



Tufts Center for the Study of Drug Development

Impact R E P O R T

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Planning, independence, feedback keep global R&D projects on track

Successful project management links outcomes to strategic company goals

- Matrix teams add value by transferring thinking and knowledge throughout the organization, not simply by conveying a US or European approach elsewhere.
- Project planning and management ensure a more rigorous and strategic approach to portfolio management.
- R&D teams are strongest when they remain independent of line functions.
- When done successfully, benchmarking motivates the organization to excel.
- Intra-company communication is of critical importance.

While R&D has always been the lifeblood of pharmaceutical companies, it takes on greater importance as innovation and product development—not cost containment—emerge as the long-term path to company growth. When growing public demand for quicker development of new drugs is added to the mix, the mandate for pharmaceutical firms is clear: no matter how effective R&D programs may have been to date, R&D productivity must improve.

To help understand this process, the Tufts Center for the Study of Drug Development, in conjunction with SRI Consulting's Healthcare Practice Group, convenes an annual workshop that examines key pharmaceutical R&D management issues. Last fall, presenters from five major pharmaceutical firms and a drug development consultant provided insights from their work in the area. Their main points are highlighted in this Report.

The third annual R&D management workshop will be held November 3, 1999, in Philadelphia.

Lessons Learned about Project Management in Global R&D Teams

Strategic life planning is key to making global matrix teams work

- **R&D in a global organization is about continuously transferring team thinking and knowledge throughout the entire organization, not how to transfer a US or European approach elsewhere.**
- **Strategic life planning is the operative model, where:**
 - ◆ Roles and responsibilities are clearly spelled out.
 - ◆ All team members must possess project management skills, which means providing project management training as needed in the use of Gantt charts and other management tools.
 - ◆ Project managers partner with the finance group and act, fulfilling a budget and forecast function within the team, and tracking progress against goals and objectives.
 - ◆ The emphasis is on eliminating duplication of operational support within regions and teams.
- **Resource forecasting helps manage the product life cycle.**
 - ◆ Five-year medical, clinical, and market forecasts provide important baselines.
 - ◆ It goes beyond traditional R&D for disease management programs to consider line extensions and operational support.
 - ◆ Resource decisions are made at distinct decision points and carried forward to two or three decision points down the line, and are subject to rethinking and re-negotiation.
 - ◆ Finding people who have the required knowledge, understand the R&D process, see the big picture, and can manage the details remains a major challenge. Traditional search firms have helped. Consulting firms that work with the industry can be a good resource for new hires.

Integrated project planning and management ties R&D to marketing and operations

- **Project planning and management encompasses a more rigorous and strategic approach to portfolio management by:**
 - ◆ Standardizing data collection.
 - ◆ Setting and maintaining rigorous standards to validate and calibrate all data and assumptions.
 - ◆ Defining roles and responsibilities within R&D, marketing, operations, and finances.
 - ◆ Reporting to the senior vice president of drug development.

- **Once senior R&D management agrees to key objectives developed by a project team, it incorporates them into its own key milestones on product approvals, global registrations, and development phase transitions.**
- **The profile and role of the project manager:**
 - ◆ Usually has one or more advanced degrees—PhD, MD, MBA.
 - ◆ Responsible for ensuring that the project gets done.
 - ◆ Strategy, as opposed to operationally, oriented. However, he/she must know everything about a project while refraining from micromanaging it.
 - ◆ Coordinates with R&D, corporate marketing, and worldwide industrial operations.
 - ◆ Although leadership styles differ, a negotiating style tends to work well.
 - ◆ Typically oversees one early stage and one late stage project.
 - ◆ Assembles a team with about 15 core members that develops 5-7 key objectives for each project.
 - ◆ Holds project team meetings every five to six weeks; sub-teams meet informally as needed.
 - ◆ Evaluates project team member performance with appropriate line supervisors.

Strong teams are independent of line functions

- **This helps ensure that the views of development, marketing, and operations get attention.**
- **Team managers report to a senior management committee that has portfolio responsibility.**
- **If they operate on both sides of the Atlantic, project managers on both sides help keep projects on track.**
 - ◆ Some functional duplication is necessary due to time and geography differences.
 - ◆ Seamless product development requires constant communication between managers.
- **Overall management style flows between coordinator, manager, and leader.**
- **Managers have independent spending authority.**
- **Managers have ability to recognize and reward team members for their work on the team.**

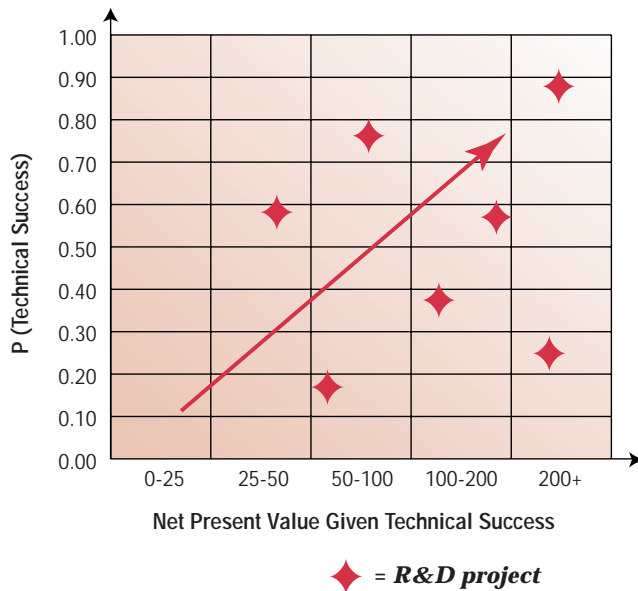
Lessons Learned about Measuring R&D Team Performance

Benchmarking productivity motivates staff and provides a growth guide

- **The power of benchmarking lies in looking at the big picture and overall trends; focusing on any one particular number can lead you down the wrong path.**
- **If done well, benchmarking will motivate staff to excel.**
 - ◆ The department being benchmarked must be actively involved.
 - ◆ Once they own the data, those involved will want to improve its quality over time.
 - ◆ Benchmarking can also spur positive internal competition among different groups.
- **Developing industry standards is extremely difficult and time consuming.**
 - ◆ Tracking apples to apples depends on clear definitions of the metrics to be measured.
 - ◆ No definition is ever exact enough; therefore, strive for good enough.
 - ◆ There is a trade-off between mandating consistency with industry standards versus customizing definitions. Get department heads and management involved in this discussion.
- **Keep the project scope manageable.**
 - ◆ Focus on a key point to start, then expand the next time around. Collecting thousands of data points becomes overwhelming very quickly.
 - ◆ Conduct periodic internal workshops to evaluate what you have collected and what you have learned.
 - ◆ Set goals, e.g. if this is what the numbers are now, where should they be in the future?
- **To succeed, benchmarking needs management support. Therefore, the company must:**
 - ◆ Allay suspicions that results may be used to browbeat the department or area being benchmarked.
 - ◆ Be willing to learn from the data and fight the tendency to say the data don't apply to us.
 - ◆ Demonstrate that it will use benchmarking as a tool to find ways to improve.

Assess projects in terms of their contribution to the portfolio

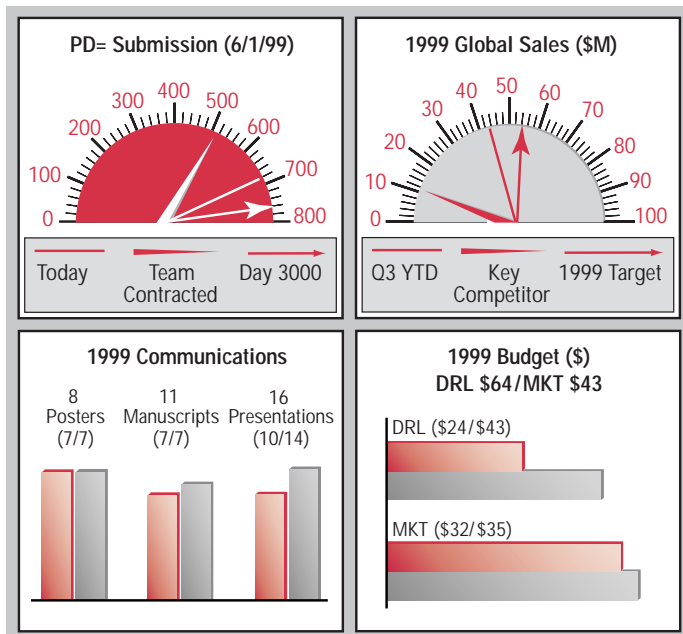
Portfolio Project Grid



- Critical evaluation parameters are probability of technical success (vertical axis on grid at left) and the net present value of a new chemical entity, given that it achieves technical success.
- The more compounds you weed out in pre-clinical, phase I, and phase II, the higher your phase III success rate; overall costs will drop because studies that survive the winnowing out process will have a greater chance to succeed.
- While the ideal is to focus on products with a high probability of success and a high net present value, the grid lets you manage overall portfolio risk by providing a rationale for shifting resources in a timely way.

Dashboard displays of critical metrics keep everyone informed

Dashboards Summarize Key Data Quickly



- Dashboards collect and report key metrics in a consistent way to product teams (in multiple locations), people in affiliates working with the team, and those in support functions.
- They also let management at different levels quickly understand how teams are doing.
- Dashboards alert viewers to pending problems in key areas—in time to act on them. They do not provide retrospective or benchmarking data.
- Important dials may include: days to application submission, projected net present value of the new product, anticipated global sales, current head count, communications, expenditures, milestones, and progress of the top five clinical trials.

Workshop Presenters

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Director

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Janet Foulkes, BSc, MBA

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Bayer Corporation

Janice Ohta, MBA

Director, Business Planning and Analysis

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About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development, affiliated with Tufts University, provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. The Tufts Center conducts a wide range of in-depth analyses on pharmaceutical issues and, in addition, hosts symposia, workshops, and public forums on related topics throughout the year.

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