

The Path to Smart R&D

Jan Malek

IT TAKES COMMITMENT FROM THE TOP DOWN TO OPTIMIZE PORTFOLIO PROJECT RESOURCE MANAGEMENT.

Jan Malek is a leader in PA Consulting's life science practice in Cambridge, MA. He can be reached at Jan.Malek@PAConsulting.com or (617) 460-0200.



One of pharma's thorniest challenges is how to optimize the potential value of its R&D portfolio with limited resources. To address that, many pharma and biotech companies have begun to enhance their capabilities in the new discipline of portfolio project resource management (PPRM). Those initiatives are beginning to bear fruit, but they face several common obstacles:

- a concern that more disciplined and standardized business processes will hamper the creativeness and independence of scientific inquiry
- apprehension that significant effort will be needed to reconcile process differences and information flow across the R&D enterprise
- fear that enhanced PPRM capabilities will lead to drastic changes in how

portfolio and resource decisions are made and who gets to make them. The problem is exacerbated by the organizational challenges of implementing PPRM. To make the system work, companies must standardize their business practices, create highly explicit procedures, and exercise a high level of managerial discipline. Like most efforts for change, PPRM requires companies to address issues they previously ignored or devised "work arounds" for, and to eliminate the ambiguities that gave rise to those issues in the first place. Although PPRM demands a significant change in mindset and although decisions made based on it ultimately affect the entire R&D enterprise, it actually changes the day-to-day jobs of relatively few people. Therefore, it is

possible for companies to implement robust PPRM capabilities without negatively affecting the science or disrupting the organization.

This article explores some of the major issues that pharma and biotech companies may encounter in implementing PPRM and suggests how management can make it succeed.

Maximizing Value

Most pharma R&D organizations operate within the confines of a fixed annual budget—largely determined by the number of people they employ—but they lack the ability to forecast the quantity of resources required to develop compounds in an optimal manner. Unwilling to regularly prune their portfolios, other than through natural attrition, they often wind up fragmenting their resources across a large number of projects.

Moreover, in the absence of company-wide decisions to set priorities, department and functional heads make *de facto* portfolio prioritization decisions by allocating staff to projects. That approach

In theory, implementing a comprehensive set of PPRM capabilities is straightforward. In reality, it is anything but.

has two significant drawbacks: it allows inconsistent resource allocation decisions and diminishes senior management's stewardship of the R&D portfolio.

PPRM enables companies to maximize the value of their pipeline portfolios within budgetary and resource constraints. But to do that, they must make consistent go/no-go, resource allocation, and project-timeline decisions based on the best available information about the risks, costs, and commercial potential of the compounds in the pipeline.

All that is not easy. Companies must have a core set of capabilities, including

- up-to-date, standardized plans for all active projects
- estimates of the human and key non-human resources required to complete each project
- availability of human and key non-human resources
- priority rankings of all active projects, from highest to lowest
- “probability of success” estimates at key decision points and for each project as a whole.

Standardized project plans. These are the backbone of pipeline management. They establish interdependencies between R&D activities and functions and provide the basis for estimating resource requirements. To create them, the company must agree on standard project templates that include major activities, milestones, decision points, and interdependencies for the full project lifecycle, from early discovery to product launch.

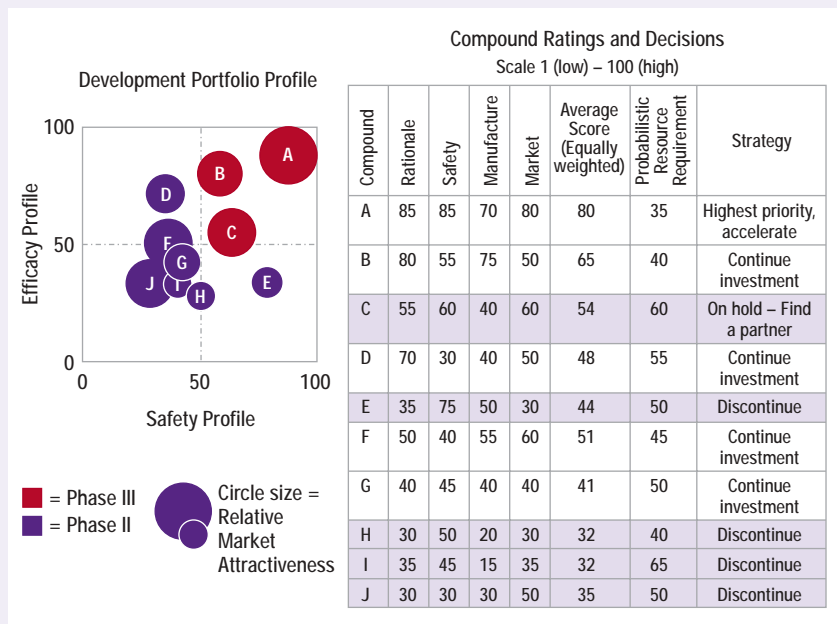
When developing templates, R&D managers must decide on the level of detail to include in these plans to meet the needs of the various constituencies. They also need to decide whether to use single- or multi-level plans, keeping in mind that, once developed, the plans must be updated regularly to reflect the latest project status and the team's latest thinking. Developing project templates and maintaining project plans require significant effort and extensive collaboration between the different functions.

Ability to estimate the resources needed to complete all projects. Companies can use standardized algorithms to estimate resource demand by resource type based on the project assumptions and deliverables—such as the development of a trials protocol or completion of a study report—defined in the project plans. The departments that will do the work need to be intimately involved in developing these resource algorithms. They also need to review, and when necessary adjust, the resource estimates that the algorithms generate for each project to correct for subtle variations between projects that the formulas may not take into account.

Thus, both the PPRM process and the

GO/NO-GO DECISIONS

A compound rating approach that uses standard scales highlights the relative merits of each compound and enables managers to consistently prioritize and allocate resources.



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system should allow for manual override of the algorithmic resource estimates but retain both sets of data for comparative purposes. The resource estimation formulas, which initially will be based on judgment more than empirical data, should be refined, over time, based on analyses of actual resource consumption. As that happens, the magnitude of the manual resource adjustments should decline.

Ability to rank projects in order of priority. To prioritize projects, companies must consider complex scientific and commercial variables, including scientific rationale, compound characteristics, manufacturing complexity, R&D complexity, and sales potential. To be able to

rank projects in different therapeutic categories (TCs) and in different stages of development in a consistent manner, pharma companies need standard evaluation criteria, rating scales, and processes to regularly evaluate programs at all milestones and decision points. (See “Go/No-Go Decisions.”) Questions that companies should ask in the course of those assessments include:

- How well do we understand what happens at the drug target site and why does it result in a specific medical condition?
- How strongly is the target correlated with the disease?
- Have similar compounds made it into human trials?

- Have they obtained marketing approval?
- How many people suffer from the disease?
- How many people could this drug help?
- Will this product be better than existing or emerging therapies and, if so, how and by how much?
- How complex is the manufacturing process?
- Are the raw materials readily available at reasonable prices?

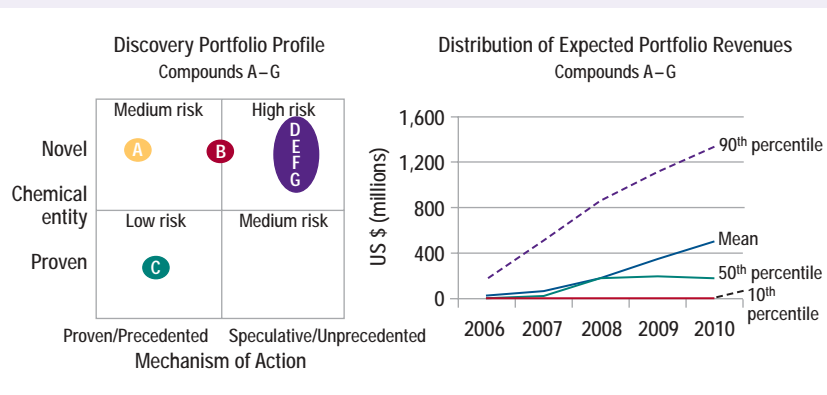
The answers to those and similar questions will provide consistent data that enable managers to evaluate and prioritize all projects.

To evaluate an R&D program requires a high degree of judgment; as a result, program assessment cannot be mechanistic. Rather, it must be the result of a dialogue among project teams, functional leaders, and senior R&D managers. Yet, the use of a consistent rating methodology, data collection process, and analysis across all programs will greatly improve the quality of the discussion and the ensuing decisions.

R&D organizations have traditionally found it difficult to take resources away from low-priority projects that hold some scientific promise. In fact, it is not uncommon for them to allocate some resources for every feasible project rather than to concentrate resources on the highest priority ones, thus dooming all projects to move at a suboptimal pace. To improve the management of the R&D pipeline, managers need to make difficult decisions that will maximize the value of their portfolios. That will also enable them to define how risky the portfolio is and ensure that it is aligned with the company's financial strategy. (See “How Risky is Your Portfolio?”)

By aggregating the resource estimates for all projects, adjusted according to their probability of success, companies can quantify total expected resource demand by time frame and resource type. Comparing needed resources with the company's actual resources will reveal the “static” demand-supply balance and identify current and expected resource bottlenecks. (See

HOW RISKY IS YOUR PORTFOLIO?



Source: Jan Malek

PE Graphic

To balance their portfolios, R&D organizations need to regularly assess their risk profile and estimate the portfolio's revenue potential. There are several ways to do that, but it is important that they make resource allocation decisions that are consistent with their business strategies. The “Discovery Portfolio Profile” shows how companies can map their portfolios based on how much they know about the targets and compounds.

The upper right quadrant, where novel compounds flirt with unprecedented targets, shows where breakthrough therapies are born. Given the greater risk of failure, the potential rewards must be correspondingly higher to make those efforts worthwhile.

The bottom left quadrant is where lower-risk/lower-reward line extensions reside. A well balanced R&D portfolio, like a well balanced stock portfolio, will have compounds in each quadrant. The question that will determine how many resources the company will allocate to each quadrant is “How much risk are we willing and able to tolerate?”

The portfolio shown here reflects the “bet the farm” strategy of a company that was pursuing novel approaches to find high-market-potential drugs for previously uncured diseases. The graph on the right represents the portfolio's annual revenues under different scenarios and their respective probabilities of occurring. That is reflected in the revenue projections, which were generated using Monte Carlo simulation and which show how low—10 percent—the probability of achieving annual revenue in excess of \$1 billion is. To align its financial and R&D strategies, the company determined that it needed to find backers to fund the portfolio and absorb some of the risk.

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“Where are the Bottlenecks?” Based on that insight, the portfolio group will be able—manually or with optimization software—to sequence project activities

so as to minimize bottlenecks and optimize aggregate pipeline output. (See “The Great Data Roundup.”)

Although maximizing pipeline out-

put is a good thing, it is not the same as maximizing the portfolio’s expected value. Doing that requires sophisticated portfolio simulation capabilities based on well defined relationships between the level of project resources and time to market, as well as between the timing of product launch—relative to competing products—and lifecycle product revenues, in addition to knowledge of the resource constraints across the company’s entire R&D value chain.

Integration. It is critical that PPRM be tightly integrated with stage-gates—predetermined hurdles that projects must meet before being allowed to continue—that pharma companies use to control projects. Stage-gate keepers need the PPRM information and analytical capabilities to make informed decisions. They need to clearly understand the resource supply–demand implications of their decisions and have ready access to project attributes and project priority rankings.

Some R&D organizations that implemented PPRM have concluded that they needed to redesign their stage-gate processes to align them with the PPRM-based management approach. Companies that have failed to symbiotically link stage-gate reviews, resource management, and portfolio management have frustrated project teams and executives alike by duplicating the information collection, review, and decision making processes.

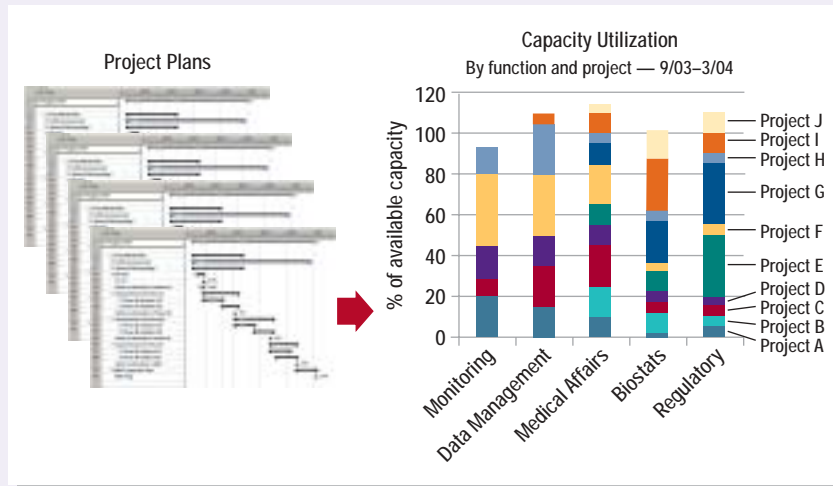
Some sophisticated companies have combined those processes by using “workflow” software for stage-gate submissions and a single database to support the stage-gate process, resource management, portfolio management, and other related capabilities. Stage-gate governance bodies are an important component of PPRM-based R&D management and need to be included in the design and implementation activities from the outset.

Setting the Course

To bridge the gap between their current and desired PPRM capabilities, pharma companies need to carefully define their multi-year, multi-stage deployment plans. Those plans will be based

WHERE ARE THE BOTTLENECKS?

By understanding the resource supply–demand relationship in advance, managers can maximize output by reducing demand, increasing supply, or both.

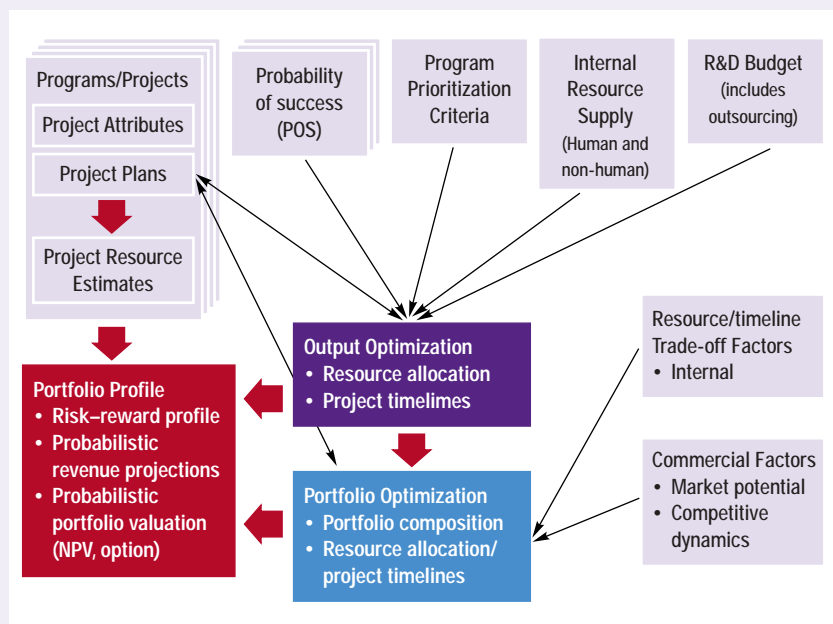


Source: Jan Malek

PE Graphic

THE GREAT DATA ROUNDUP

To optimize portfolio value and pipeline output, companies must collect a consistent set of data across all compounds.



Source: Jan Malek

PE Graphic

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on each company's specific needs, capabilities, and ability to absorb change. First, the company must decide on the scope of the effort, taking into consideration the company's purpose in using PPRM, its organizational reach, and the specific needs of the different functions.

Users. Next, the company needs to clarify who will use the PPRM system. Is it employing PPRM to give senior management a strategic view of resources and the portfolio, to make it part of the project teams' everyday management activities, or both? Those alternatives imply vastly different PPRM capabilities as well as a need for different levels of effort and complexity. They also raise different organizational issues.

Organizations. There are important differences in the business process characteristics of the main areas of R&D: discovery, pre-clinical, pharmacology, full development, and pilot plant. Those differences manifest

themselves in the number and size of projects, scheduling predictability, complexity defined as the number of interdependencies and diversity of skills required, and project duration, to name a few.

Such differences in business characteristics naturally lead to differences in PPRM requirements. For instance, discovery may primarily need to monitor and manage resources that are chronically overburdened, such as high-throughput screening and computational chemistry. Pre-clinical functions may derive the greatest benefits from the ability to assign specific resources, such as labs and animals, to specific studies. Development may need the ability to identify functional areas in which resource constraints are most likely to occur.

As companies plan their PPRM strategy, they need to take those differences into account, while ensuring that a core set of capabilities is available

across the entire R&D enterprise. At the same time, R&D organizations must take care not to create unnecessary complexity by extending PPRM capabilities to units and functions that don't need them. For example, it may be essential for the toxicology group to assign specific resources to individual studies, but using that capability to manage a small medical writing group could create unnecessary complexity.

Width and depth. To ensure that they deploy PPRM systematically, pharmaceutical companies should plan along two dimensions: specific capabilities and the sophistication level of each. It is also important to realize that not all companies require the full suite of PPRM capabilities, nor do they need to reach the advanced stage of those they choose to implement. The choice will depend on the portfolio's size and complexity as well as on the level of resources that the company is willing to dedicate to the PPRM effort.

In doing so, they need to take into account the inherent interdependency between different PPRM capabilities. For instance, parametric resource estimation presupposes the existence of standardized project plans, and static resource supply and demand balancing requires probability-adjusted resource estimates and resource supply information. Thus, even sophisticated companies must carefully map out internal dependencies and build capabilities sequentially. Integration with other systems that contain important data is another piece of the puzzle that companies must incorporate into their implementation plans.

Toward Transformation

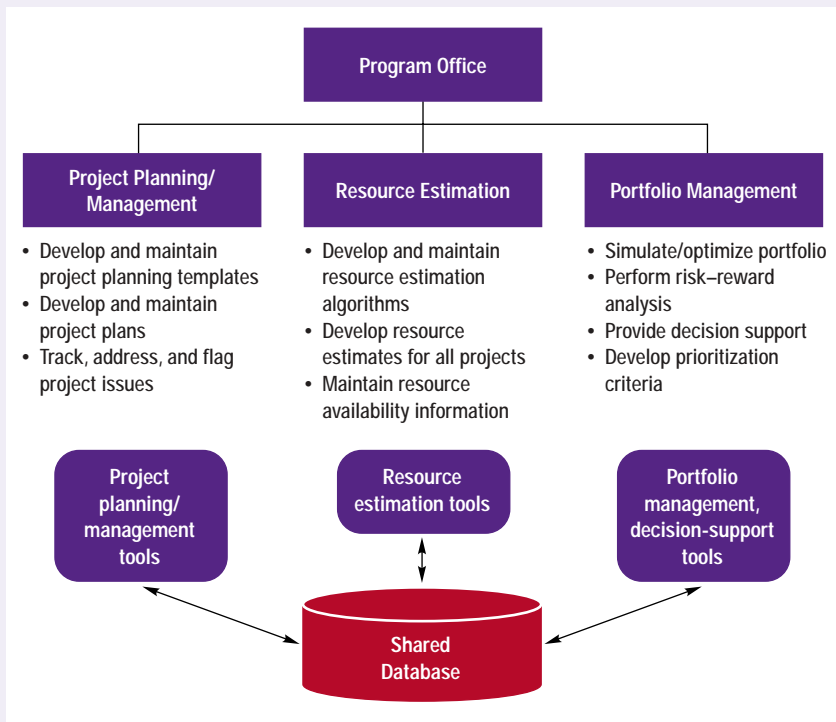
In theory, implementing a comprehensive set of PPRM capabilities is quite straightforward. In reality it is anything but. The challenge lies in enrolling the entire R&D organization in the effort and in making many detailed decisions in a timely and consistent manner.

Every company operates in a state of equilibrium based on a combination of explicit and implicit agreements about a gamut of issues, including

- who has access to what information

UNDER ONE UMBRELLA

Effective management of R&D portfolios requires an integrated organization to collect and analyze a comprehensive and consistent set of compound information.



Source: Jan Melek

PE Graphic

- who has the authority to make which decisions
- the degree of standardization within and across functions
- the level of independence that functions and franchises enjoy.

PPRM's very purpose is, of course, to redefine that equilibrium. To get the ball rolling, the head of R&D must set the tone and engage in three key activities:

- enroll the R&D unit, therapeutic area, and function leaders in the effort
- decide who will lead the effort
- decide how to organize the relevant staff functions to support it.

Experience shows that the support of unit, TA, and function leaders is critical to the success of such efforts. R&D presidents should realize that those leaders have reasons to both support and fear the

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initiative. On one hand, new tools and processes could help them better manage their functions. On the other, the increased transparency that the new system creates could expose them to greater scrutiny. They may fear that PPRM will portray them in an unfavorable light, with consequences for their standing in the company and career prospects.

Furthermore, because PPRM by its very nature is integrative, it will reduce their autonomy and require them to coordinate more closely with one another. They will also be concerned that the increased transparency will make it possible for executive management to take on more decision making authority to itself.

None of these are positive developments for individuals who are used to running their respective organizations with considerable autonomy. For that reason, R&D presidents must address those concerns before implementing any

changes. If they are serious about changing how the organization makes resource allocation and portfolio selection decisions, they will be actively involved in negotiating the new agreement and making it stick.

Leadership alignment and buy-in are essential steps that cannot be skipped to get the effort underway quicker. Companies that have tried to take shortcuts have found their implementation efforts bogged down, both by legitimate questions and by resistance from those who are not ready for the change.

When conducting those negotiations, R&D presidents have several levers at their disposal. First, they can exert some pressure on people to agree to certain changes for the "common good" of the company, but there are limits to what people will do to be seen as good corporate citizens. Second, they can eliminate much of the paralysis that frequently follows in the wake of change by clarifying key issues, such as

- how the enterprise will operate in the new PPRM environment
- who will make which decisions
- how performance will be evaluated
- how the budgeting process will work.

At the same time, they must invite people to participate in further defining the new processes. Third, they must acknowledge that the needs of executive managers and unit, TA, and function managers are not identical: executive management needs aggregate data over a longer time horizon, while operations managers need tactical information. They must also be open to including capabilities, such as allocating staff, labs, and animals to specific studies, that will help unit leaders manage their respective areas. That makes good business sense and will generate significant goodwill and support for the effort.

Next, R&D presidents must decide who will lead the initiative and how to organize staff functions—such as project, resource, and portfolio management—to support PPRM's implementation and ongoing activities. In principle, those staff functions can either be imbedded within the different R&D functions or be centralized across the functions. In either case, the informa-

tion needs to be standardized and aggregated across all of R&D.

The most straightforward way to unite them is to consolidate them into a program office under a single leader, reporting directly to the head of R&D. (See "Under One Umbrella.") The person leading the program office needs to be well grounded in R&D as well as process design, process/systems implementation, and organizational redesign. That person must already have, or be able to quickly gain, the trust and support of a majority of the unit/TA/function leaders.

The R&D president will also have to determine whether the program office should be led by someone with a scientific or a business background. The answer will depend on the company's culture and the specifics of the situation. But it is worth considering that the skills required to implement PPRM—good organization and processes and systems knowledge—may be somewhat different from those required to run the program office once it is established and that the function may therefore undergo a change in leadership as it matures.

The Challenge

Every biopharmaceutical company needs well honed PPRM capabilities to survive and prosper in today's demanding R&D environment. Such change efforts are primarily organizational, and their success depends on the deftness and persistence of R&D presidents and their closest lieutenants in enrolling senior leaders and in anticipating issues and addressing them as they arise.

The technology facilitates data collection, storage, analyses, and dissemination, but the organizational negotiations will determine which information will be collected, who will have access to it, how it will be analyzed, and who will make which decisions. To reach the desired end, R&D presidents must roll up their sleeves and champion the effort, enroll unit/TA/function managers, and personally help to resolve conflicts. Only then will pharma companies succeed in developing the capabilities required to successfully manage R&D in an increasingly challenging environment. ■