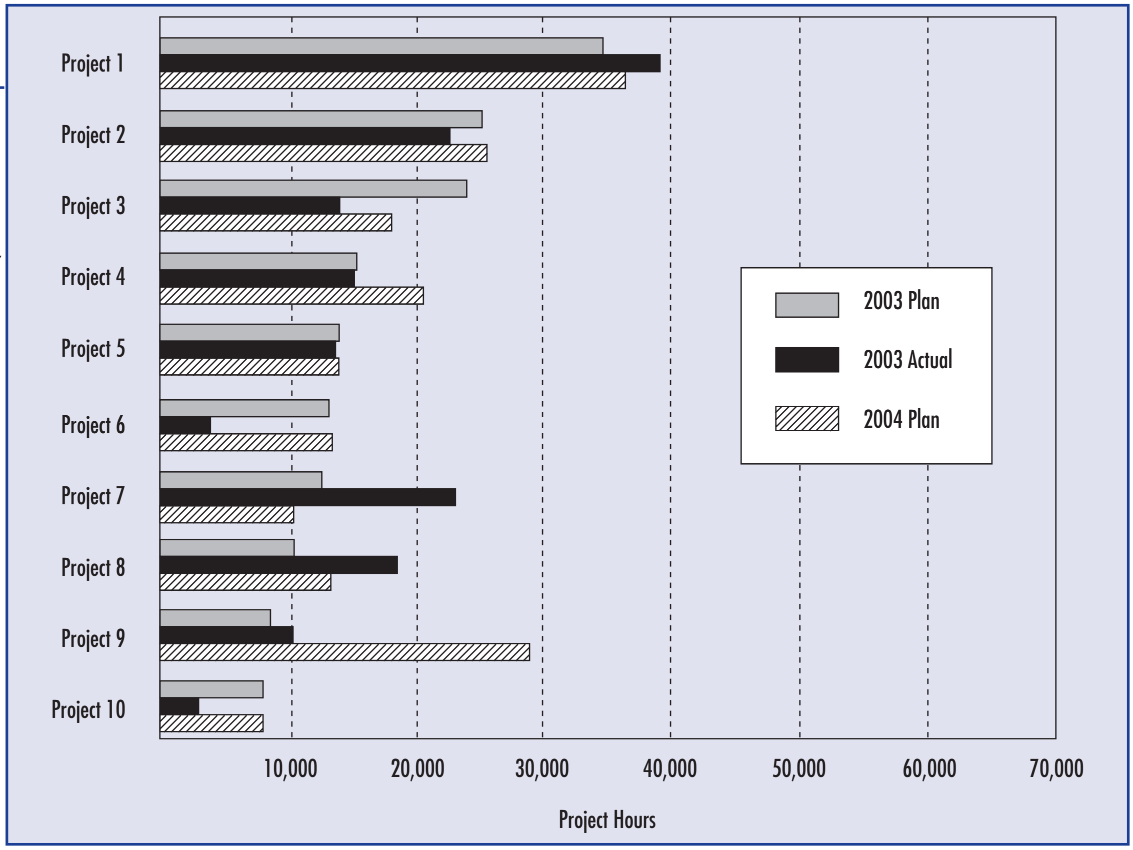


FIGURE 3

Schematic diagram depicting flow of data between the PPR&D functional STAR capacity database and the cross-functional SAP portfolio data repository. The input and output from the system are also shown.

FIGURE 4

SAP report on planned versus actual project hours for a series of selected drug development projects. Both planned and actual project hours are shown for 2003, while the planned hours for 2004 are given for a year-on-year plan comparison.



fy resource gaps, bottlenecks, and excess capacity. As a result, the resource planning process and portfolio management have greatly improved.

This improvement is evidenced by an enhanced capability to plan for the portfolio of drug development projects, thus allowing management to ensure that there is the correct number of people with the appropriate skill sets in place to meet the demand of a given drug development project as well as a portfolio of projects. In addition, it has allowed line management to know how many people with a given skill set are working on a given drug development project so that these resources can be rapidly redeployed if the project is terminated for business or technical reasons.

For organizations in which multiple drug candidates are being developed, scarce resources must be allocated between different drug development projects. This scarcity of resources within the product development organization creates interdependences; that is, the performance of a given product is not independent of the outcome of the other projects. For example, if a given project experiences technical problems that require additional resources to solve, those resources must come from other product development efforts, thus potentially slowing their development and ultimately their introduction to the market. This changing of project resource allocation has the ability to affect every other project currently in the drug development portfolio.

To understand and manage scarce resources across a large portfolio of drug development projects, some type of electronic tool or system is required. Such a task is far too complex and far too important to leave to a back-of-the-envelope calculation. The introduction of such tools, when used properly, can have a positive impact on the entire portfolio of drug development projects. We believe that the introduction of the STAR tool will allow for better resource utilization.

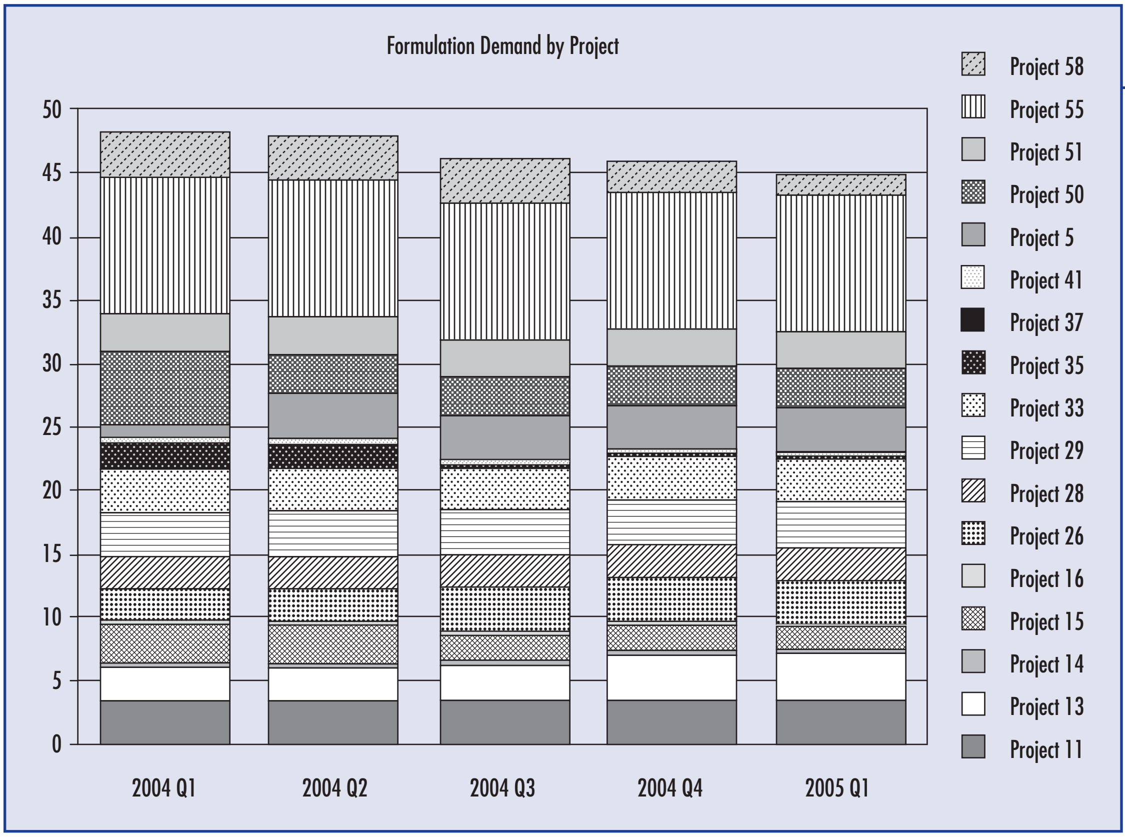


FIGURE 5

Capacity report generated from the STAR database depicting demand for formulations scientists over a five-quarter period for 17 different drug development projects.

This contention is supported by the work of Repenning and others. Rather than focus on the process of decision making as others have (4), Repenning has suggested that there is greater potential in the examining of the structure of the product development process itself (5). One example he provided of how a process can be improved through redesign efforts to be more robust and produce better results is that of resource allocation (5). In this study of resource allocation between current and advanced projects, it was suggested that managers allocate scarce resources by overinvesting in current projects and ignoring longer-term investments (6,7). The combination of these behavioral traits with an environment in which resources are constrained has a number of undesirable characteristics; for example, the system is not responsive to variations in workload (5). Attempting to change the behavior of managers is problematic and may not be the most prudent or productive approach to solving this problem. Rather than leaving resource allocation to the discretion of the managers, Repenning suggested that controlling resource allocation will greatly increase the robustness of the process to variations in workload (5). Placing constraints on the allocation of resources between projects is an example of how the product development process can be redesigned to be more robust and produce consistently better results (5).

The implementation of the STAR tool has allowed for an improved understanding of resource supply and demand in a resource-scarce environment across a diverse portfolio of drug development projects. This improved understanding is fundamental to improved business-critical allocation of resources, which according to the work of Repenning (5), should lead to improved results.

There are additional steps to be taken and value to be derived from the capacity model and supporting STAR tool that have been developed and implemented. Work is under way to develop similar models for other components within our research labs, allowing integration and detailed resource planning on an even broader scale. The scenario planning functionality remains to be further developed and utilized to drive portfolio optimization. There is some overlap of responsibilities among project managers, capacity planners, human resource managers, and financial representatives. Elimination of lingering redundancy within these roles will lead to a more efficient, streamlined process while still maintaining appropriate levels of interaction. Efforts are ongoing to develop common processes, databases, and forms at all levels of the organization. This will facilitate the consistent transfer of project information and enhance forecasting ability. Finally, sustained commitment to the process of cultural change is essential as the organization drives more rigorous, data-based decision making within and across functions.

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