



PRTM

*Global Management
Consultants*

**Successful Portfolio and
Resource Management
Practices for
Pharmaceutical &
Biopharmaceutical
Companies**

Industry Benchmarking Report

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Successful Portfolio and Resource Management Practices for Pharmaceutical and Biopharmaceutical Companies

Pharmaceutical and biotechnology companies are faced with increasing pressure to improve R&D productivity, delivering more results with less investment. This shift has been difficult for pharmaceutical organizations, as most have not yet embraced best-in-class portfolio and resource planning and management practices, having enjoyed abundant resources in recent years. In order to drive up R&D productivity, it is clear that pharmaceutical companies must adopt what has worked well in other industries, including the automotive, packaged goods and aerospace sectors. Leading companies in these industries have adopted integrated portfolio and resource management processes to enable timely and efficient project and portfolio decisions.

As part of the PharmCentric Cross-Functional Performance series, PRTM recently conducted a focused study to better understand the practices being used within in the industry today. Thirteen pharmaceutical and biotechnology companies participated in the study.

Abbott Laboratories
Acambis Inc
Astra Zeneca
Biogen

Bristol-Myers Squibb
Daiichi Pharma
Pfizer Inc.
Proctor & Gamble Pharmaceuticals

Roche Laboratories
Sankyo Pharma
Taro Pharma
Wyeth
3M

The following topics were addressed:

- Portfolio and Resource Management issues
- Impact of these issues on business performance
- Practices adopted to respond to these issues

This document summarizes the findings and conclusions of the study, based on participant responses. In addition, we offer a set of best practices drawn from PRTM's experience in helping companies address these management challenges.

Key Findings:

- Pharmaceutical and Biopharmaceutical companies continue to make project decisions without regard for resource constraints and trade-offs within the development portfolio
- Project decisions made in isolation and unclear or changing priorities lead to overloaded resources and bottlenecks, resulting in missed timelines and objectives
- Companies that have implemented well functioning portfolio and resource management practices have better visibility to the overall pipeline and resource needs across projects, leading to better decision making and more effective project resource allocation decisions
- Companies that have implemented enterprise-level IT solutions without effective portfolio and resource management practices in place continue to suffer from overloaded resources, capacity shortages and missed timelines

Issues and Impact

The study was designed to better understand the key portfolio and resource issues of the pharmaceutical industry along three key dimensions: Decision Making, Process Capability, and Organization Alignment.

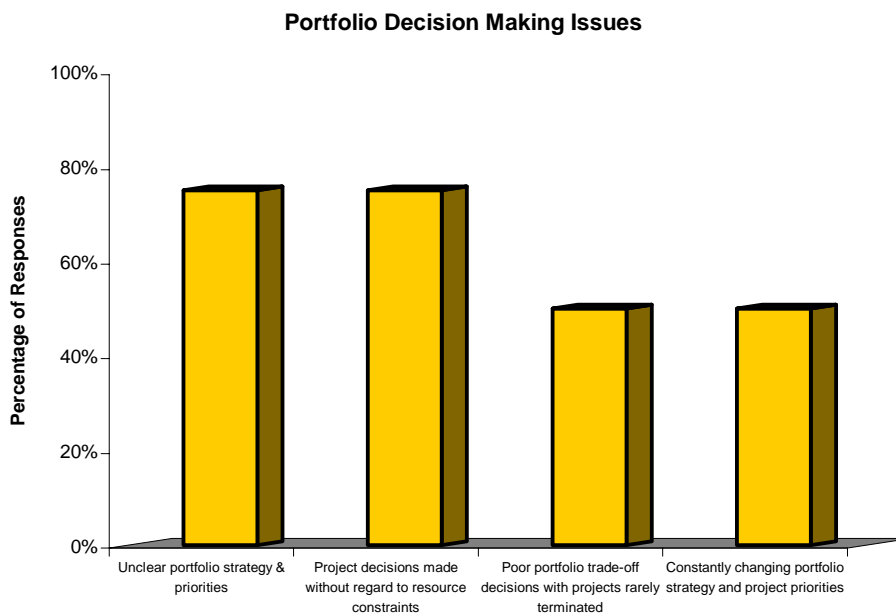


The study also assessed the contribution of these issues to the following outcomes:

- *Overloaded resources*
- *Resource shortages*
- *Limited visibility to resource demand*
- *Unskilled or inappropriate resource mix*
- *Missed timelines or goals*
- *Uncompetitive cycle times*

Decision Making: Poor decision-making with respect to portfolio trade-offs, priorities, and resource requirements are adversely impacting project timelines and goals

Over 70% of participants indicated that project decisions are typically made on a one-off basis, not considering the impact on overall resources and the project portfolio. Half of the participants also reported that project trade-off analysis is poor and that projects are rarely terminated.

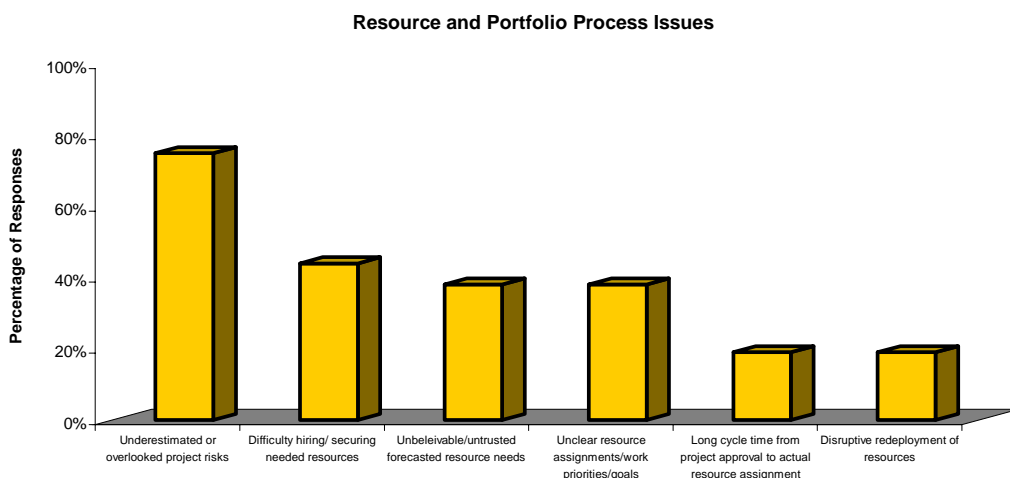


While pharmaceutical companies have been able to easily take on additional projects and obtain the necessary resources in the past; Going forward, constraints on budgets and headcount will force companies to be more selective, focusing on projects with the best strategic fit and balance across appropriate risk-return measures.

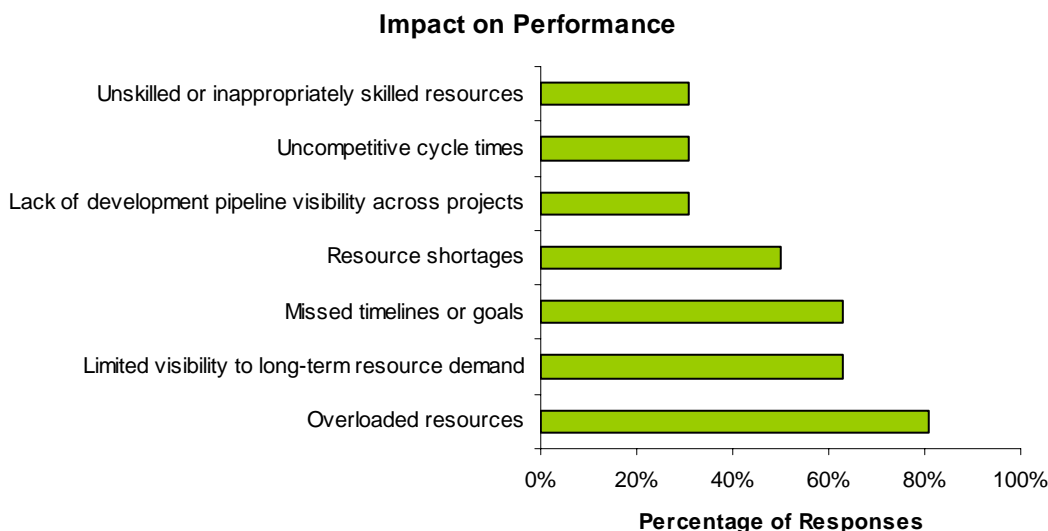
Process Capability: The industry has been slow to adopt best-in-class portfolio and resource management practices

The practices of resource management, project planning, and risk management have all been identified as areas where process capabilities could be improved. More specifically, a number of participants (38%) reported that their forecasted resource numbers were often unbelievable or un-trusted. Some companies have moved to estimation algorithms, only to find the estimates challenged or the models found to be too complex. Additionally, historical data or relevant benchmarks may be hard to come by, opening predictive models to skepticism.

Compounding the resource management issue is poor project planning practices, which makes it very difficult to see required demand, for functions and project teams, and proactively manage impending resource bottlenecks. This can then result in missed project milestones or goals. A majority of participants that reported poor process capability in this area also reported resource shortages and missed milestones as key issues.



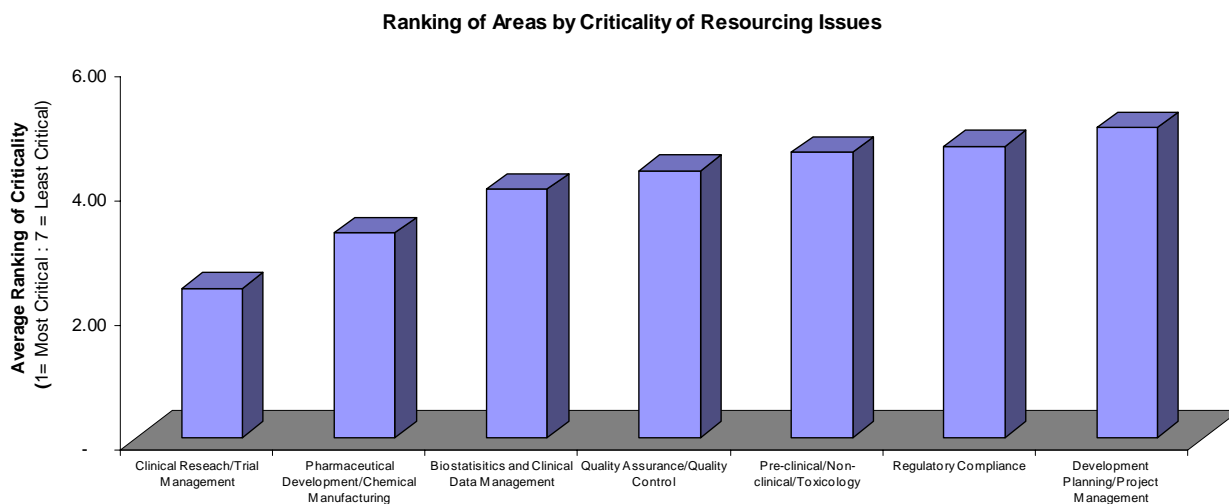
Pharmaceutical companies are continually looking to improve their risk assessment and management practices and still have room to improve upon current practices, as evidenced by respondents. A majority (>70%) reported that underestimated and overlooked risks continue to be a challenge. The assessment and management of risk is paramount to the overall success of projects. Given the relatively high attrition rates of pharmaceutical development projects, risk-adjusted resource planning is critical to keeping a healthy pipeline moving without driving up development costs.



Organization Alignment: Pharmaceutical companies have difficulty obtaining and deploying resources to the right projects

Over a third of the participants reported that unclear resource assignments and work priorities were an issue. Given their limited visibility into long-term resource demand, these organizations have difficulty in hiring or securing the right resources. Despite these challenges, only a minority of participants (<20%) reported that disruptive redeployment of resources—the constant shift from project to project—as a key issue.

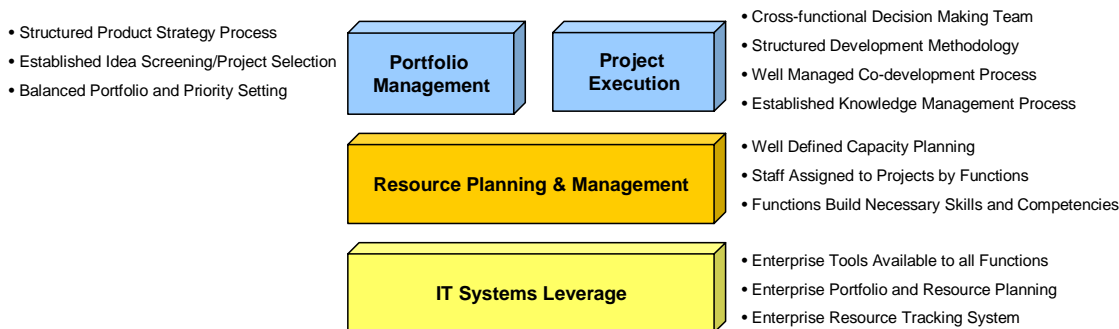
In a forced ranking of functional areas with the greatest resource issues, Clinical Research and Pharmaceutical Development were reported as the highest, while Regulatory and Project Management were the lowest. In pharmaceutical companies, it is often perceived that “shared resource” functions such as QA and RA tend to be the most resource constrained; however, as companies are forced to add more and more projects, the headcount-intensive functions are the ones that feel the greatest pain.



One common issue reported by almost all participants was overloaded resources. As companies try to do more with less, there is a constant battle between managerial expectations of output and the capacity of available resources. Unclear project priorities combined with limited visibility into project resource demand can lead to a constant state of work overload.

Responses and Benefits

The study also assessed how companies are responding to the portfolio and resource management challenges they face, focusing on practices being adopted in four main areas: Portfolio Management, Project Execution, Resource Planning and Management, and IT System Leverage. Participants were asked if the practices were already adopted or being planned and, if adopted, whether the practices were working well.



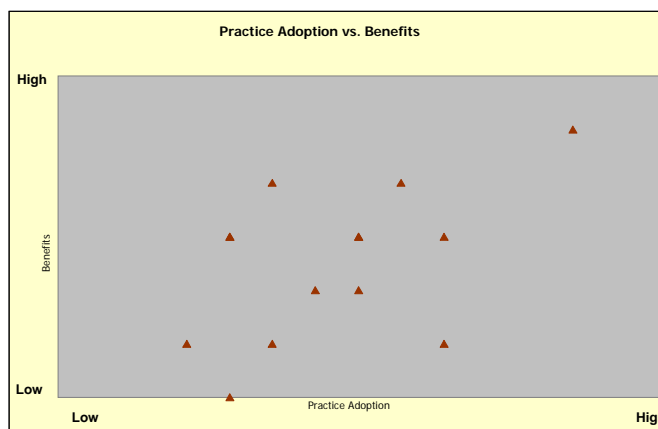
It is clear from the responses of the participants that few of the companies have established, well-functioning processes. As can be observed in the scorecard below, the majority of participants responded that they are either in the midst of implementing processes or that their established processes are not working well. It is also evident that pharmaceutical companies are beginning to implement IT systems to enable portfolio and resource management at the enterprise level. However, many risk not realizing the real benefits afforded by these systems by not having the right processes and organization alignment in place.

Practices Scorecard

	Being Implemented/Planned	Not Working Well	Some Aspects Working Well	Working Well
Portfolio Management	●	●	●	●
Resource Planning & Management	●	●	●	●
Project Execution	●	●	●	●
IT Systems Leverage	●	●	●	●

Size of bubble— Relative Percentage of Responses

We compared how companies responded to their level of adoption of portfolio, resource, and project execution practices against the benefits of improved resource availability, milestone achievement and visibility. The chart below illustrates that companies that have implemented well-functioning practices realize higher overall benefits compared to those companies that have yet to implement processes or have processes that do not work well.



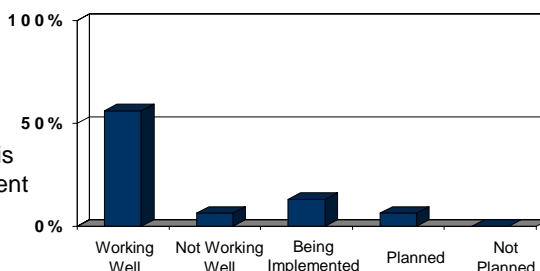
Portfolio Management: Pharmaceutical companies do a good job forming product strategy and identifying opportunities but are less successful in setting and communicating priorities

Approximately one-third of the participants reported that their front-end practices—setting product strategy and identifying and screening ideas—were working well. Another third of the participants reported that they were planning to or are currently implementing these capabilities. However, despite having good screening practices, half of the participants reported that project priorities were not clear and balanced across relevant dimensions.

Portfolio Management

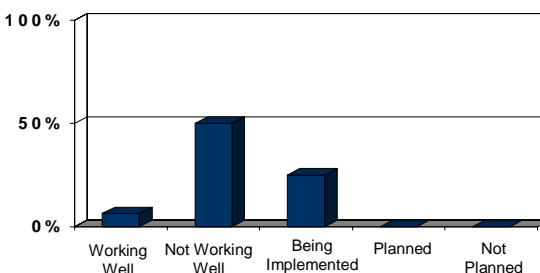
Working well:

A formal process exists for identifying, qualifying, and approving new development opportunities, and the process is linked to the product development process (i.e., through a shared decision-making body)



Not working well:

Priorities are set through a structured decision process for projects and are reflected in a portfolio that is strategically balanced to include a proper mix of compounds, indications, and projects



In our experience, pharmaceutical companies tend to take a bottoms-up approach to project prioritization: projects in the pipeline and new ideas are ranked without appropriate guidance from senior management on target investment by strategic categories. In addition, resource constraints are seldom considered or given due consideration in portfolio decisions. Hence, attempts to rationalize the pipeline typically do not result in concrete decisions to cancel/delay projects, thus continuing to overload pipelines.

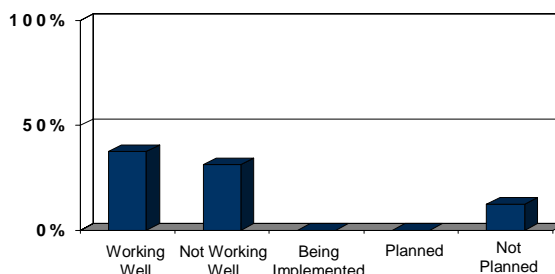
Resource Planning & Management: Resource planning and deployment capabilities are still in their infancy within the pharmaceutical industry

Very few participants (<15%) indicated that their long-term resource planning practices were working well. For all companies, cross-project trade-off decisions are hard to make when forecasted numbers are not trusted. Not surprisingly, the majority of participants also reported that their functions were not able to evaluate their existing skill-sets against future needs and continually plan to close gaps.

Resource Planning and Management

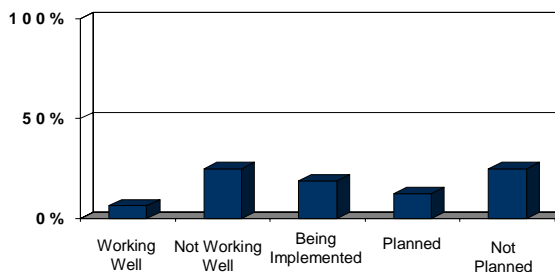
Working well:

Staffing for development projects is assigned by functional managers on a project-by-project basis based on an overall view of the development project pipeline and priorities



Not working well or not planned:

Each function continually evaluates existing resources and skills relative to forecasts of future resource/ skill needs and develops plans for closing resource/ skill gaps. Plans are reviewed and approved by a cross-functional management group



A number of participants (44%) reported that their functional managers effectively staffed projects by taking a view of the overall pipeline and priorities. Conversely, 31% of participants reported that this practice was not working well in their companies. The latter also reported that they had limited visibility into believable resource demand forecasts—a critical input to making effective staffing decisions. An additional complication we observe in the industry is the clarity of who owns resources and who is responsible for their deliverables—the functions or the teams? This is a common contention and a consequence of ill-defined matrix management structures.

Project execution success is just as dependent on having the right resources working on the project as it is on having a well-defined process that is followed by teams and functions. In the study, participants who reported that their resource management practices worked well also reported fewer issues in resource shortages and timeline/goal achievement.

Project Execution: Project execution practices are widely adopted, but there is still opportunity for improvement

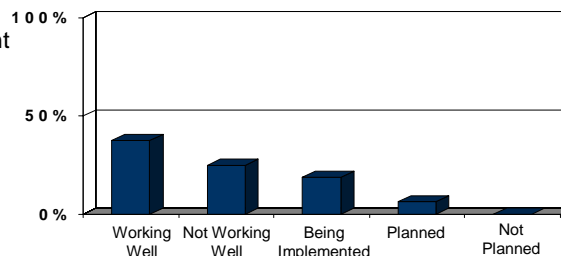
Over a third of the survey participants reported to have cross-functional management team making effective project decisions. These companies also reported that they had good visibility into the overall pipeline and into believable long-term resource forecasts—both critical elements to making effective project decisions.

A quarter of the survey participants responded that the cross-functional team making project decisions was not working well. Poor visibility into forecasted resource needs limited the team to making project decisions without regard for resource constraints resulting in overloaded resources and missed timelines.

Project Execution

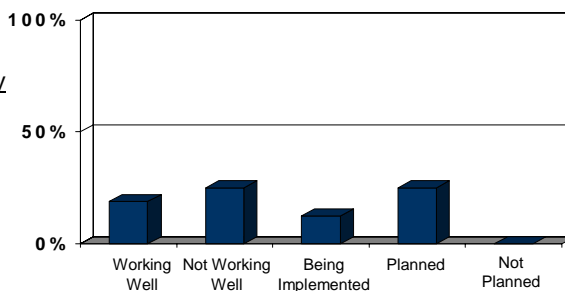
Working well:

A cross-functional management team makes project go/ no-go decisions and allocates resources to projects looking across all project forecasts including projected project milestones and resource commitments



Not working well:

The development methodology is well defined, end-to-end by phase from late lead optimization through product launch. It is integrated across all relevant functional areas and is the starting point for all development project plans



Surprisingly, less than 20% of the participants responded that they had a well-defined, end-to-end development methodology that was well integrated across the functions. Companies without well-defined development methodologies found that overlooked or underestimated risks were a key issue, as was their ability to reliably forecast project resource needs.

IT Systems Leverage: Matching processes to systems is critical in building solutions

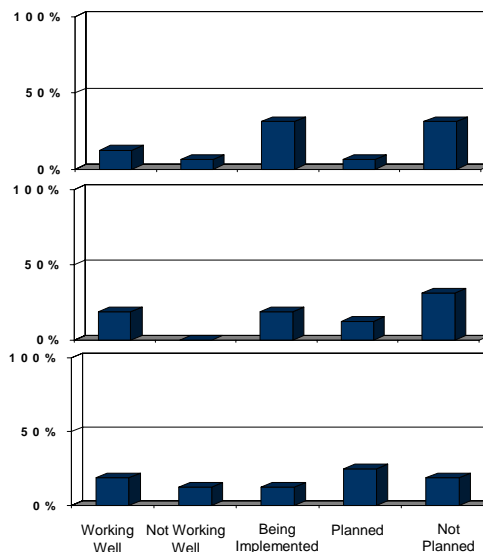
Whether to implement an enterprise-level project and resource management system appears to be a lingering question within the industry. Less than 20% of the participants reported having enterprise-level project and resource management systems in place and working well. Another 32% reported that they are planning or currently implementing such systems. The remaining participants responded that they did not plan to use such systems. It is interesting to note that even in companies that reported that their enterprise systems were working well, overloaded resources and missed timelines continue to be key issues in their company.

IT Systems Leverage

Enterprise tools and templates are available and used cross-functionally to support all relevant aspects of development project and resource planning, tracking, and management

Enterprise project and resource management system

Resource forecasting algorithms



It is commonly perceived that the planning and management of projects and associated resources requires the collection, analysis and reporting of vast amounts of data. Further complicating this exercise is the perceived need to constantly update the information. These perceptions have encouraged many organizations to adopt complex systems to manage the data involved. However, without well-defined processes and clear responsibilities, these systems do not always deliver on the promised results. Also critical to the success of these systems is the ability to report information in a simple, useful format.

	System In Place Good Practices	System In Place Inadequate Practices	No System Good Practices	No System Inadequate Practices
Performance	High	◆		
		◆		◆
		◆ ◆		
			◆	◆
Low			◆	◆ ◆ ◆

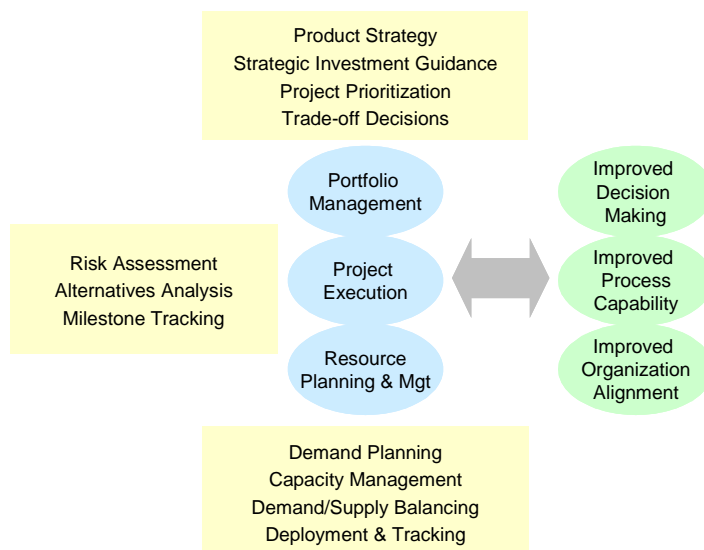
As can be observed in the above chart, there is a need for good practices coupled with a system than can provide the timely generation of relevant portfolio and resource information to enable decision-making. While enterprise-level systems provide a broad set of features and flexibility, companies must identify up front the suppliers and customers of information, as well as the information to be used in decision-making and when it will be provided.

Best Practices: Sharing What Works

As pharma companies are being forced to drive up R&D productivity, the organization's focus is moving beyond "What can be done with what resources we have?" to "How can we do more with what we have?". Many companies have begun to address this question by streamlining functional processes and leveraging automation, as appropriate, to drive up productivity. While companies have made progress in these areas, a significant source of productivity has been overlooked – optimizing one's scarce resources to drive projects through the pipeline.

Given the inherent uncertainty of drug development, planning to a great degree of precision is time consuming and of limited value. It is critical to establish integrated portfolio and resource practices, and align the organization around these practices, prior to implementing a total system solution. These foundational capabilities will help drive the development and execution of agreed upon strategies and plans across functions, teams and decision makers, helping to optimize scarce resources and move projects rapidly through the pipeline. This in turn will help ensure the *right resources* are assigned to the *highest priority projects* and can quickly be re-deployed to the *right projects* when internal and external factors change the original plans.

Companies that are credited with the greatest productivity share some common capabilities that have been built in stages and integrated to reinforce key business processes and practices in the areas of portfolio, project and resource management. These capabilities support decision-making, execution, and alignment at all levels of the organization. In order to reap the real productivity benefits, companies must seek to enhance/redefine existing processes and capabilities, align organizational structure and capabilities with required changes, and drive acceptance/adoption of desired changes at all levels of the organization.



Capability 1: Managing a portfolio that is aligned with strategic objectives and within the resource constraints of the company

- Clearly defining a product strategy that is tied to the overall business strategy and corporate objectives
- Providing top-down guidance on objectives and target investments by strategic buckets (Therapeutic Areas, Disease Areas, Risk Profile etc.)
- Setting project priorities by objectively scoring and ranking projects within and across strategic buckets based on relevant criteria for different stages of development
- Weeding out non-strategic projects early in the pipeline using the objective criteria and resource constraints
- Defining the highest priorities that will be fully resourced and not considered in trade-off decisions and fully resourcing these projects
- Conducting periodic portfolio reviews (one to two times a year) to assess the ability of the pipeline to deliver set objectives and decide on necessary course corrections

Capability 2: Planning and managing projects to ensure predictable achievement of milestones and deliverables

- Planning approved projects off agreed to scope, timing and approach assumptions across the functions
- Assessing technical, operations and market risks and the impact on the project value, cost and timing and building actionable contingency plans
- Project teams developing the “what and when” (deliverables and timing) and functions determining the “how and who” (approach and resource needs) for the project
- Using project contracts to effectively empower project teams, functions and senior management to move projects through the pipeline
- Evaluating alternative scenarios on development options to optimize risk and reward
- Making stage gate decisions in light of future project decisions and impact on overall budget and people resources
- Aggregating cross-project resource demand information and developing “what-if” scenarios to enable effective project decision making
- Ensuring discipline in executing project decisions to enable rapid start, continue and close down of projects

Capability 3: Deploying the right functional resource skills to support project teams and keep projects on track

- Forecasting resource demand within functions using the key set of agreed to project assumptions, demand drivers and complexity factors
- Aggregating the resource needs at a project level and across projects at a functional and cross-functional level to enable effective decision making
- Planning for success; however, staffing up the resource (budget and people) levels on a project risk adjusted basis (attrition adjusted)
- Balancing demand and supply and action planning at a functional level (staff meetings) and at a cross-functional level (stage gate meetings) to keep projects on track
- Functions planning and providing options to meet project needs using internal and external supply sources (available capacity)
- Functions deploying resources to projects based on skill-match, resource availability, project priorities and available project slack to keep projects on track
- Providing clear visibility to project priorities and changes to project assumptions (scope and timing) and project status across teams and functions
- Functions using efficient “local” processes to quickly re-plan and assess alternatives to re-deploy resources to change course and keep the pipeline moving

Capability 4: Establishing the right organizational structure, business processes, systems and tools for efficient data collection, analysis, and reporting to drive effective decision-making

- Having a central repository of ongoing and planned projects, key assumptions, and timing and sequence of key project deliverables that is updated on a defined periodic basis
- Defining the *relevant* project, resource and portfolio views that are required for effective decision making by project teams, functions and senior management committees
- Clarifying the roles of planners supporting functions, project teams and senior management to eliminate duplication of effort and data consistency across the organization
- Establishing a common set of templates to enable functional and cross-functional plans to be generated when a project is considered/approved
- Establishing an agreed to set of resource demand drivers for each function and a methodology to forecast and validate the resource estimates
- Defining the process and update calendar to integrate functional level plans and aggregation of cross-project information to support portfolio decisions and budgeting
- Leveraging appropriate IT system and relevant tools and templates with a focus on streamlining the collection, analysis and reporting

Portfolio and Resource planning and management is a critical part of effecting R&D productivity. Designing it to the simplest level needed to enable the right decision- making will be essential to ensure organizational discipline around the process and value generation.

About PRTM

PRTM works closely with leading companies to achieve core process excellence and exceptional business performance. A recognized thought leader and innovator; PRTM's proven frameworks and methodologies have become the gold standard in industry and government. PRTM's PACE® (Product and Cycle Time Excellence®) methodology has been implemented in over 500 organizations worldwide to drive product development excellence. If you need further information regarding this report or PRTM's capabilities, please contact Mahesh Singh, Director Life Sciences (e-mail: msingh@prtm.com)

Appendix



Pharmaceutical Portfolio and Resource Management Benchmarking Study Conducted by Pittiglio Rabin Todd & McGrath, September 2003

Number of Participants	13 companies
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All data provided as % of responses unless otherwise noted

Participant Company Information

	> \$1 B	\$200 M 1B	< \$200 M		
What was your company or organization's (if you are part of a large/ diversified corporation) annual revenue in 2002?	80%	13%	7%		
	> \$500 M	\$100 M to 500M	< \$100 M	Do Not Know	
How much did your company spend on clinical management (pre-clinical through phase III) in 2002? This includes designing, recruiting, running, and analyzing clinical trials.	7%	27%	27%	40%	
	> \$500 M	\$100 M to 500M	< \$100 M	Do Not Know	
How much did your company spend on drug substance and drug product development in 2002? Include everything in chemistry, manufacturing, and controls for clinical trials and tech transfer/ scale up.	0%	13%	33%	54%	
	> 5000	1000 to 5000	< 1000	Do Not Know	
How many people in total were employed by your company's development organization worldwide in 2002?	13%	33%	40%	14%	
What proportion of your development dollars were spent on biologics versus small molecules in 2002?	> 80%	50 to 80%	20 to 50%	< 20%	Do Not Know
Biologics	6%	0%	25%	38%	31%
Small Molecules	38%	19%	6%	6%	31%
What proportion of your development dollars were spent on new molecular entities/ compounds versus line extensions in 2002?	> 80%	50 to 80%	20 to 50%	< 20%	Do Not Know
New Chemical Entities	19%	38%	13%	0%	30%
Line Extensions	0%	6%	44%	13%	37%
What proportion of your clinical research was conducted in the following areas in 2002?	> 80%	50 to 80%	20 to 50%	< 20%	Do Not Know
North America	13%	31%	19%	0%	37%
Latin America	0%	0%	0%	19%	81%
Europe	0%	6%	13%	31%	50%
Asia Pacific	0%	0%	6%	13%	81%
Africa and Middle East	0%	0%	0%	6%	94%

Appendix

What were your company's major therapeutic areas of focus in 2002?	% of Responses
Oncology	56%
Cardiovascular diseases	63%
Immunology	38%
Metabolic disorders	38%
Infectious diseases	56%
Inflammation	19%
Respiratory disorders	13%
Nervous system disorders	44%
Dermatology	25%
Ophthalmic	0%

Portfolio and Resource Management Issues

Portfolio Management Issues	Current Issue	Greatest Concern
Unclear portfolio strategy and project priorities	75%	31%
Constantly changing portfolio strategy and project priorities	50%	6%
Project decisions made without regard to resource capacity constraints	75%	44%
Poor portfolio trade-off decision making with projects rarely terminated	50%	25%
Lack of development pipeline visibility across projects	31%	13%
Unbelievable or untrusted forecasted resource needs	38%	13%
Underestimated or overlooked project risks	75%	19%
Misalignment between company and co-development partner priorities	19%	6%

Resource Management Issues	Current Issue	Greatest Concern
Limited visibility to long-term resource demand	63%	25%
Limited visibility to near-term resource demand	25%	13%
Overloaded resources	81%	44%
Unskilled or inappropriately skilled resources	31%	6%
Long cycle time from project approval to actual resource assignment	19%	6%
Disruptive redeployment of resources	13%	0%
Difficulty hiring or securing needed resources	44%	0%
Unclear resource assignments/ work priorities/ goals	38%	6%
Large discrepancies between planned and actual resource usage	19%	13%
Poor partner/ vendor performance	13%	6%

Please rank each area according to resourcing issues where 1 is the area with the most critical resourcing issues and 7 is the area with the least critical resourcing issues.	Average of Responses	No of #1 Ranks
Pre-clinical/ Non-clinical/ Toxicology	4.6	1
Clinical Research/ Trial Management	2.4	6
Biostatistics and Clinical Data Management	4.0	1
Regulatory Compliance	4.7	1
Quality Assurance/ Quality Control	4.3	1
Pharmaceutical Development/ Chemical Manufacturing	3.3	1
Development Planning/ Project Management	5.0	1

Appendix



Impact on Performance

Which of the following problems is your company currently facing?	Yes	No
Declining profit margins	19%	81%
Late stage development project failures	25%	75%
Uncompetitive development cycle times	31%	69%
Clinical supply overages or shortfalls	25%	75%
Regulatory compliance problems	6%	94%
Missed development project timelines or goals	63%	37%
Resource or capacity shortages	50%	50%
High employee turnover	0%	100%

Practices

	Not Planned	Planned	Being Imp	Not Working Well	Working Well	Do Not Know
Product/ compound strategy follows a clearly defined process, is aligned with overall company and therapeutic area strategies, and drives development project planning and review	13%	0%	38%	13%	31%	6%
A formal process exists for identifying, qualifying, and approving new development opportunities, and the process is linked to the product development process (i.e., through a shared decision-making body)	0%	6%	13%	6%	56%	19%
Priorities are set through a structured decision process for projects and are reflected in a portfolio that is strategically balanced to include a proper mix of compounds, indications, and projects	0%	0%	31%	44%	6%	19%
A cross-functional management team makes project go/ no-go decisions and allocates resources to projects looking across all project forecasts including projected project milestones and resource commitments	0%	13%	13%	25%	38%	13%
Long-term development capacity is managed by forecasting product development requirements based on therapeutic area and product strategies, and determining the mix of skills and resources needed to meet those requirements	13%	25%	19%	13%	13%	19%
The development methodology is well defined, end-to-end by phase from late lead optimization through product launch. It is integrated across all relevant functional areas and is the starting point for all development project plans	6%	19%	13%	25%	19%	19%
Staffing for development projects is assigned by functional managers on a project-by-project basis based on an overall view of the development project pipeline and priorities	6%	0%	0%	31%	44%	19%
Each function continually evaluates existing resources and skills relative to forecasts of future resource/ skill needs and develops plans for closing resource/ skill gaps. Plans are reviewed and approved by a cross-functional management group	25%	6%	19%	31%	6%	13%
Continuous improvement takes place systematically and involves capturing and evaluating project performance, resource consumption, and lessons learned from every project. Prior history is used in planning future projects and creating initiatives to close specific performance gaps	38%	13%	13%	25%	0%	12%
Co-development partners and vendors are closely managed and their performance is tracked and evaluated when making product development and resourcing decisions	13%	6%	0%	25%	13%	44%
Centralized resource planning group	44%	13%	13%	6%	13%	12%

Appendix



<i>IT Tools/Systems</i>	Not Planned	Planned	Being Imp	Not Working Well	Working Well	Do Not Know
Enterprise tools and templates are available and used cross-functionally to support all relevant aspects of development project and resource planning, tracking, and management	25%	13%	31%	6%	13%	12%
Enterprise resource tracking system	31%	19%	13%	0%	19%	19%
Resource forecasting algorithms/ tools	25%	25%	13%	6%	19%	12%
Enterprise project and resource management system	31%	13%	19%	0%	19%	19%

How frequently does your company manage clinical development internally, outsource to a CRO, or partner/ co-develop?	Never	Rarely	Frequently	Exclusively	Do Not Know
Internal clinical management	0%	19%	63%	0%	19%
CRO (clinical research organization) or outsource vendor	0%	6%	75%	0%	19%
Partnerships/ co-development	6%	44%	31%	0%	19%

How frequently does your company manufacture your clinical materials internally, outsource to a CMO, or partner/ co-develop?	Never	Rarely	Frequently	Exclusively	Do Not Know
Internal manufacturing	0%	6%	69%	6%	19%
CMO (clinical manufacturing organization) or vendor/ supplier	0%	31%	50%	0%	19%
Partnership/ co-development	6%	56%	13%	0%	25%