

**Project Management and Organization Structure in Drug
Development**

by

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Submitted to the Alfred P. Sloan School of Management
in Partial Fulfillment of the Requirements for the Degree of
Doctor of Philosophy in Management

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Abstract

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This questionnaire survey study of 45 drug development teams examines how the locus of decision influence between project leaders and departmental managers affects the performance of drug development projects at the US R&D laboratories of six large, multinational pharmaceutical firms. In this sample, three of the firms employ a single leader project leadership system and the other three employ a dual leader system. Leadership structure is correlated with locus of influence and project performance. Performance is higher for those teams operating in firms with a dual leader project coordination system. Project performance is higher when team members perceive functional managers to have greater influence over go/no go decisions during early and late phases. Project performance is also higher when project leaders have greater influence over clinical decisions during later phases. The technical knowledge of the project leader is related to project performance in a complex fashion. Technically knowledgeable project leaders are more effective during late phase projects. During early phases, project leaders who are rated as having greater technical knowledge head lower performing teams.

Across firms in the sample, team members do not feel that teams have autonomy to carry out their mission, organizations do not have clear criteria for assessing team performance, and individual team member rewards are not linked to their performance as a project team member. These characteristics of the organizational milieu are also correlated with leadership structure. Dual leader firms appear to provide a better environment for project teams.

The study examines a series of relationships among locus of decision making influence, project leader characteristics, organizational support for teams, project phase, leadership structure, and project performance. It concludes with guidelines for structuring organizations.

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Dedication

This thesis is dedicated to my parents and to Wen Luo.

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Chapter I

Introduction

This study examines how the distribution of influence between departmental managers and development project leaders in pharmaceutical firms affects development project performance. Using data gathered via questionnaires and interviews, a series of hypotheses regarding relationships among organization structure, project leader characteristics, team functioning and development project performance are tested. The study extends work done on R&D and new product development (Katz and Allen, 1985; Clark and Fujimoto, 1991).

This study is timely because it occurs at a moment of significant change in the competitive and political environments that are forcing internal and external reorganization of firms in the pharmaceutical industry (Financial Times, 1993a).

Bringing new drugs from discovery through development to market is costly, time consuming and risky. For firms in the ethical segment of the pharmaceutical industry this is an important task because these firms rely on positive economic profits from successive rounds of patented prescription drugs they develop and market to fund the next round of discovery and development.

These profits are threatened by both internal and external sources. Over the past few decades there have been increases in the cost and time required to bring a new drug to market as well as an

increase in the pace of price erosion for first-to-market drugs (Financial Times, 1993b). More recently the uncertain effects of health care reform and the evolution of the health care market in the U.S., especially the increasing concentration of buyer power, have placed pressure on these profits. These forces have contributed to a decrease in the expected quasi-rents from pharmaceutical R&D.

In response managers in the industry seek ways to make their firms more efficient and effective at drug development. Their goals are to reduce the cost and time needed to discover a new chemical entity, to generate evidence of its safety and efficacy, and to launch it on the market as a new therapeutic agent (Financial Times, 1993b).

Historically, pharmaceutical R&D organizations have benefitted from a munificent environment that permitted researchers to operate without much concern for the economic returns from R&D (Browning, 1995). The functional structures with relatively weak interdepartmental links that were common in the industry fit well with the strong disciplinary orientation of the highly trained and narrowly focused professional workforce. These structures could exist only because there was adequate organizational slack to accommodate the longer development schedules that poor cross-functional communication necessitates (Galbraith, 1974, 1994).

Because of this history of strong functional organization, project management is seen by many in the industry to be a key element in a strategy designed to make drug development operations more

efficient and effective. Managers in the pharmaceutical industry are trying to accomplish this partly by mimicking practices they observe in other industries hoping to gain the benefits they¹ attribute to these practices.

Across a portion of firms in the pharmaceutical industry, managers are revamping the systems they employ to coordinate project activities. The two changes most frequently mentioned by senior and upper-middle level R&D managers are: 1) giving project leaders more control over project decisions and budgets, and 2) empowering teams. These prescriptions are drawn from recent research in the automobile industry demonstrating the benefits of project organization and advocated by the popular business press that espouses project organization and team empowerment (Clark and Fujimoto, 1991; Stalk and Hout, 1990).

While strong project organization does lead to more rapid new product development in the automobile industry (Clark and Fujimoto, 1991), there are a series of underlying structural aspects of this task in the pharmaceutical industry, as well as in others, that raise questions concerning the limitations of these organizational mechanisms, particularly in R&D intensive industries where there is significant uncertainty in the outcome of development projects.

In designing an organization, it is important to keep in mind that the benefits of any organization structure are finite. They need to be balanced with the costs. As decision making authority is given

to project leaders, department heads and others, there are trade-offs that occur among the proximity to and detailed knowledge of an issue, breadth of perspective for assessing the options, and time needed to take and implement a decision. As decision making authority moves downward in the hierarchy, the perspective employed by each person narrows. At the same time the level of detailed knowledge of project or functional issues increases. The goal in designing an organization is to find some balance between proximity to an issue to bring adequate attention, expertise and organizational influence to decision making, while maintaining a perspective for choosing a course of action and commitment of resources that supports the overall objectives of the organization.

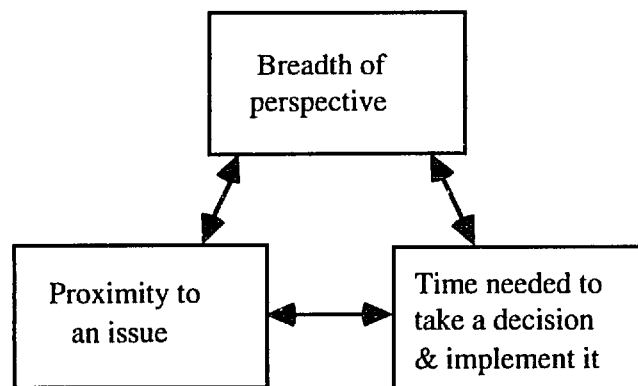


Figure 1. Organizational trade-offs during decision making

A descriptive view of drug development

Research and development in the pharmaceutical industry can be divided into two phases: discovery and development (Spilker, 1989). Discovery is the process of synthesizing or finding a new chemical entity (NCE) having some chemical or biological property that indicates it may have a therapeutic effect *in vivo*.

Once an NCE is identified as a possible candidate drug, preliminary studies in non-human models are conducted to generate data on its pharmacological properties and toxicity. If there is adequate evidence that the possible therapeutic efficacy for some indication is likely to outweigh the anticipated toxicity in humans, an investigatory new drug application (IND) is prepared and submitted to the Food and Drug Administration (FDA).¹ The IND contains both the results of the preliminary pharmacokinetic, metabolic, and short-term toxicity studies as well as a preliminary plan for conducting clinical trials in humans. In the U.S., the FDA has thirty days following IND filing to respond to the firm if they have any concerns. If the FDA doesn't request any changes or object to the initial human testing plan within this waiting period, the firm is free to undertake human trials. Due to the limited information available regarding an NCE, the IND usually contains protocols only for preliminary human safety, metabolic and pharmacokinetic studies. These data need to

¹ This discussion focuses on drug registration in the U.S. because the research was conducted at the U.S. R&D operations of multinational and domestic pharmaceutical firms. Registration in each country follows the same general pattern, although some regulatory regimes are notably less stringent than that in the U.S.

be gathered and examined before protocols for later phase clinical studies can be designed and submitted to the FDA.

Human trials, if undertaken, occur in three phases. During Phase I, safety in healthy humans is assessed. During Phase II, dose ranging and then preliminary efficacy studies are conducted in select patient groups. During Phase III, larger scale studies with greater statistical power are conducted in those patient groups for whom the drug is intended. These studies gather additional efficacy and safety data, as well as helping to establish prescribing recommendations, including contraindications to use and information on drug interactions. These studies are also designed to provide support for marketing claims and package insert statements. Marketing claims are important because they are likely to affect the adoption of the drug by physicians, and ultimately its success in the marketplace.

Following Phase III trials a New Drug Application (NDA) is submitted to the FDA. After reviewing and evaluating the evidence presented in the application, the FDA may approve the drug for release or reject it. If the drug is approved, the firm is allowed to launch the drug on the market for one or more specific therapeutic indications (Figure 2). Following market launch, Phase IV trials comprise reports of adverse reactions and outcomes that occur as larger numbers of patients are administered a drug by practising physicians. While drugs often have unwanted side-effects, on occasion there are serendipitous discoveries of beneficial side-effects

and previously unknown therapeutic effects after the drug is released.

In addition to the development of NCEs, there are a number of other types of development projects. While these are primarily reformulations of existing drugs, some portion of these projects are developments of previously registered drugs for new therapeutic indications. Development for additional indications is important since pharmaceutical firms are only able to advertise for approved indications, even though physicians are able to prescribe for non-approved indications.² In such cases, pharmacokinetic and human safety studies have already been performed. These projects entail far less uncertainty than NCE development. The risk is due primarily to a possible lack of adequate therapeutic efficacy, rather than to toxicity or lack of bioavailability etc. Getting the drug approved for the new indication is largely a matter of designing correctly and executing effectively the requisite efficacy studies. Development projects of this sort usually involve only a subset of the trials conducted to support the originally approved NDA, although the FDA may request additional studies, including ones that assess the economic benefit of a new drug against other drugs and other therapies.

The registration process described above is based upon the regulatory system in the U.S. Registering a drug in other countries

² Physicians prescribe for non-approved indications based upon their own experience and judgement as well as upon the research reported at conferences and in journals.

may differ in a number of ways, but one important difference that is often taken advantage of by firms is the relative ease with which drugs can be taken into humans in England and elsewhere. In addition to this, in some areas of the world there are unique diseases and access to patient populations that are not available in the developed world.³ A more complete discussion of the differences is beyond the scope of the study.

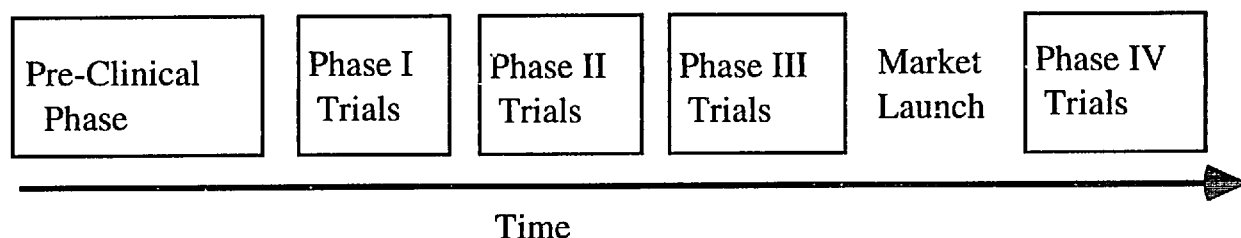


Figure 2. Steps in the Drug Development Process

The development of an NCE or other candidate drug requires coordinating among the administrative and functional departments in a pharmaceutical firm, other cooperating firms, external contractors, government regulatory agencies, universities, and hospitals and other test sites where non-human and human trials are conducted over a period of between seven and twelve years on average (Financial Times, 1993b; Figure 3). This involves monitoring diverse subtasks being conducted across departments and across organizations. It involves synchronizing the activities of these actors as well as responding to information generated and events that occur during the course of a project. It also involves integrating the flows

³ In at least one case, patients living in an LDC having a disease common in the developed world and who had not received a therapy considered standard in the developed world were available as clinical test subjects.

of information and material generated and used by actors in the process.

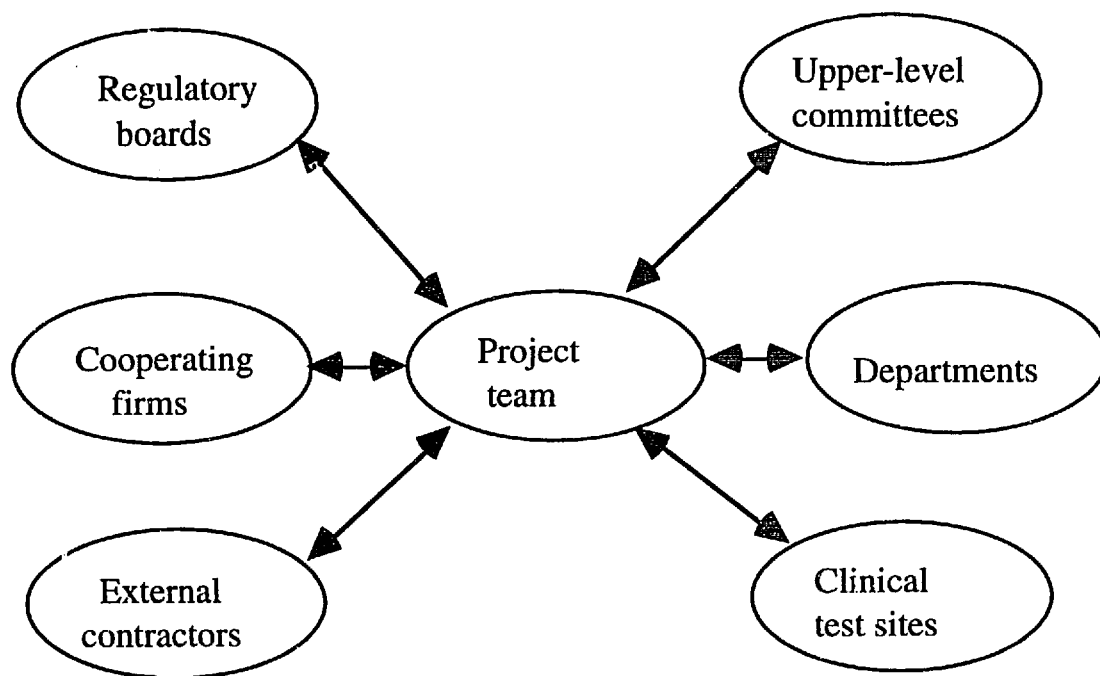


Figure 3. Actors whose interdependent activities have to be coordinated during drug development

Drug development is a highly uncertain task. It is a process of gathering data and discovering, step by step, the viability of a candidate compound. As nonhuman model toxicity, metabolism and pharmacokinetic data demonstrate that a compound is likely to be adequately safe and bioavailable, the probability that the candidate will be approved increases. Similarly, as human safety and dose ranging and preliminary efficacy studies are completed and show favorable results, the probability that a drug will be approved continues to increase in discrete increments.

Because of the underlying test-to-failure nature of the task, managers in the industry report that candidate drugs begin with a clean record and accumulate negative marks until they either make it through development and are approved by the FDA, or until they receive enough negative marks and are discontinued.

To manage the stochastic nature of drug development and the low probability of a drug successfully surviving development, firms have instituted a series of reviews at predefined points where explicit go/no go decisions are made based upon the accumulated information. These project reviews are also conducted on an *ad hoc* basis as clinical trial results signal unanticipated toxicity or lack of efficacy, or as information from the FDA or information on competing firms or technologies makes a candidate compound less attractive or even nonviable for registration as a new drug. These decisions are taken by senior management committees based upon the input they receive from project and functional personnel.

Early in preclinical testing there are technical issues that cut across a broad range of disciplines. During clinical testing, in contrast, the issues that need to be addressed have a more focused technical content that involves a narrower range of technical disciplines as compared to many earlier phase issues. The integration of technical expertise is still needed, but task demands have changed and the technical questions are most likely to be clinical, manufacturing or regulatory questions. Once a candidate enters Phase III trials, the

probability of it being approved are approximately one in two, rather than the one in a thousand chance for a candidate entering preclinical testing (Financial Times, 1993b). Coordinating the interdependent efforts of diverse actors involved in development assumes greater importance as a drug moves through clinical trials where the requirements of large-scale trials and separate test sites need to be accommodated.

At moments when technical uncertainty is high, the detailed knowledge of technical issues required for taking well-informed decisions is likely to reside within the function rather than the team. Conversely, during later phase studies, when technical issues are more focused, decisions may be better taken by the project leader or by members of the team who have an overview of the interdependent issues that must be addressed to allow rapid movement of a drug toward the market. When adjusting schedules and coordinating information flows and activities, local knowledge of cross-functional issues assumes greater importance for effectively moving a candidate drug forward using the resources committed.

The temporal variation in the task coupled with the stochastic nature of the task places significant demands on the organization. Where in the organization information and expertise for designing effective strategies resides varies with the type of issue that needs to be addressed. Team members possess local knowledge of many interdependent issues, while the departments house technical

expertise, and senior-level managers have an overarching view of the mission and strategy of the firm.

Organizational structures and systems in R&D

This research is based on the premise that project coordination systems vary in their effectiveness, and that this variance is caused, in significant part, by the details of the organizational structure and arrangements implemented in each firm as well as by how these are enacted during the course of each development project.⁴

To aid the coordination of activities and integration of information and expertise, pharmaceutical firms have implemented a variety of organizational structures and systems to manage product development projects. These are the same as those used in R&D operations across industries. They range from pure functional organizations structured along departmental lines and that have only very weak project coordinators performing primarily a clerical role through true project organizations where project leaders control budgets, task assignments and have final authority over project decisions. Most firms, especially larger ones, employ a matrix arrangement that lies between these two extremes where a project

⁴ Project coordination system is a broad term encompassing the organization structure and other organizational systems that are part of the process of managing projects. It includes senior management committees that oversee the portfolio, functional managers and those functional personnel assigned to the project team, as well as the project leader and others who provide support services to the project team. It is a broader term than project management system that sometimes refers to a specific information technology utilized in project planning, or, in other cases, to the staff group that provides project scheduling support.

focus and dotted line reporting relationships are overlaid on a functional backbone (Larson and Gobeli, 1988; Spilker, 1989).

In matrix R&D organizations in the pharmaceutical industry leadership of teams in the project-focused overlay takes two primary forms (PMA, 1994). The first has a single project leader drawn from a project management department or from a technical department. The second has dual leaders with the project head usually drawn from a technical department and a project coordinator taken from a project management department. In this system, the coordinator is responsible for most administrative matters.

These organizational structures and systems establish the conduits for bringing information from divergent sources to people and groups responsible for taking strategic and operational decisions. These structures and systems operate along lateral, hierarchical, and temporal lines to coordinate and control activities (Spitz, 1982).

There are trade-offs made when an organization structure is chosen. By organizing along any particular dimension of a task, other dimensions along which organizational attention and coordination are needed may be neglected (Galbraith, 1974). Strong functional organizations link technical people back to their specialties effectively, but are slow at performing tasks involving interdependencies that cross departmental boundaries. Project organizations are faster at coordinating across departments because people are directly responsible to the project head, but project

organizations tend to isolate technical personnel from others in their field. Over time technical specialists performing project work lose touch with the advances in their field eroding the technical knowledge base of the firm. This is especially the case when the underlying technologies are evolving quickly (Allen, 1977).

The departments underlying R&D matrix structures help people stay informed of advances in their technical field. These structures also allow sharing of specialized resources, as people can be assigned to multiple projects. The project team overlay is a formal mechanism for organizing across departments and speeding task completion.

When used appropriately, matrix structures are able to accomplish tasks that require cross-department coordination more quickly than functional organizations (Hall and White, 1979). Matrix project teams are a mechanism for bringing cross-functional expertise and representation to project decision making. These teams allow information regarding interdependencies among subtasks and departments to be shared quickly. The concomitant delegation of decision making authority for some cross-department issues reduces the time required for conducting interdependent development activities because every cross-department issue and decision doesn't need to make its way up the hierarchy for resolution.

The ability of upper-level managers to delegate authority and responsibility for cross-functional tasks to lower levels in the

organization reduces the attention these managers need to pay to operational issues while maintaining sight of the goal of getting a product to market. This reduces the cognitive load on upper-level managers and pushes decision making authority for many operational issues lower in the organization where personnel closer to the issues who have the information needed for taking many of these decisions are located.

These benefits are not without cost. The matrix structure is complex. The dual focus of the management structure and reward scheme causes conflict between the projects and the departments, primarily over personnel assignments and resource allocation (Davis and Lawrence, 1979; Butler, 1979).

Delegating relieves senior managers of part of their managerial workload and may bring greater technical expertise and attention to decisions, but it also bounds the perspective employed in taking project decisions. This bounding narrows the decision makers' scope of objectives and, in some cases, excludes an overview of the organization's overall strategy from project-level decision making (Figure 4).

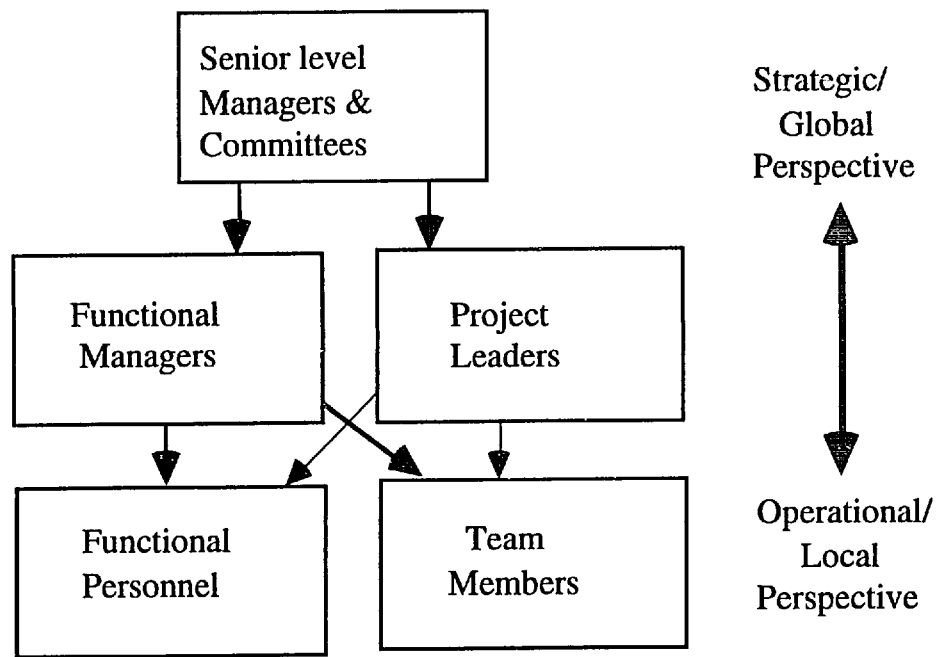


Figure 4. Organizational perspective by functional area and role

Chapter II

Past Research and Hypotheses

Given this theoretical conceptualization of the trade-offs that occur when coordinating interdependent development tasks, past research related to managing R&D projects within a range of organizational structures is reviewed. This research focuses on the locus of influence in the matrix, the task of the project manager, and characteristics of team functioning related to high project performance.

Locus of Influence

Past research on matrix organization and R&D projects point to the importance of the distribution of influence between project and functional management as a driver of project performance. Allen and Katz (1985) found that projects are rated as higher performing when project team members perceive functional managers to have greater control over technical decisions relating to the project, and project managers to have greater influence over pay and promotion decisions and to have more overall power in the organization. These authors reasoned that functional manager control over technical decisions ensures a high quality design, while project manager control over team member rewards keeps them focused on getting a product to market. Katz and Allen's findings are consistent with Marquis and Straight's (1965) findings that stronger project control correlates with better schedule performance and fewer cost

overruns, while stronger functional control is associated with better technical performance.

Clark and Fujimoto (1991) found that faster design cycle times were associated with heavyweight product managers who had significant formal or informal power to make decisions, mobilize resources and direct the personnel assigned to the project. The heavyweight product managers had direct contact with engineers in departments performing project tasks. In this way they were able to ensure that the essential aspects of the product concept were translated into engineering specifications and did not get lost in the morass of issues and compromises encountered in the design and development of an automobile. The heavyweight product managers didn't rely upon functional managers to safeguard the product concept. They also didn't wait for the functional managers. They were proactive and, to some degree, intrusive in departmental matters relating to their projects.

Larsen and Gobeli (1988) classified matrix structures into five categories representing a spectrum of power sharing between the functional and project sides of the organization. These are pure functional, functional matrix, balanced matrix, project matrix, and pure project. In their study of projects across a range of industries they found the project matrix to be the structure associated with the greatest percentage of successful projects and the balanced matrix to be second most effective.

Although these results are not completely in agreement, they demonstrate that locus of control over different project-related and reward decisions between the department and project sides of the organization are related to project performance (Figure 5).

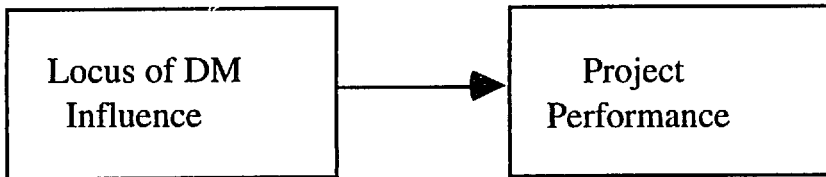


Figure 5. Relationship between locus of decision making influence and project performance

Drawing on Marquis and Straight (1965) and Katz and Allen (1985) two hypotheses are put forward.

Hypothesis 1

Teams operating in project coordination systems where the locus of influence over early phase technical decisions lies with functional managers will be perceived as higher performing.

Hypothesis 2

Teams operating in project coordination systems where the locus of influence over late phase technical decisions lies with project leaders will be perceived as higher performing.

What affects team members' perceptions of the project leader and the locus of decision influence?

Given the important effect locus of decision making influence has on project performance, it is useful to examine what leads project heads to have more influence, or at least to be perceived that way.

Past research demonstrates that the influence managers wield is determined largely by their hierarchical position, resource control and network centrality (Pfeffer, 1981; Astley and Sachdeva, 1984). And while these characteristics are highly dependent upon structural factors, such as the formal organization, they are also affected by the experience and personal characteristics of individual managers (French and Raven, 1959; Pfeffer, 1981; Schein, 1985).

Team members' perceptions of a project leader's power and the locus of influence between the project and functional sides of an organization are affected by both the formal authority and informal influence of the project leaders and department heads. The formal authority project leaders and department heads have over various decisions and their responsibility for project outcomes are derived from the formal organization, senior management support and cultural expectations. The informal influence project leaders and department heads have is dependent upon their technical and managerial expertise and reputation, experience in development, and proactivity in addressing project issues. Formal role requirements establish some bounds on behavior, but managers have the opportunity to enact roles that go far beyond that specified.

The model in Figure 6 illustrates these relationships. Note that in this model project leader characteristics are hypothesized to be affected by the formal organization. The people chosen to head projects in firms employing single leader systems may be quite different from those heading projects in dual leader systems. Project

leaders in dual leader systems do not have to spend as much time performing administrative tasks. Those duties are part of the coordinator's role. This may allow project leaders in dual leader systems to remain more focused on the technical dimension of their role.

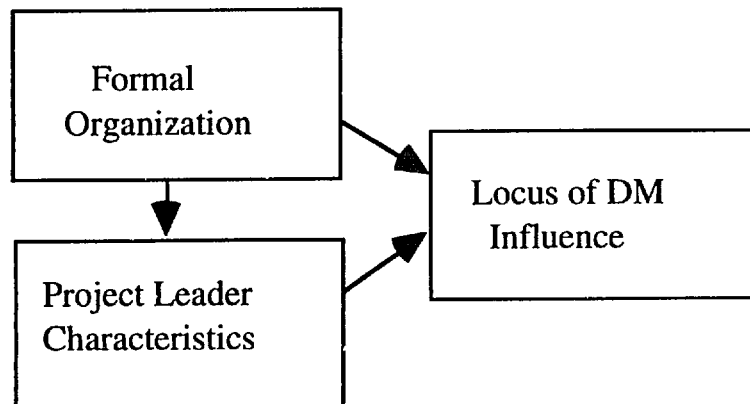


Figure 6. Causal model relating organization structure and leader characteristics to locus of decision influence

Two hypotheses pertaining to leadership structure, technical knowledge of the project leader and locus of decision making influence are put forward.

Hypothesis 3

Project leaders who are perceived as more knowledgeable in technical matters will be perceived as having greater influence over project decisions.

Hypothesis 4

Project leaders in organizations employing a dual leader system will be perceived as having greater influence in project decision making than project leaders in organizations with a single leader system.

Organizational support for teams and team process

In addition to the locus of decision making, organizational support for teams and team process have also been demonstrated to affect project performance (Hackman and Morris, 1975; Goodman, 1986; Larson and LaFasto, 1989). Teams are higher performing when they have clear goals, senior management support and adequate resources, including funding and personnel. Teams are also higher performing when embedded in organizational systems that effectively support task performance. Finally, teams are higher performing when team members perceive that their rewards are tied to project outcomes (Blinder, 1990; Mohrman and Mohrman, 1994; Lawler and Cohen, 1992; Cole, 1989).

These organizational supports delineate a milieu in which teams enact their task. The behaviors in which team members engage (i.e. team process) as they perform their work is also related to performance. Team leaders and team members can enact internal (Bales, 1950; Benne and Sheets, 1948; Fiedler, 1967) and external (Adams, 1980; Allen, Tushman, and Lee, 1979; Ancona and Caldwell, 1992) roles in performing their work.

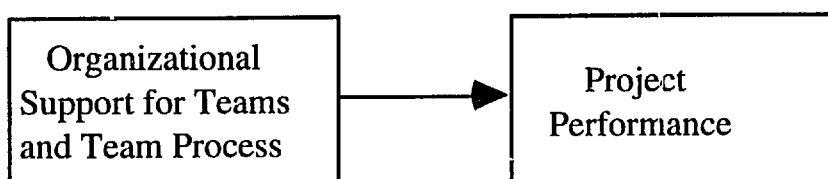


Figure 7. Relationship between organizational support for teams, team process and project performance

The following hypothesis relates team member perceptions of the team supportiveness of the organization to team performance.

Hypothesis 5

Teams in organizations where members perceive a more supportive environment will be higher performing than teams where members perceive a less supportive organizational environment.

Past research demonstrates that the roles team leaders assume have the capacity to help or hinder team performance. Fiedler's (1967) and Herold's (1978) work provide evidence of the contingent nature of the relationship among leadership style, task demands, and team performance. In contrast, there is little rigorous research on the task of being an effective project manager. Most writing about project managers has been anecdotal, although there are exceptions (Petersen, 1991). In an inductive study of project integrators at one firm in the petrochemical industry Spitz (1982) described the task of being a project integrator in detail, and identified a variety of skills that project integrators need to have and activities they need to perform to facilitate lateral communication and coordination.⁵

⁵ The skills and activities identified by Spitz include:

- 1) interpersonal and negotiating skills for interacting with members of the team and people outside the team
- 2) the ability to understand the different functional perspectives and technologies as well as the modes of operation of people in the functions
- 3) the ability to deal with complexity and to synchronize the efforts of functional personnel
- 4) the ability to procure resources necessary for the project
- 5) the ability to motivate team members

Unfortunately Spitz did not relate these skills and activities to project performance. These characteristics may be part of being a project leader, but they may not differentiate between highly effective and less effective project leaders, nor be related to team performance.

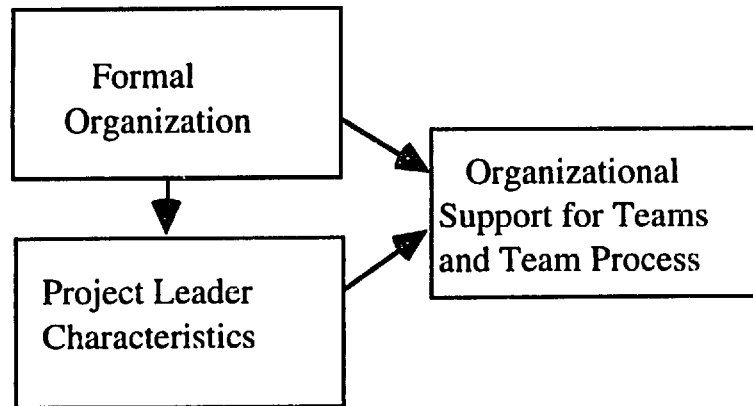


Figure 8. Causal model relating organization structure and leader characteristics to team member perceptions of organizational support for teams and team process

Organizational support for teams is largely determined by the context in which teams are embedded. However, team leaders do have the opportunity to affect team members' perceptions of this context. A team leader is able to interpret demands placed upon the team, and help define clear performance-reward contingencies in response. A team leader who is perceived by senior managers as possessing a clear understanding of the range of technical and regulatory issues that development entails, may have somewhat greater autonomy than one who is perceived as less knowledgeable.

6) the ability to manage the boundary between the team and the rest of the organization.

Team leaders are also able to affect team process during task execution.

The following hypothesis relating project leaders' technical knowledge to team members' perceptions of the organizational milieu is put forth.

Hypothesis 6

Project leaders who are perceived to have greater technical knowledge will lead teams where team members perceive a more supportive organizational milieu.

In Figure 9 is a model that includes the relationships discussed above. This model includes single versus dual leadership structure as an operationalization of formal organization structure. Project priority is included as one indicator of organizational support for a team. Project phase is included to represent temporal changes in task demands that occur as projects move from safety to clinical efficacy testing.

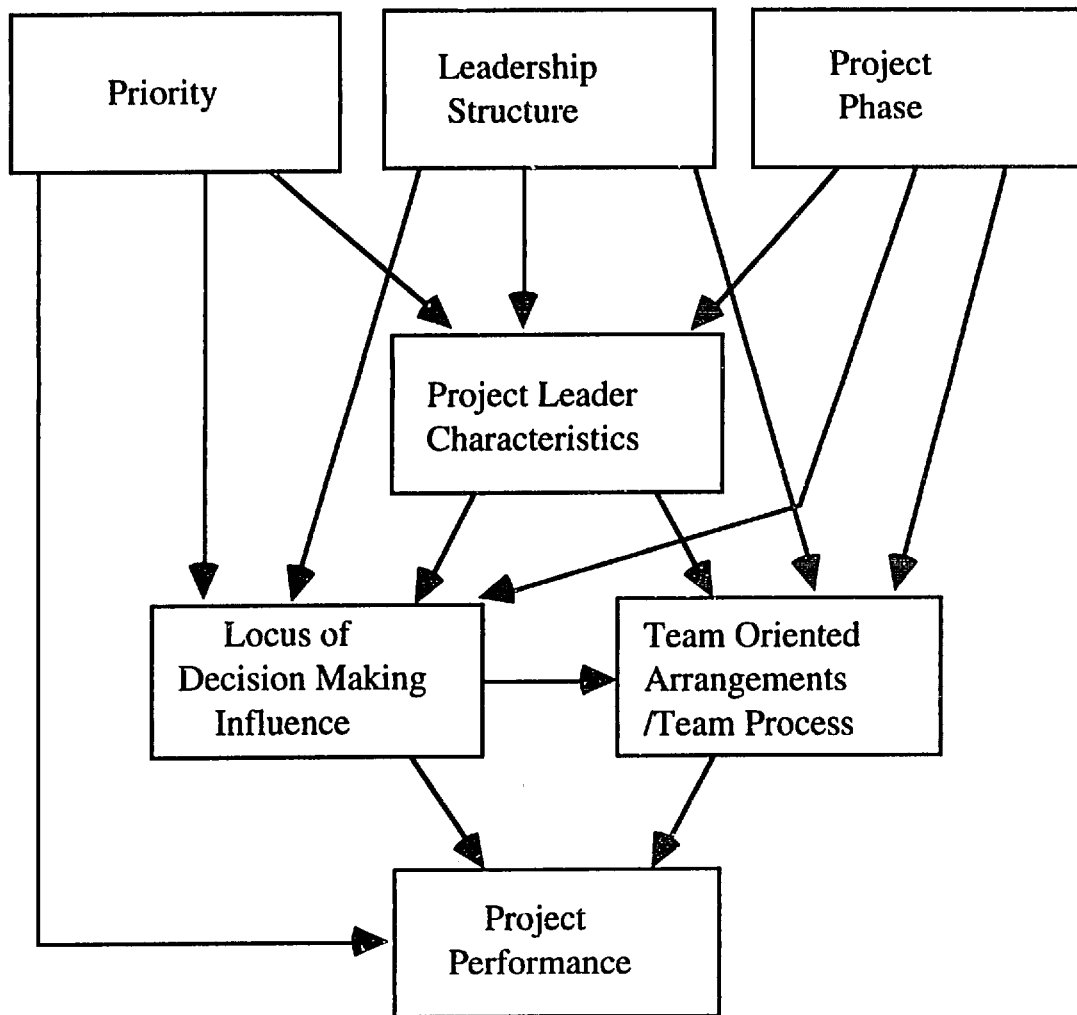


Figure 9. Model relating organizational structure, project phase and priority to team leader characteristics, locus of decision influence, team functioning and development project performance

Chapter III

Research Design and Method

The study is a cross-sectional correlation survey design. Questionnaires were administered to a sample of teams at six major pharmaceutical firms. Four of these firms are in the top ten by sales in the industry. The remaining two are in the top fifteen.

The sample of teams surveyed was chosen by managers at each of the firms. Between three and ten teams were selected for participation at each firm. A total of forty-five projects are included in this study. The managers responsible for assigning teams were asked to choose a sample that contained variance in phase, therapeutic area and performance.

Team members, team leaders, and senior managers were surveyed at each of the firms. At four of the six, separate surveys were distributed to core members of the project team and the team leader. At the first two firms in the sample, the project leaders were administered team member questionnaires absent the middle section that asked for an assessment of their performance as team leaders. After the first two organizations were surveyed, a team leader/coordinator survey, distinct from the team member one, was written. It addressed aspects of the project history that would be most likely known by the team leader or coordinator.

The team member survey is divided into three sections (See Appendix A). Each of these contains items that assess team member


perceptions across broad domains. The first portion of the survey is composed of approximately forty questions that focus on a series of critical decisions that must be made during the course of a drug development. These decisions range from early ones concerning the choice to take a chemical entity into development through decisions made during the preclinical and clinical phases of drug development. For each of these items team members are asked to assess the relative influence of their project team leader and, if their project has one, coordinator as compared to department managers on a seven point Likert scale. These items are the primary operationalization of organization structure in the study.

7. The decision to take the proposed new drug into humans (i.e., to initiate Phase I clinical trials).
- | | | | | |
|---------------------------------|-------------------------------------------|-------|-------------------------------------------|----------------------------------------|
| Project
Leader
influences | ----- ----- ----- ----- ----- ----- ----- | Equal | ----- ----- ----- ----- ----- ----- ----- | Functional
Management
influences |
|---------------------------------|-------------------------------------------|-------|-------------------------------------------|----------------------------------------|

The second section of the questionnaire asks team members to assess their project leaders' managerial skills, influence in the organization, and technical knowledge and understanding. Team members were not asked to assess the project coordinator, if this person existed. He or she was omitted from this section of the survey; The focus was on the team leader.

44. My team leader has considerable influence which is useful in obtaining resources necessary to carry out this project effectively.
- | | | | | |
|------------------------|-------------------------------------------|----------------------|-------------------------------------------|------------------|
| Not at all
accurate | ----- ----- ----- ----- ----- ----- ----- | Somewhat
accurate | ----- ----- ----- ----- ----- ----- ----- | Very
accurate |
|------------------------|-------------------------------------------|----------------------|-------------------------------------------|------------------|

The final section of the survey focuses on team members' perceptions of the team and how it operates within the organization in which it is embedded.

63. Development teams have significant autonomy to plan and carry out their mission in this organization.	
	Not at all accurate Somewhat accurate Very accurate

The survey administered to project leaders and, in those firms that had them, coordinators is largely the same as the team member questionnaire. Those items that refer to the locus of decision influence and team functioning are identical for team members and leaders/coordinators in each of the firms. The most significant difference between the team member and leader/coordinator surveys is in the second section that focuses on team leader characteristics. That portion of the team member survey is replaced in the leader/coordinator survey with a number of items querying the history of the project and characteristics of the technology and development organization.

While the questionnaires are largely identical there are minor variations from firm to firm because the surveys were tailored to fit the language and organizational systems employed in each of the organizations. Firms differ in the terms used to refer to team leaders. In some organizations the person is called project director, while in others he or she is referred to as project chair or co-chair or project leader. Several of the organizations have a dual leadership structure. These firms have a separate person with the title of

project manager or coordinator drawn from a staff department. People in this role assist the project leader by tracking the schedule and by keeping tabs on the progress of tasks in each of the departments.

Firms also differ in the specifics of the operating procedures implemented. The questionnaire was altered to accommodate these differences. This took the form of excluding several items because the point at which firms institute project teams to take a compound through development varied. Managers in one firm also asked for a few items to be added because of the distribution of team members between the US and Europe. These managers had a specific interest in this aspect of their team structure.

The senior manager questionnaire is completely different from the other two (Appendix B). It doesn't focus on the locus of decision making, rather it asks upper level managers to assess the performance of each of the development projects and team leaders. It also queries senior managers on how well the technology fits the R&D strategy and capabilities of the organization as well as their expectations for the product in the marketplace. Senior manager assessments were gathered within two months of the team member questionnaire being administered.

The surveys were written in consultation with managers and consultants working in the pharmaceutical industry. Drafts were

circulated for comments and these comments incorporated into the final versions.

The study design is strong in two respects. First, evaluations of team performance are gathered from sources external to the team. This provides evaluations of the team by managers who bring an overview of the projects contained within the portfolio. While these evaluations may not be objective, they suffer from a different subjectivity than team members assessments do. Second, the evaluations by the team members preceded the senior managers evaluations. Temporal precedence of cause to the effect is the first requirement for demonstrating causality.

There are three primary threats to validity in the study. They are selection bias in choosing the sample, the comparability of performance assessments across firms, and the subjectivity of team member perceptions.

While there may have been a selection bias, simple tests demonstrate no statistically significant differences between the samples of projects selected at the firms in terms of performance, phase or therapeutic area. The results of these statistical tests are presented in the results section of the report.

The most significant threat to validity is the comparability of performance assessments across firms. Senior managers were asked to indicate how projects were performing relative to their initial

expectations. While it is possible that managers in different firms have widely divergent views of what is expected, the mobility between firms at the higher levels of management as well as the attention of capital market analysts and the attention managers in these firms give to benchmarking data makes this variance across firms less plausible.

Another threat is the subjectivity of the measures employed in the study. This also is not a serious threat if one accepts the tenet that people act on their perceptions. Behavior is often driven more by what is in people's minds, rather than by the objective structure of the world in which they are embedded. While this reasoning is applicable to team member perceptions of who influences decisions, the characteristics of project leaders and the functioning of teams within the organization, it is not a relevant argument for defending the subjectivity of performance assessments by senior managers. One could argue that objective measures such as time to market or quantitative benefit statement data would be more valid metrics for measuring performance. But due to the large number of factors that affect the outcome and complicate the comparison of some of these more objective measures, the simple subjective measures employed may be a necessary and allowable compromise in the design and execution of the study.

A very pragmatic difficulty with more objective measures comes from the proprietary nature of much of this data and firms' unwillingness to release them. Research in organizations often

involves more uncertainty because the instruments that are utilized to measure constructs are less reliable and possibly less valid than those employed in harder sciences. Better performance measures may exist, but since they are not available there is no reason not to utilize other data that can be gathered but are more open to criticism.

On the question of external validity, the findings from this study are applicable to development teams in large ethical pharmaceutical firms. They are also likely to be applicable in other industries where there are organizations with large R&D staffs performing development tasks that require the collaboration of highly trained technical personnel. These findings are probably not applicable to biotechnology firms and other firms that have far smaller R&D staffs. The types of coordinating mechanisms that are effective in smaller organizations are essentially different from those required to coordinate R&D tasks in organizations containing several hundred or even several thousand technical personnel.

Chapter IV

Results

The strategy in our data analysis is to explore the relationships among the locus of decision making influence, the characteristics of the project leader, the organizational milieu in which teams operate and development team performance. Two approaches are taken. First, bivariate and partial correlations are examined. Project phase, leadership structure and priority are used as control variables. Project phase is used as an operationalization of temporal change in task demands. Leadership structure is used as an indicator of a key difference in formal organizational structure and systems among firms. Priority is used as a control variable because higher priority projects are expected to be higher performing. Second, following the correlation analyses, multivariate regression is used to test the variables in concert.

Before the more detailed exploration of the interrelationships among these constructs is conducted, a brief picture of the sample is presented.

The study sample

The sample in the study consists of forty-five teams from six major pharmaceutical organizations. Four of these are in the top ten firms by sales and the remaining two are in the top fifteen firms in the industry. The number of teams and the phases of teams surveyed in each firm are listed in Table I.

Table I. Number of teams and phases of teams by firm.

Firm	Number of teams	Pre-Clinical	Phase 1	Phase 2	Phase 3
1	7	2	0	4	1
2	10	2	0	2	6
3	10	2	5	0	3
4	5	0	1	0	4
5	3	1	0	2	0
6	10	0	4	6	0
Total	45	7(16%)	10(23%)	14(31%)	14(31%)

Description of teams

Phase data are available for the forty-five teams surveyed. Sixteen percent (16%) were in the preclinical phase at the time of surveying, 23% were in or just finishing Phase 1, 31% were in or just finishing Phase 2, 27% were in Phase 3, and 4% had completed Phase 3 testing and were either in the final stages of NDA preparation or were awaiting FDA response to the NDA.

Mean core team size is sixteen with 49% of the teams having between eleven and sixteen members. Only five teams (11%) in the sample have twenty or more members. The core team members were identified by managers in each firm. These managers were asked to choose those people they thought composed that group central to accomplishing project tasks.

Across organizations in the sample, teams have similar functional representation. Although there is some variation by phase

of the project, teams had people with expertise in non-human and human testing, formulation, synthesis, manufacturing process development, packaging, quality control, project planning, and regulatory regimes and drug registration issues. Interview data indicates that the presence or absence of members from discovery research and marketing varies by phase. Some organizations have formal marketing representation on teams early, while others bring marketing people onto teams only as the IND is nearing completion. Managers in all the firms claim to have early marketing input when selecting compounds to take into development. Similarly, basic science representation on teams decreases as the drug moves closer to NDA submission. Team members indicate that the level of functional expertise of team members is adequate to the task (mean=5.7 on a seven point scale). Overall, the differences between companies are primarily in the number of representatives from each function who are considered part of the core team.

There is variation in the percentage of time respondents spent on work related to a particular project. The average for teams ranges from 10% to 61% with a median of 32% and an interquartile range from 20% to 43%. There is variance in the percentage of time personnel from different departments work on projects. During Phase 2 and Phase 3 studies representatives from clinical testing are likely to report spending a larger share of their time on a project, while process development personnel report that they spend a smaller portion of their time on any one project. Mean percentage of time for project leaders in single leader systems is 56% with a

standard deviation of 34%. The figure for dual leader systems is a mean of 41% with a standard deviation of 45%. This difference is not statistically significant. The sum for project leaders and coordinators in firms with dual leader systems totals 89% on average.

The therapeutic areas for forty-three of the forty-five teams in the sample are shown in Table II.⁶ Thirty-three of these drugs were grouped into five therapeutic categories that appear relatively homogenous. An ANOVA test of the drugs that could be classified reliably into groups with five or more members demonstrated no differences in overall performance, schedule performance or team leader performance among the groups. The one significant difference among the groups is that traditional anti-cancer agents are lower priority than the others. This is likely due to an ongoing shift toward developing anticancer therapies relying upon more recent scientific advances in cell biology and immunology, and away from the relatively non-specific poisons that have been the mainstay of cancer chemotherapy in the past. There were no significant differences among the five categories in terms of fit with the R&D strategy of the firm, firm capabilities, market needs or expected profitability.

Across firms projects are similar on a series of metrics. Average project priority by senior manager report is 2.6 on a four point scale (1=below average priority, 4=highest priority). Expected profitability averages 2.9 on a four point scale (1=not profitable, 4=highly profitable). Averages for the alignment of candidate

⁶ The remaining two are not classified due to confidentiality issues.

compounds with the overall R&D strategy of the firm and with firm capabilities are both 3.7 on a five point scale (1=poorly aligned, 5=very well aligned), while the alignment of candidate compounds with market needs is 3.8 on the same five point scale.

Table II. Therapeutic area of development candidates in the sample

Therapeutic area	Number of teams (percentage)
Cardiovascular-pulmonary	5(11%)
Central nervous system	11(24%)
Metabolic	5(11%)
Anti-bacterial	3(7%)
Anti-viral	3(7%)
Immunologic	4(9%)
Endocrine	3(7%)
Anti-cancer	5(11%)
Dermatologic	3(7%)

ANOVAs performed on these items using companies as the nominal variable are not statistically significant. This is evidence that the projects chosen across firms are similar. There is no evidence of any significant selection bias.

Univariate statistics for the decision influence, project leader and team process items

Team mean univariate statistics for the three broad classes of decision, project leader and team functioning items are shown in Tables III, IV and V, respectively.

Two observations regarding these data are highly significant in the context of the study. First, the low values on three items - 1) There are clear performance criteria for teams (2.6); 2) My individual rewards are linked to my performance on this team (2.6); 3) Teams have significant autonomy to carry out their mission (3.7) - may indicate that managers attempts to give project leaders and teams more power to carry out their work have been only partially successful.

Second, only six of twenty-four decision influence items have means below a Likert scale value of four. These data indicate that there is a bias toward greater functional manager influence in various project decisions. This finding is not surprising and fits well with the description of these organizations provided by senior managers and project leaders who, in interviews, indicate that they observe this functional bias, and, in some cases, see it as a cause of slowdowns in development projects.

Scales for decision influence, team leader characteristics and team functioning

Team member and team leader responses for the decision variables were factor analyzed using listwise deletion, principal components extraction and varimax rotation. Seven factors were extracted from the decision variables. These factors were used as guides in selecting items representative of the inferred underlying

constructs in the process of assembling scales. The decision construct scales are shown in Exhibit 1.

Table III. Means and standard deviations of team averages for decision influence items

ITEM	MEAN	STD DEV	MIN	MAX
CONSIDER NEW CANDIDATE	5.28	.65	3.88	6.75
INITIAL RX (THERAPEUTIC) INDICATION(S)	4.50	.73	2.60	6.00
DOSAGE & DELIVERY SYSTEM(S)	4.10	.88	2.75	5.86
SUBMIT IND	3.88	.83	1.71	6.00
CONTINUE/DISCONTINUE PRECLIN TO PH I	4.18	.80	2.33	6.00
DISCONTINUE DURING PH II	4.20	.87	2.17	6.00
DISCONTINUE RX INDICATION	4.22	.73	2.00	6.00
CONTINUE/DISCONTINUE PH II TO PH III	4.43	.86	2.43	6.25
SUBMIT NDA	4.31	.87	2.50	5.83
DISCONTINUE DURING PH III	4.53	.94	2.50	6.25
CHANGE PRECLIN PLAN DUE TO ANIMAL TEST	4.29	.65	2.88	5.83
ADD DUE TO INADEQUATE PRECLIN PROFILING	3.86	.56	2.75	5.00
CHANGE CLIN PLAN DUE TO SLOW ENROLLMENT	3.77	.69	2.00	5.33
CHANGE CLIN PLAN DUE TO LACK OF EFFICACY	3.90	.66	2.38	5.25
CHANGE CLIN PLAN DUE TO TOXIC/SIDE EFFECT	4.07	.58	2.67	5.33
ADD RX INDICATION	3.84	.57	2.50	4.88
CHOICE OF PERSONNEL ASSIGNED TO TEAM	5.74	.62	4.43	6.75
MOVE BUDGET WITHIN DEPARTMENT	5.71	.70	3.17	6.80
REASSIGN BUDGET TO NEW DEPARTMENT	5.27	1.13	1.86	6.71
SEEK ADDITIONAL FUNDING	3.52	.76	1.50	6.00
AQUISITION OF EQUIPMENT	4.82	.68	2.83	6.17
HIRE NEW TECHNICAL STAFF FOR PROJECT	5.78	.61	3.86	6.60
PROMOTION DECISIONS	6.09	.60	4.25	7.00
SALARY DECISIONS	6.27	.61	4.13	7.00

Table IV. Means and standard deviations of team averages for team leader items

ITEM	MEAN	STD DEV	MIN	MAX
ENCOURAGES PARTICIPATION IN DECISION MAKING	5.69	.73	3.93	7.00
PROACTIVE WHEN ADDRESSING PROJECT ISSUES	5.53	.74	3.00	6.67
RECOGNIZES AND MEDIATES CONFLICT	5.12	.82	3.00	6.50
UNDERSTANDS NON-HUMAN TESTING	4.83	.77	3.13	6.50
UNDERSTANDS HUMAN TESTING	5.29	.92	3.17	7.00
KEEPS CURRENT IN TECHNICAL FIELD	5.26	.82	2.75	6.67
EXTERNAL R&D CONTACTS	4.14	1.06	2.00	6.67
INTERNAL R&D CONTACTS	5.24	.64	3.75	6.50
OBTAINS RESOURCES	4.50	.92	2.00	6.50
SIGNIFICANT INFLUENCE WITHIN ORGANIZATION	4.18	.99	1.75	6.00
SIGNIFICANT INFLUENCE WITHIN MY DEPT	3.14	.83	1.00	5.00
EXCELLENT SOUNDING BOARD FOR IDEAS	5.00	.84	3.00	6.33
HIGH STANDARDS OF PERFORMANCE	5.43	.69	3.50	6.67
PROVIDES RECOGNITION FOR WORK WELL DONE	5.33	.79	3.25	7.00

Table V. Means and standard deviations of team averages for team process items

ITEM	MEAN	STD DEV	MIN	MAX
CLEARLY DEFINED TEAM GOALS	5.76	.62	4.00	6.67
TEAM MEMBERS COMMITTED TO SHARED GOALS	5.35	.66	3.90	6.67
OPEN COMMUNICATION WITH OTHER GROUPS	4.84	.63	3.33	6.00
TEAM HAS ADEQUATE FUNCTIONAL EXPERTISE	5.68	.52	4.38	6.45
TEAM HAS AUTONOMY TO CARRY OUT MISSION	3.69	.85	1.50	5.17
CLEAR TEAM PERFORMANCE CRITERIA	2.64	.66	1.29	4.19
INDIVIDUAL REWARDS LINKED TO TEAM	2.61	.77	1.00	4.18
PROJECT HAS HIGH PRIORITY IN MY DEPT	4.90	1.12	2.22	7.00
THIS PROJECT HAS CLEAR SENIOR MGT SUPPORT				
CONFLICT BETWEEN MY DEPT AND TEAM ROLES	2.33	.60	1.38	3.71
TEAM MEMBERS EXHIBIT HIGH MORALE	5.13	.68	3.88	6.50
OVERALL TEAM PERFORMANCE	5.03	.81	3.00	6.50

A factor analysis of the team leader characteristic items was also performed. Only team member responses for the team leader items were used in this factor analysis because team leaders had not been asked to assess themselves. This factor analysis was also performed with listwise deletion, principal components extraction and varimax rotation. Four factors were extracted and these were used to construct scales. The items composing these scales are listed in Exhibit 2.

A third factor analysis was performed on a subset of the team functioning items. Items that are more appropriately considered outcomes, (i.e., team morale and team performance) were excluded from the factor analysis. Two factors were extracted from the data and used to construct scales. They are listed in Exhibit 3.

Cronbach's alpha was computed for each of the scales. It ranged from a low of 0.58 up to 0.94. The lower values were considered adequate given the face validity of the items being combined and the small number of items in several of the scales.

- Construct 1 Initiate development project (Cronbach's alpha=0.74)
- Consider new chemical entity as development candidate.
 - Initial choice of therapeutic (Rx) indications for the new drug.
 - Decisions relating to choice of dosage and delivery systems.
- Construct 2 Go/No Go decisions (Cronbach's alpha=0.94)
- Decision to submit the IND.
 - Decision to continue or discontinue between Phases 1 and 2.
 - Decision to discontinue during Phase 2.
 - Decision to continue or discontinue between Phases 2 and 3.
 - Decision to discontinue during Phase 3.
 - Decision to discontinue development for a Rx indication.
 - Decision to submit the NDA.
- Construct 3 Preclinical testing decisions (Cronbach's alpha=0.72)
- Decision to change preclinical testing plan.
 - Decision to add non-human tests due to inadequate preclinical profiling.
- Construct 4 Clinical testing decisions (Cronbach's alpha=0.91)
- Decision to change clinical testing plan due to lack of efficacy.
 - Decision to change clinical testing plan due to toxicity or side effect.
 - Decision to test drug for an additional a Rx indication.
 - Decision to change testing plan due to slow enrollment of clinical trial subjects.
- Construct 5 Personnel assignments
- Choice of personnel assigned to this project.
- Construct 6 Budget decisions (Cronbach's alpha=0.76)
- Decision to move budget from one task to another within a department.
 - Decision to reassign budget from one department to another.
 - Decision to seek additional funding for the project.
 - Decision to acquire equipment for the project.
 - Decision to hire new staff for the project.
- Construct 7 Pay and promotion decisions (Cronbach's alpha=0.93)
- Promotion decisions for project team members.
 - Salary decisions for project team members.

Exhibit 1. Scales derived from factor analysis of decision items

- Construct 1 Human relations/political skills (Cronbach's alpha=0.78)
- Encourages team members to participate in important decisions.
 - Proactive when dealing with project issues.
 - Recognizes and mediates conflict between individuals and groups.
- Construct 2 Technical knowledge/contacts (Cronbach's alpha=0.80)
- Excellent understanding of technical aspects of non-human model testing.
 - Excellent understanding of technical aspects of clinical testing.
 - Keeps current and is well informed of latest advances in his or her field.
 - Has useful contacts with other R&D professionals inside this firm.
 - Has useful contacts with other R&D professionals outside this firm.
- Construct 3 Influence within the organization (Cronbach's alpha=0.80)
- Has considerable influence which is useful in obtaining resources necessary to carry out the project effectively.
 - Has significant influence within the overall organization.
 - Has significant influence within my department.
- Construct 4 Feedback on performance (Cronbach's alpha=0.80)
- Is an excellent sounding board for new ideas.
 - Maintains high standards of performance.
 - Effective at providing appreciation and recognition for work well done.

Exhibit 2. Scales derived from factor analysis of team leader items

Construct 1 Facilitating factors (Cronbach's alpha=0.74)

Goals are clearly defined and communicated to team members.
Team members are committed strongly to shared goals.
Open communication between team and other groups in this organization.
Team members have adequate functional expertise to accomplish tasks.

Construct 2 Team oriented organizational arrangements (Cronbach's alpha=0.58)

Teams have autonomy to carry out their mission in this organization.
There are clear criteria for assessing team performance.
Individual rewards are linked to my performance as a member of this team.

Exhibit 3. Scales derived from factor analysis of team functioning items

Scale values for each of the constructs were computed two ways. First, individual responses to the items were standardized and then averaged across the scale items. Means of the individual scale values were then calculated by team. The correlation coefficients shown in the tables below were computed using the normalized scale values. Scale values were also computed as means of the raw individual scores, and then aggregated by individual and then by team. Tables VI and XV list the mean team scores for the non-standardized decision influence and project leader characteristics scales, respectively.

Table VI. Means and standard deviations of team averages for decision influence scales

SCALE	MEAN	STD DEV	MIN	MAX
INITIATE DEVELOPMENT PROJECT	4.62	.57	3.21	5.57
GO/NO GO DECISIONS	4.22	.71	2.43	5.71
PRECLINICAL PLAN ADJUSTMENTS	4.04	.57	2.81	5.42
CLINICAL PLAN ADJUSTMENTS	3.89	.55	2.63	5.06
CHOICE OF PERSONNEL	5.74	.62	4.43	6.75
BUDGET CONTROL	5.03	.53	3.67	6.28
PAY AND PROMOTION DECISIONS	6.18	.59	4.19	7.00

The scale values in Table VI are used to categorize teams into those with greater departmental management influence versus greater project management influence versus a more balanced system where influence is roughly equal. The middle Likert scale category lies between 3.5 and 4.5 units. This range is used as the criterion for defining teams with an equal balance of influence between project and departmental management. The mid-range was

made relatively narrow to separate those projects that had even slightly more influence from either departmental or project management from those that were truly balanced. Sensitivity testing shows little effect from varying the width of the balanced range. Making it narrow, however, allowed us to test whether true equality of influence has any relation to performance. The distribution of teams exhibiting a departmental, project or equal locus of decision influence for each decision scale is shown in Table VII.

These data indicate that in personnel, resource allocation and reward decisions team members on the majority of projects perceive functional managers to have the greatest influence or control. Similarly, in decisions regarding the initiation of development projects functional managers also have greater influence. In other decision areas, in contrast, - go/no go decisions and preclinical and clinical testing plan changes - the majority of team members perceive there to be a near equal balance between project leader and functional manager influence.

An ANOVA performed on the decision influence scales using company as the categorical variable indicate significant differences between firms (Table VIII). These data indicate there are significant differences between firms in how influence is allocated. A similar ANOVA for senior manager assessments of project performance demonstrates no differences among the firms. This statistical result is further evidence that managers across firms chose projects that

are comparable, and that no significant selection bias among firms is present in the sample.

Table VII. Number of teams in each influence category by decision type

Type of decision	Locus of influence over decision		
	Project leader	Equal	Functional management
Initiation decisions	1	19	25
Go/no go decisions	5	25	15
Preclinical decisions	6	30	9
Clinical decisions	10	30	5
Personnel decisions	0	2	43
Budget control	0	7	38
Reward decisions	0	2	43

Table VIII. Average of team means for locus of decision influence by company

Locus of Decision Making	Firm 1	Firm 2	Firm 3	Firm 4	Firm 5	Firm 6	p value
Initiation decisions	4.9	5.0	4.6	4.8	4.0	4.2	0.01
Go/no go decisions	4.2	3.4	4.8	4.5	3.9	4.5	0.001
Preclinical decisions	4.3	4.4	4.1	3.5	3.9	3.8	0.05
Clinical decisions	4.5	3.7	4.0	3.6	3.6	3.8	0.01
Personnel decisions	5.9	6.2	5.4	5.4	5.8	5.7	0.10
Budget control	4.8	4.7	5.1	5.2	4.8	5.5	0.01
Reward decisions	6.0	5.9	6.2	6.2	6.1	6.7	0.10

Early versus late phase development projects

During the course of drug development the task evolves from one focused primarily on non-human models and animal tests to one focusing on human models and clinical tests.⁷ To test whether there are differences between early and late phase projects or phase-based contingencies among the factors that affect performance, projects in the sample are split into early and late phase categories using the beginning of Phase 2 as the dividing mark. This division serves as a gross operationalization of the temporal changes that occur in the task.⁸ The forty-five teams were grouped into seventeen (38%) early phase and twenty-eight (62%) late phase teams. Specific differences between early and late phase projects are presented below.

Single versus dual leader project coordination systems

Project teams were separated into those operating in R&D organizations having single leader and dual leader systems. This serves as an operationalization of a salient difference in the organization structures and project coordination systems employed in the pharmaceutical industry. Sixty percent (60%) of the forty-five teams in the sample operate in single leader systems. The remaining 40% of the teams are in dual leader systems. Fifty-nine percent

⁷ If the drug is intended for chronic or long term use, long term non-human model studies are likely to continue well into the later phases of development.

⁸ As discussed earlier, the technical uncertainty associated with any candidate compound decreases as it moves through development, so this categorization also separates projects having greater technical uncertainty from those with less technical uncertainty. This does not mean that early stage projects invariably involve greater uncertainty than later stage projects. Other forms of uncertainty, such as that associated with scheduling multiple tasks across organizations, do not vary in a predictable manner. Because of this, estimates of "total" uncertainty are problematic.

(59%) of the teams in organizations with single leader systems are late phase teams. For teams in dual leader systems, 67% are late stage projects. This difference is not significant.

Project heads in single leader and dual leader systems have similar tenure in the industry (141 months versus 142 months). Project heads in firms with dual leader systems have slightly longer tenure with their current firms (108 months versus 123 months), although this difference is not significant. Project heads also have similar experience in the industry as well as in their current firms. Approximately 75% of project heads in both single and dual leader systems report having experience working in clinical testing at some point in their tenure with their current firm. In dual leader firms a similar percentage of project heads report preclinical testing experience, while the figure was approximately fifty percent (50%) for single leader firms.

The two groups of team leaders vary in their educational backgrounds. All of the project heads in firms with dual leadership structures have technical experience and doctoral level training. In the single leader system, some of the project leaders are people with business and/or technical backgrounds having only master's level training.

Project coordinators in firms employing dual leader systems report having shorter tenures than the project leaders. On average,

project coordinators report industry tenure of 131 months and firm tenure of 88 months.

Senior Manager Assessments of Project and Team Leader Performance

Team performance assessments by senior managers were averaged across those senior managers who indicated they were familiar enough with each project to be able to make an informed judgement of team performance. The mean overall performance is 2.9 out of five with a standard deviation of 1.0. For schedule performance and project leader performance the figures are 2.7 with a standard deviation of 1.1 and 3.6 with a standard deviation of 0.76, respectively.

Tests of concordance between senior managers' performance assessments were conducted. Kendall's W comparing rankings of overall project performance varies from a low of 0.74 through a high 0.95 with an average value of 0.81.

As expected, overall and schedule performance are correlated strongly with priority (overall $r=.45$, $p<0.01$; schedule $r=.43$, $p<0.01$), as is team leader performance ($r=.41$, $p<0.01$).

Senior Manager Perceptions of Candidate Compounds

Senior managers' responses indicate compounds in the sample are aligned with the overall R&D strategy, firm capabilities and market needs.

When broken down by phase there are two significant differences in senior managers' perceptions of early versus late phase compounds (Table IX). Senior managers indicate that they are less well informed regarding early phase projects and that early phase projects fit the overall R&D strategy of the firm better. The first of these differences is likely to be due to two causes. First, because of the greater costs of later stage trials, senior managers probably invest more effort in attending to these projects. Second, the uncertainty surrounding any candidate, in general, decreases over time as more information regarding that candidate is generated.

The difference in fit with the overall R&D strategy may be attributed, in part, to evolution of the firms' technical strategies as new opportunities for therapeutic agents present themselves. There is a lag between the time a firm's strategy changes and the portfolio of compounds in development reflects that change. A change in R&D strategy is likely also to first manifest itself in the selection of compounds for preclinical testing. Later stage projects have a momentum due to the prior commitment of resources and expectations of future revenues that are likely to carry them forward regardless of moderate shifts in R&D strategy. In some cases, difficulty killing later stage projects may account for the poorer fit of those development candidates. This difference in fit may also be partly due to the attention that health care reform and changes in the marketplace have drawn to criteria in addition to just safety and efficacy, such as cost-benefit, used by the FDA and other regulatory

boards. Senior managers' assessments of what market needs can be met by the firm may have changed in response.

There are no differences between early and late phase projects on fit with market needs or expected profitability.

Table IX. Average senior manager perceptions of development candidates broken down by project phase

Development candidate characteristic	Early phase	Late phase	p value for t-test
Overall performance	2.9	2.9	n.s.
Schedule performance	2.8	2.7	n.s.
Performance of project leader	3.3	3.7	n.s.
Well informed regarding project progress	3.5	3.9	p<.05
Priority of project*	2.6	2.3	n.s.
Aligned with overall R&D strategy of firm	4.0	3.5	p<.10
Aligned with firm capabilities	4.0	3.6	n.s.
Aligned with market needs	3.8	3.8	n.s.
Expected profitability*	3.0	2.8	n.s.

* Based on 4 point scale. All others based on 5 point scale.

When grouped by leadership structure, the only significant difference between single leader and dual leader teams is that those operating in a dual leadership structure perform better, both in terms of schedule and overall performance (Table XI). There are no other statistically significant differences among senior managers' perceptions of candidate compounds or team leaders.

With this preliminary description of the sample complete, the analysis now moves on to examine the relationship between the locus of project decision making influence and project performance.

Distribution of decision influence and project performance

The aggregated single-item and multiple-item scale scores for decision influence were correlated with the averaged senior manager evaluations. None of the bivariate correlations are significant in a statistical or practical sense. The above mentioned correlations between priority and schedule performance, and between priority and overall performance mask the underlying associations between decision influence and performance. Controlling for project priority reveals the correlations displayed in Table X.

Note that a positive correlation indicates that higher performance is associated with relatively greater functional manager influence over the type of decision, while a negative correlation means that higher performance is associated with relatively greater team leader influence.

From Table X it can be seen that higher overall performance is correlated with greater functional manager influence over budget, go/no go decisions and reward decisions. The only decisions in which project manager influence is associated with higher schedule performance are in clinical testing.

Table X. Correlations (Pearson's r) between decision influence scale team averages and senior manager assessments of schedule and overall project performance controlling for project priority

Type of decision	Correlation between locus of influence and:	
	Schedule performance	Overall performance
Initiation decisions	-.09	-.08
Go/no go decisions	.19	.25**
Preclinical decisions	.04	.03
Clinical decisions	-.26**	-.14
Personnel decisions	.05	.06
Budget control	.24*	.27**
Reward decisions	.17	.22*

(* p<.10, ** p<.05, *** p<.01)

The raw decision scale means shown in Table VI are consistent with team leaders having more influence over tactical decisions relating to preclinical and clinical testing, and less influence over more strategic decisions such as initiating projects and continuing or terminating a project. Team leaders have very little influence over funding, personnel and reward decisions. Regardless of the project leaders' influence over some operational decisions, the functional managers maintain strong control over resources.

Further examination of the data indicate that the bivariate correlations coefficients in Table X present an incomplete picture of the relationships among the loci of decision influence and project

performance. These relationships are contingent upon leadership structure and project phase. These contingencies are explored below.

Leadership structure, locus of influence and performance

A comparison of the firms employing a single leader versus a dual leader structure shows significant differences between team means for five of the seven decision types as well as for schedule and overall performance (Table XI). These data indicate project leaders in dual leader structures have more say in most project decisions, although in reward and budget decisions they have less influence than project heads in single leader systems. These data also indicate that leadership structure, or some other correlated organizational characteristic, affects the loci of decision making influence and project performance.

Table XI. Average of team means for locus of decision influence by project leadership structure

Type of decision	Single Leader	Dual Leaders	p value of t-statistic
Initiation decisions	4.8	4.3	p<.01
Go/no go decisions	4.1	4.4	ns
Preclinical decisions	4.2	3.7	p<.01
Clinical decisions	4.0	3.7	p<.05
Personnel decisions	5.8	5.6	ns
Resource decisions	4.9	5.3	p<.01
Reward decisions	6.0	6.4	p<.01
Schedule performance	2.4	3.1	p<.05
Overall performance	2.6	3.4	p<.01

When broken down by single and dual leader systems and controlled for priority, the correlations between the locus of preclinical decision making and performance indicate that for single leader systems both schedule ($r=.39$, $p<0.05$) and overall ($r=.36$, $p<0.05$) performance are higher when these decisions are influenced more strongly by departmental managers. The corresponding correlations for dual leader systems have the opposite sign from those for single leader systems, but neither correlation is significantly different from zero ($r=-.25$, ns; $r=-.16$, ns). However, the correlation between preclinical decision influence and schedule performance for single leader teams is significantly different from that for dual teams ($p<0.05$).

When controlled for leadership structure, the correlations in Table X change, but fail to provide a clear picture of the relationship between locus of influence and project performance. It is possible that there is no relationship between locus of influence and overall project performance. Alternatively, the relationship between locus of decision making influence and project performance may be hidden by some factor.

Project phase, locus of decision influence and performance

Separating the teams into early and late stage projects provides a more complicated picture of the associations between decision influence and performance measures (Table XII). For the early stage projects, higher schedule and overall performance are associated

with greater functional manager influence over project initiation and personnel decisions. Higher schedule and overall performance are also associated with relatively greater team leader influence over reward decisions. The correlations among influence over go/no go, preclinical, clinical and resource decisions and schedule and overall performance are not significantly different from zero. They also are not significantly different from the corresponding correlations for the late phase projects.

For the late stage projects, higher schedule and overall performance are associated with relatively greater functional manager influence over go/no go, budget and reward decisions. Both schedule and overall performance are also higher if the team leader has relatively greater influence over personnel decisions and, in the case of schedule performance, greater influence over clinical decisions.

Note that the negative correlations among influence over initiation decisions and schedule and overall performance imply that project leaders had significant influence in these decisions. Since initiation decisions typically are made by functional managers before teams are put together, these correlations are likely caused by the retrospective misattribution of the role played by project leaders in past events. Team members who perceive the team to be performing well may attribute greater influence to the team leader due to a halo effect.

A comparison of means test (t-test) for early versus late stage teams yields no statistically significant differences for any of the decision influence scales. This is true even though there are trends in the data that indicate a shift toward greater project leader influence over some decisions during later phases. As noted above, there also are no significant differences between early and late stage teams on any of the three performance measures (Table IX).

Table XII. Correlations (Pearson's r) between decision influence scale team averages and senior manager assessments of schedule and overall project performance controlling for project priority broken down by phase

Type of decision	Correlation of locus of influence controlling for priority with:					
	Schedule performance			Overall performance		
	Early	Late	p	Early	Late	p
Initiation decisions	.33*	-.35**	p<.05	.34*	-.29*	p<.10
Go/no go decisions	-.20	.36**	n s	-.15	.43**	n s
Preclinical decisions	.27	-.07	n s	.10	.00	n s
Clinical decisions	-.19	-.36**	n s	-.06	-.21	n s
Personnel decisions	.54**	-.26*	p<.01	.39*	-.25*	p<.05
Resource decisions	-.06	.29*	n s	-.15	.37**	n s
Reward decisions	-.38*	.29*	p<.05	-.39*	.33**	p<.05

(* p<.10, ** p<.05, *** p<.01)

The relationship between locus of influence and performance appears to exist, but it may be obscured in bivariate analyses by its multivariate nature. Multiple regression is employed at the end of this chapter to examine how leadership structure and project phase

interact to affect this relationship. But before doing this, team leader characteristics and team functioning are brought into the analysis.

Team leader characteristics and locus of decision influence

Team members' perceptions of project leaders' technical knowledge are strongly correlated with perceptions of locus of decision making influence (Table XIII). Project leaders' overall influence within the organization is correlated only weakly with perceptions of their influence over decisions pertaining to personnel and other project resources.

Table XIII. Correlations between project leader characteristics and the locus of decision influence

Type of decision	Human relations	Technical knowledge	Influence	Provides feedback
Initiation decisions	.00	-.60***	-.18	-.07
Go/No go decisions	-.15	.09	-.16	-.22*
Preclinical decisions	.01	-.44***	-.05	-.07
Clinical decisions	-.02	-.46***	-.13	-.12
Personnel decisions	-.06	-.27**	-.24*	-.12
Resource decisions	-.12	.03	-.23*	-.13
Reward decisions	-.07	.08	-.14	-.05

(* p<.10, ** p<.05, *** p<.01)

When broken down by leadership structure, the pattern of results is largely unchanged. For both single and dual leader systems, project leader technical knowledge is correlated with greater influence over initiation, preclinical, clinical and personnel

decisions. Differences between single and dual leader teams are the significant relationships among team leaders' human relations and political skills, their ability to provide feedback, and their influence over go/no go and resource decisions for single leader teams. These relationships are not significant for dual leader teams. Note that characteristics of the leader are not related to their influence over rewards in single or dual leader systems. The correlations among the locus of decision influence and priority are small, so controlling for priority has no significant effect on these results.

A t-test of means for single versus dual leader teams shows a significant difference for technical knowledge of the team leader (4.7 versus 5.4, $p < 0.01$). There are no other differences in project leader characteristics between these two groups.

When separated into early and late phase teams, correlations among team leader technical knowledge and decision influence over initiation, preclinical, clinical and personnel decisions increase slightly for late stage projects. These correlations fall slightly for the early phase teams, but, except for the correlation between technical knowledge and personnel decisions, remain significant. For early stage teams, there is also a strong relationship between technical knowledge and departmental control over reward decisions ($r = .51$, $p < 0.05$). There are no significant relationships among human relations and political skills, influence in the organization, ability to provide feedback, and any of the loci of decision making influence.

The above results demonstrate there are relationships among project leaders' technical knowledge and the locus of influence over some types of project decisions. The next step is to examine the relationship between team leader characteristics and performance.

Team leader characteristics and project performance

Project leader characteristics scale scores were correlated with mean senior manager evaluations. The results of this are displayed in Table XIV. The mean and standard deviation for each of the scales aggregated by team are listed in Table XV.

Table XIV. Correlations between team leader characteristics scores and team leader performance

	Schedule performance	Overall performance	Team leader performance
Human relations /Political skill	.11	.08	.25**
Technical knowledge	.27**	.25**	.27**
Influence within organization	.08	.11	.22*
Provides feedback	.15	.11	.25**

(* p<.10, ** p<.05, *** p<.01)

There are two aspects of the data that stand out in Table XIV. First, there are correlations among a project leader's technical knowledge and both schedule performance and overall project performance. Project leaders who are perceived as being more

knowledgeable of the technical aspects of drug development are more likely to lead higher performing projects. When controlled for priority, which is moderately correlated with project priority ($r=.24$, $p<0.10$), these correlations decrease slightly and remain significant. Technical knowledge of project leaders appears to be related positively to project performance, but this may be a spurious correlation because of the relationship between leadership structure and leader technical knowledge. This issue is addressed below.

Table XV. Means and standard deviations of team averages for project leader characteristics scales

SCALE	MEAN	STD DEV	MIN	MAX
HUMAN RELATIONS/POLITICAL	5.46	.67	3.79	6.67
TECHNICAL KNOWLEDGE/CONTACTS	4.98	.64	3.46	6.37
RESOURCE PROCUREMENT	3.94	.86	1.75	5.83
PROVIDES FEEDBACK	5.25	.69	3.25	6.33

The second aspect of Table XIV that stands out is the pattern of correlations among the four dimensions along which team members perceive project leaders and senior manager assessments of leader performance. When controlled for priority, these correlations also decrease, but technical knowledge as well as human relations and political skills remain significantly correlated with leader performance. In contrast, the correlations among a project leader's ability to provide feedback, influence within the organization and senior manager assessments of his or her performance decrease significantly when controlled for priority. A plausible explanation

for these results is that more influential managers are chosen to lead higher priority projects.

Leadership structure, phase and leader characteristics

Separating teams into those operating in single versus dual leader systems and controlling for priority reveals differences between single and dual leader teams. In firms having a dual leadership structure, team leaders' human relations and political skills, ability to provide feedback, and technical knowledge are positively associated with project performance. For teams operating in single leader systems, it appears that human relations and political skills as well as the ability to provide feedback are uncorrelated or have a weak inverse correlation with project performance.

Table XVI. Correlations among team leader characteristics and senior manager assessments of project performance broken down by single and dual leader controlling for project priority

	Correlation of leader characteristics controlling for project priority with:					
	Schedule performance			Overall performance		
	Single	Dual	p	Single	Dual	p
Human relations	-.26*	.81***	p<.01	-.25	.73***	p<.01
Technical knowledge	-.10	.36*	n s	-.18	.38*	n s
Influence within organization	-.24	.29	n s	-.19	.28	n s
Provides feedback	-.29*	.70***	p<.01	-.30*	.55**	p<.01

(* p<.10, ** p<.05, *** p<.01)

Note that the data in Table XVI provide a more complicated picture of the relationships among leader technical knowledge and project performance. It appears that leader technical knowledge is not related to project performance for single leader teams.

The extremely high correlations among human relations skills and schedule and overall performance for the dual leader teams are due partly to two outliers in the data. Correlations calculated using smoothed data are slightly lower, but still large and significant. The outliers do not appear to distort underlying relationships in the data.

For single leader teams, the correlations among leader characteristics and senior manager assessments of project leader performance are not significant. In dual leader systems, all four characteristics are correlated with team leader performance (Table XVII).

Table XVII. Correlations between team leader characteristics scores and team leader performance controlling for priority

Correlation of leader characteristics controlling for project priority with:			
	SingleLeader	Dual Leader	p
Human relations /Political skill	-.19	.78***	p<.01
Technical knowledge	-.01	.43**	n s
Influence within organization	-.11	.47**	p<.10
Provides feedback	-.14	.56***	p<.01

When separated into early phase and late phase projects, the correlations among leader technical knowledge and schedule performance ($r=.47$, $p<0.01$) and overall performance ($r=.48$, $p<0.01$) are strong and significant for late phase projects. The corresponding correlations for early phase projects are weak and not significant for schedule performance ($r=-.18$, ns) and moderately strong and weakly significant for overall performance ($r=-.39$, $p<0.10$).

The only correlation among leader characteristics and leader performance that is significant is that between leader technical skill and leader performance ($r=.45$, $p<0.01$) for late stage teams. The corresponding correlation for early phase teams is not significant ($r=-.31$, ns), although the difference between the correlations for early and late phase teams is statistically significant.

The analysis now shifts to examine relationships among organizational support for teams, team facilitating factors and project performance.

Team functioning and project performance

The team-oriented arrangements scale is interpreted to measure how supportive of teams is the external organizational milieu in which a team operates.⁹ Autonomy to carry out a team's mission, linking individual rewards to their performance as team members, and communicating clear criteria for defining high team performance to team members are all attributes of organizations that help motivate and enable high performance by teams (Larson and LaFasto, 1989; Mohrman and Mohrman, 1994). The team facilitating scale measures team members' perceptions of the internal capabilities of the team. Past research has linked these factors with high performance (Larson and LaFasto, 1989; Goodman, 1986).

The correlations among the team-oriented arrangements scale, the team facilitation scale, the role conflict item, and schedule and overall performance are shown in Table XVIII. Two observations that can be made are:

- 1) both internal and external aspects of team functioning are associated with project performance

⁹ The author would like to acknowledge and thank Ralph Katz for suggesting the internal versus external interpretation of the two team functioning scales.

2) the role conflict experienced by team members is directly correlated with project performance

This latter result probably reflects greater commitment to the team by members of higher performing teams. This creates greater conflict with what is expected of them in their departmental role. Where departmental role dominates, there is less commitment to the team and project performance suffers.

Table XVIII. Correlations among team functioning scales and senior manager assessments of project performance

	Schedule Performance	Overall Performance
Team oriented organizational arrangements	.41***	.43***
Team facilitating factors	.32**	.23*
My role as a development team member is frequently in conflict with my role as a member of my department.	.25**	.21*

(* p<.10, ** p<.05, *** p<.01)

Separating the sample into single leader and dual leader groups reveals several differences (Table XIX). First, correlations among team-oriented arrangements and schedule and overall performance decrease for both single and dual leader teams, but remain weakly significant for the single leader teams. In contrast, the correlations for the team facilitating factors vanish for the single leader teams, but increase for the dual leader teams. Finally, the associations between role conflict and performance may reflect a greater tension

between the project and department in firms that use the single leader system.

Table XIX. Correlations among team functioning scales and senior manager assessments of project performance broken down by single and dual leader controlling for project priority

	Correlation of team functioning scales controlling for project priority with:					
	Schedule performance			Overall performance		
	Single leader	Dual leader	p	Single leader	Dual leader	p
Team-oriented organizational arrangements	.31*	.23	n s	.30*	.22	n s
Team facilitating factors	.06	.55***	n s	-.07	.48**	n s
Team versus department role conflict	.42**	.01	n s	.36**	.05	n s

(* p<.10, ** p<.05, *** p<.01)

A comparison of means test demonstrates teams in firms with single leader systems to have significantly lower means on both the team-oriented arrangements and facilitating factor scales (Table XX).

Table XX. Team functioning scale mean values for single versus dual leader teams

	Single leader	Dual leader	p value for t-statistic
Team functioning scales			
Team-oriented arrangements	2.7	3.4	p<.01
Team facilitating factors	5.3	5.6	p<.01
Team versus department role conflict	2.4	2.2	n s

The results presented in Tables XIX and XX indicate that organizations that employ single leadership structures are less supportive of teams than organizations with dual leader systems.

When separated into early and late phase projects, the correlations among all three team functioning measures and schedule and overall performance vanish for early stage teams. For late phase teams, in contrast, these correlations remain strong and significant.

Team leader characteristics and team functioning

Correlations among the team-oriented arrangements scale, team facilitating factors scale and team leader characteristics demonstrate positive associations among these indicators.

Table XXI. Correlations among team functioning scales and team leader characteristics

	Team-oriented arrangements	Team facilitating factors
Human relations/ political skills	.24*	.55***
Technical knowledge	.53***	.49***
Influence in organization	.37***	.43***
Feedback on performance	.36***	.63***

(* p<.10, ** p<.05, *** p<.01)

When separated into single and dual leader teams, correlations among perceptions of leader characteristics and the team facilitating factors are strong and significant for both groups (Table XXII). For

the team-oriented arrangements scale, the correlations for the single leader teams decrease, but remain weakly significant. The correlations for the dual leader teams change in a mixed manner. Those for the leaders' technical knowledge and influence within the organization remain significant, while those for leader human relations and political skills and for the ability to give feedback lose their statistical significance, although the magnitude of the change for the feedback scale is small.

Table XXII. Correlations among team functioning scales and team leader characteristics broken down by single and dual leader

Project leader characteristic	Team-oriented arrangements			Team facilitating factors		
	Single leader	Dual leader	p	Single leader	Dual leader	p
Human relations/political skills	.29*	.15	n s	.56***	.59***	n s
Technical knowledge	.31*	.34*	n s	.38**	.34*	n s
Influence in organization	.32*	.46**	n s	.41**	.44**	n s
Feedback on performance	.32*	.30	n s	.59***	.67***	n s

(* p<.10, ** p<.05, *** p<.01)

The pattern of results for the correlations among the team functioning scales for early and late phase projects is similar to the pattern in Table XXII. The correlations among the facilitating factors and all four project leader characteristics remain significant for both early and late phase teams. The correlations among team-oriented arrangements and all four leader characteristics remain significant

for early phase projects. For late phase projects, only the correlations among team leader technical knowledge, influence within the organization and team-oriented arrangements remain significant.

Distribution of influence and team functioning

Project leader influence over clinical decisions is significantly correlated with both team functioning scales (team-oriented $r=-.25$, $p<0.05$; team facilitating factors $r=-.26$; $p<0.05$). One explanation for this result is that when there is greater commitment to teams by the surrounding organization, project managers are more likely to exert greater influence over clinical decisions.

When separated into single and dual leader teams, the correlation between locus of clinical decision making and the team facilitating factor scale remains significant only for single leader teams. All the other correlations among these indicators lose their statistical significance.

When divided into early and late phase teams, the correlations for the late phase teams remain significant (team-oriented $r=-.28$, $p<0.10$; team facilitating factors $r=-.37$; $p<0.05$). The correlations for early phase teams decrease and are not significant (team-oriented $r=-.28$, ns; team facilitating factors $r=-.14$; ns).

Regression analyses

The preceding analysis of correlation coefficients provides a perspective on the contingent relationships among locus of influence, team leader characteristics, team functioning, and project performance, but the multivariate nature of these relationships is not explicated clearly.

To put the above results into a more succinct multivariate form a series of regression analyses were performed. The initial model that guided this analysis is shown in Figure 8. Embedded within the model are a series of hypothesized causal links. The first hypothesis is that the locus of decision making has an effect on project performance. The second is that team functioning also has an effect on project performance. The third and fourth hypotheses embedded within the model are that perceptions of a project leader's characteristics affects project performance indirectly through the project leader's affect on the locus of decision making influence and through his or her effect on team functioning. The final hypothesis in the model is that the locus of decision making affects member perceptions of team functioning. This model forms a core around which project priority, leadership structure, and project phase affect and qualify these causal links (Figure 7).

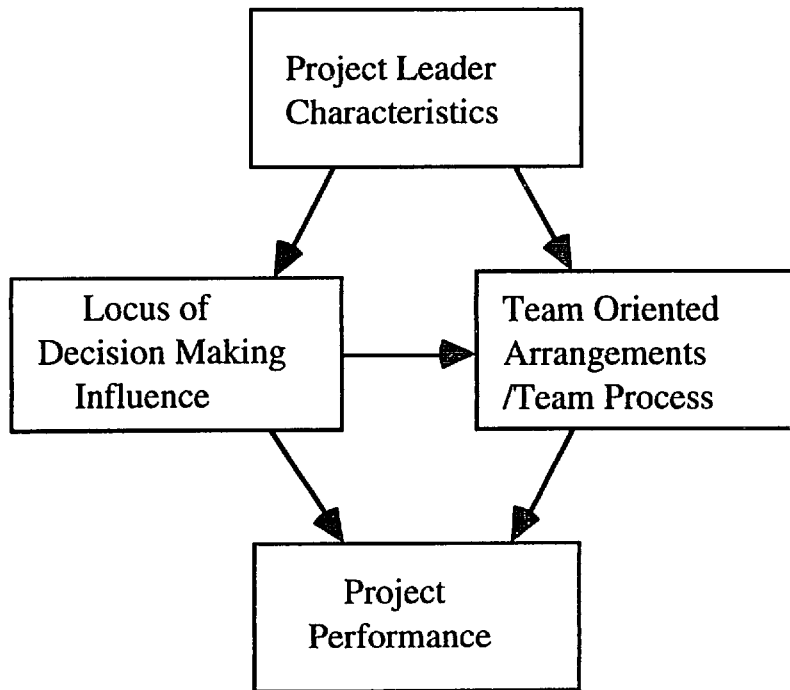


Figure 10. Core model underlying regression analyses

Hierarchical regression was used to estimate model parameters. Project priority as assessed by senior managers, phase of the project, and project leadership structure were entered into the regression model first. This was done to test the incremental explanatory power of other variables added to the model. Phase and leadership structure were entered both as independent and as interacting variables. The second block entered included indicators of the locus of decision influence, project leader characteristics and team functioning. The selection of which operationalizations to include was guided partly by theory and past research and partly by the above correlation analyses. Influence over go/no go decisions and clinical plan decisions were selected to represent strategic and operational decisions, respectively. Influence over rewards was

included because past research pointed to its importance (Katz and Allen, 1985). Project leaders' technical knowledge and their human relations/political skills were chosen because these two constructs roughly correspond to the process and task dimensions of leader behavior that have been repeatedly found in empirical studies of groups (Hackman and Morris, 1975). The final block included indicators of interactions among leadership structure, project phase, locus of decision making and leader characteristics.

The indicator of internal team process was discarded after initial model estimations because of its insignificant explanatory power.¹⁰ Models 1 and 2 in Table XXIII differ only in how leadership structure and project phase are entered into the regressions. Model 1 breaks the teams into four categories (Early Phase and Single Leader, Early Phase and Dual Leader, Late Phase and Single Leader, Late Phase and Dual Leader), while Model 2 treats project phase and leadership structure as independent. The results of the two models are quite similar, although Model 1 has marginally better explanatory power.

A number of conclusions can be drawn from the parameter estimates. First, project priority is related to performance. This is as expected. High priority projects receive attention and resources which are likely to help these projects perform better, although one might argue the reverse causal order.

¹⁰ The team-oriented arrangements scale and team facilitating scales are correlated .58, with $p < 0.01$.

Second, projects are perceived as higher performing when functional managers have relatively greater control over go/no go decisions and project heads have relatively more control over clinical decisions.

Third, although the data are grossly skewed toward functional managers influencing reward decisions, relatively greater project leader influence over rewards during early phases is associated with higher performance.

Fourth, performance is higher for late phase projects and lower for early stage projects when project heads are perceived as more technically knowledgeable.

Fifth, teams where members perceive a supportive organizational milieu are higher performing.

Other regression equations were estimated in a path analytic fashion to identify precursors to those conditions associated with higher performing teams in Model 1. From the parameter estimates in Table XXIV the following observations can be made. Late phase/single leader teams appear to have leaders who have significantly more influence over go/no go decisions than the other three conditions. Given that functional influence over go/no go decisions is associated with higher performance, this is probably inappropriate. Go/no go decisions need to be taken by technically

knowledgeable personnel who are able to be objective in their assessments. Team leaders may be too close to the issue to be objective when taking decisions to discontinue their projects. Another observation that can be made is that a project leader's influence over clinical decisions is related to his or her perceived technical knowledge. Similarly, a project leader's technical knowledge is associated with members perceiving a team-oriented organizational milieu. And, finally, team leaders in firms with dual leadership structure are likely to be perceived as more technically knowledgeable.

Table XXIII. Beta coefficients for two regression models predicting overall project performance

	Model 1	Model 2
Dependent Variable	Overall Performance	Overall Performance
Independent Variables		
Project Priority	0.29**	0.33***
Early Phase x Dual Leadership	0.16	
Late Phase x Single Leadership	0.15	
Late Phase x Dual Leadership	-.15	
Early Phase versus Late Phase		-.04
Single Leader versus Dual Leader		-.01
F value	2.81	2.72
Significance of F value	0.05	0.06
Go/No go Influence Locus	0.34**	0.30*
Clinical Influence Locus	-.40**	-.41**
Reward Influence Locus	-.60*	-.46
Technical Knowledge of Team Leader	-.42**	-.34*
Team Oriented Organizational Milieu	0.36**	0.32**
F value	3.60	2.92
Significance of F value	0.01	0.05
Late Phase x Technical Knowledge	0.45**	0.30*
Late Phase x Reward Influence Locus	0.95***	0.77**
F value	7.85	6.65
Significance of F value	0.01	0.01
Adjusted R Square	0.53	0.50
F value	5.47	5.47
Significance of F	0.001	0.001

Table XXIV. Beta coefficients for models predicting clinical decision locus, team oriented organizational milieu, go/no go decision locus, and team leader technical knowledge

	Model 3	Model 4	Model 5	Model 6
Dependent Variable	Clinical Decision Locus	Team Oriented Milieu	Go/Nogo Decision Locus	Leader Technical Knowledge
Independent Variables				
Project Priority	-.07	-.05	-.01	-.16
Early Phase x Dual Leadership	-.20	0.12	-.07	0.36**
Late Phase x Single Leadership	-.23	-.07	-.47**	0.09
Late Phase x Dual Leadership	-.17	0.41**	-.10	0.56***
F value	0.56	2.44		
Significance of F value	0.69	0.06		
Technical Knowledge of Leader	-.42**	0.29**		
F value	6.16	3.78		
Significance of F value	0.02	0.06		
Adjusted R Square	0.16	0.35	0.09	0.27
F value	2.68	5.68	2.10	4.99
Significance of F	0.05	0.001	0.10	0.01

Chapter 5

Conclusions

The results presented above support the hypothesis that the locus of decision influence in an R&D matrix affects project performance. In this sample, departmental management influence over go/no go¹¹ decisions is associated with higher project performance across project phases. During early phase testing the breadth of technical expertise required is likely to limit the ability of project leaders to take well informed go/no go decisions, while a lack of objectivity on the part of project leaders may be the reason that performance is higher when departmental managers more strongly influence these decisions during later phases.

In contrast, higher project performance is associated with greater project leader influence over clinical decisions. Higher performance is also associated with relatively greater project leader influence over reward decisions during the early phases of development. The ability to affect reward decisions provides a project leader with a tool for focusing people on the goal of keeping the project moving forward. During the early steps of drug development, only limited organizational commitment has been made to any candidate compound or project. Departmental personnel are likely to be assigned to more than one project. Team members have duties in their departments in addition to those

¹¹ Note that "go/no go" decisions, in many cases, might more accurately be termed "no go" decisions. The decision to continue a project is easily made. The decision to discontinue is usually more difficult, especially in later phases when much effort and resources have been invested. -T. Allen

pertaining to an individual project. Tying rewards to achievement of project goals is likely to provide a timely assessment of the toxicity and pharmacokinetic properties of a compound. If a candidate is going to fail in the first steps of testing, at least it will do so quickly and free up resources for other projects.

The results presented further demonstrate that team leader characteristics and organization structure affect the locus of decision influence. Team leaders who are perceived as technically more knowledgeable are also perceived as having greater influence in clinical decision making. Technical knowledge of the team leader is, in turn, associated with organization structure. In firms employing dual leader coordination systems, project leaders are perceived as technically more knowledgeable. This is one of the drivers of the difference in project performance between the single leader and dual leader systems.

Note that the loci of reward decision influence and go/no go decision influence are not related to characteristics of the project leader. Organization structure, in contrast, is associated with the locus of go/no go decision influence. In single leader systems, team leaders have greater influence over go/no go decisions. The prior result that go/no go decisions are better taken by departmental managers points to the inadvisability of this practice. Team leaders should be given greater influence over clinical decisions rather than over go/no go decisions.

Another conclusion is that pharmaceutical firms, especially those employing a single leader system, do not provide an organizational milieu that is perceived by team members to be supportive of teams. Without data from other industries it is impossible to know if the pharmaceutical industry is, in fact, any worse. But when empowering teams to achieve better performance is a goal espoused by upper-level managers, the result seems surprising. This lack of concordance with team member perceptions deserves attention. What does it represent and by what is it caused?

The results regarding team functioning point to the external environment of teams being a more important determinant of project performance than internal team process. This isn't to say that internal process is unimportant. It does say that internal process is not a limiting factor. Internal team process may, on average, be adequate across project teams in the industry. The real lever that can be used is to provide a more team-supportive milieu in which clear team performance criteria and reward contingencies are communicated to team members. Team leaders who are perceived as technically knowledgeable appear to be able to affect how team members perceive the organizational context. These team leaders may provide team members with a clearer picture of what comprises high team performance in an organization. They may clarify the contingent links between team performance and rewards (Nadler and Lawler, 1977).

In summary, these results point clearly to the contingencies between type of decision, development phase, leadership structure, locus of decision making influence, project leader characteristics, team-supportiveness of the milieu, and project performance. The existence of most of the causal links posited in the model in Figures 10 are demonstrated. The link between locus of influence and a team-supportive milieu is not demonstrated by the regression analyses.

A question that has been addressed only peripherally is whether leadership structure causes the difference in performance observed between single leader and dual leader teams. It is possible that some other characteristic of the firms employing dual leader systems is actually the cause of higher project performance. Because no organization in the sample employs both leadership structures, it is impossible to demonstrate unequivocally that leadership structure is the cause of the difference in performance.

An argument can be made that organizations employing dual leader systems choose more technically knowledgeable people to lead projects, and this difference is largely the cause of the higher performance, especially for late stage projects. Organizations having dual leader systems also appear to provide teams greater autonomy and clearer links between team performance and rewards. These perceptions of the milieu are also associated with the team leader's technical knowledge. There may be other differences between firms with single and dual leader systems, but the perceived technical skill

of the project heads in the firms having dual leader structures is a strong candidate for explaining the difference in performance.

One final question that has not been addressed is: Does it make sense to use Clark and Fujimoto's heavyweight product manager in the pharmaceutical industry? A key point to remember is that the task of drug development as well as where expertise for addressing technical or other project issues lies varies over time. Managing drug development effectively requires accomodating these temporal changes. In engineering tasks, a single person may be able to understand the different design decisions that need to be taken well enough to effectively influence them, but in the early phase of drug development there is a need to integrate expertise across a broad range of technical disciplines. No one person is likely able to be expert enough across disciplines. There is no evidence that a heavyweight project manager would be effective during early phase projects. In contrast, during the later phase of development, the technical issues that need to be addressed are more focused. One person may be expert enough to take effective operational decisions.

Designing a car and developing a drug are different tasks. The latter entails significant uncertainty, especially during early phases. This makes a more consultative decision making style appropriate (Fiedler, 1967; Herold, 1978). Heavyweight project managers are probably no panacea for the pharmaceutical industry, although giving project leaders greater influence over operational decisions during later phases may be effective.

Chapter 6

Limits of the study

This final chapter will discuss an important limitation of the study, and conclude with a set of guidelines for managers who are attempting to design development organizations.

This study examined how project coordination systems affect the relationships among team member and senior manager perceptions. The linkage between what is effective project coordination and firm level economic outcomes is problematic. The study excludes two factors that are probably at least as important as project management as precursors to effective drug development and financial performance. These are:

- 1) maintenance of the portfolio
- 2) the stream of compounds that are discovered or in-licensed.

Neither of these issues is addressed in this study, and both are important. In pharmaceutical firms with a portfolio of development projects, there is a simultaneous need to prioritize projects. Limited resources - money and personnel - need to be allocated across a set of projects. The goal is to keep promising projects moving forward and to cut off failing projects before resources are wasted. Managers across firms in the pharmaceutical industry indicate that this is an extremely difficult task.

Role of senior managers

At higher managerial levels, especially in pharmaceutical firms with large and diverse portfolios of development projects, monitoring and decision making in large part concern more strategic rather than operational issues. Firms have upper level committees that review and maintain the development portfolio. They make decisions to take some set of compounds forward in development and discontinue others. While the focus at this level of management is largely on strategic issues, contentious operational issues that cross functional boundaries or those that are perceived to be of significant strategic importance may move up the hierarchy for resolution.

There are a series of points in development that are well suited to assessing projects. Monitoring of individual projects and go/no go decision making by these upper level committees occurs at the major decision points, such as deciding to consider an NCE or other agent as a candidate for development, before starting human trials, before undertaking large scale Phase III trials, and before filing the NDA. These milestones are used by all firms in the sample as points for cutting off low promise projects. Other milestones are also used, but they often do not involve as close scrutiny by senior managers. Assessments also occur on an *ad hoc* basis when information that may affect the viability of a candidate compound is discovered.

There are differences among firms, however, in the frequency and nature of ongoing monitoring. In some firms, there are monthly or bi-monthly progress reports on each project made in front of

senior R&D managers and the heads of all the departments. The goal, according to one senior manager from an organization that uses this form of monitoring, is to bring attention to and address early any difficulties projects are experiencing. By having reviews conducted in this forum, departmental and project performance are exposed to public scrutiny. Open discussion of project progress in front of their superiors and peers has a strong motivating affect on department heads and project leaders. Public discussion facilitates open and explicit trade-offs between projects when adequate functional resources and services are not available. Senior managers are forced to be aware of the need to make trade-offs.

In other firms progress reports across projects in front of senior managers are less frequent. They occur only on a semi-annual or annual basis. In firms with less frequent senior manager monitoring, some form of director-level or department head-level monitoring is conducted. These types of reviews focus on particular projects and project issues. These reviews usually do not involve all the department heads. Monitoring in this fashion may be well suited to identifying obstacles projects are encountering and the bottlenecks occurring in departments. The narrower scope and lack of strategic perspective encompassing the overall portfolio and R&D strategy addressing may make it difficult to align quickly functional and project goals. Trade-offs between projects are more difficult.

Frequent meetings reviewing the minute operational details of all the projects may absorb excessive hours of senior managers' time

and attention. Some logical in-between where the level of detail of project issues being discussed doesn't drag senior managers too far down into the operation of each team may exist. A point that allows senior managers enough information to intervene when conflict or unclear goals are hampering the achievement of strategic priorities.

Another difference among firms is the clarity with which an overall set of goals and priorities are articulated and acted upon by senior managers. During interviews managers across firms indicated that maintaining a focused portfolio is a difficult task. A focused portfolio prevents the dilution of resources and efforts that may cause systemic delays in development efforts. A focused portfolio also cuts off possible paths for achieving new revenues.

Managers from some firms report that clear criteria for making a decision to continue or discontinue a project are defined and communicated to team members. These criteria may be in the form of a fixed time and budget to bring a preclinical candidate to the point where it is able to be taken into clinic trials. In the case of candidates in clinical trials, target efficacy, toxicity and side-effect profiles are communicated to each project team as hurdles for continuing that project.

But even with objective reasons for stopping a project, managers indicate it is still difficult because there are often political obstacles and other costs incurred in discontinuing projects. This may be the case especially if there are few other compounds in the

R&D pipeline, or if significant resources have already been invested in developing a compound.

Designing organizations

An important question for managers in the pharmaceutical industry is: How can a development organization be structured so as to effectively prioritize and coordinate projects?

When designing an organization, a number of issues need to be considered. Below are questions explicitly or implicitly taken in the design of pharmaceutical R&D organizations.

Where does monitoring occur in the organization?

What information is monitored?

Who attends to this information?

Who has the knowledge and interest to influence various decisions and decision makers?

Who has the authority to take decisions in response to the information?

Who is responsible for resultant outcomes?

How are rewards allocated?

The roles enacted by those involved and participating are closely linked to the answers. The roles performed by the actors affect the functioning and, in turn, the effectiveness of a project coordination system.

As a final bit of advice for organization designers, a set of prescriptions for structuring a development organization are listed below. These are taken from a group of writings on organization structure and organization development. These authors draw upon contingency theory (Woodward, 1965) and information processing models of organization (Galbraith, 1974) as underlying paradigms. The guidelines for constructing an effective organization are:

- 1) Push decisions down to the lowest level in an organization where the information necessary for taking a decision is available (Beckhard and Harris, 1987).
- 2) Use bureaucracy for structured and routine tasks where efficiencies can be derived from systematizing work.
- 3) Employ more flexible forms of organization where decisions and activities cannot be routinized.
- 4) Group by important dimensions of the task (Nadler and Tushman, 1988).
- 5) Use lateral coordination to supplement the overall structural grouping to manage interdependencies among people and subunits without pushing each cross-department decision upward in the hierarchy (Galbraith, 1994).
- 6) Empower teams by providing the correct goals, people, resources and rewards (Larson and LaFasto, 1989).

These guidelines are designed to have several effects. First, they help prevent overloading senior managers with operational decisions that can be taken at lower levels of the organization. There are many issues and decisions that cross departmental lines in drug

development. In an organization that does not have effective lateral coordination, these issues and decisions push their way up the hierarchy. The issue may be resolved once it reaches a manager who has oversight over the involved departments. Effective lateral mechanisms enable cooperation and accommodation across functions. Decision authority can be given to managers at lower level of the hierarchy. This division of labor leaves upper level managers more time to focus on strategic issues. This division also gives people at lower levels more autonomy and responsibility for operational issues. Departmental personnel with adequate technical expertise and time attend to operational project issues and decisions. Lateral coordination helps insure the departmental focus on technical issues is coupled with the team's goal of keeping their project moving forward.

The guidelines also promote efficiency via bureaucracy and standard operating procedures for accomplishing routine tasks, as well as adaptiveness for addressing the uncertainty inherent in non-routine tasks.

Finally, the guidelines promote high team performance by providing the opportunity for empowering teams and encouraging decision ownership via participation (Beckhard and Harris, 1987). This team empowerment strategy requires senior managers to select a set of organizational arrangements that provide team members motivating project goals and rewards that reinforce the overarching objectives of the organization (Lawler and Cohen, 1992).

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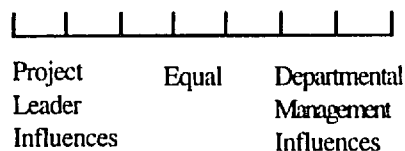
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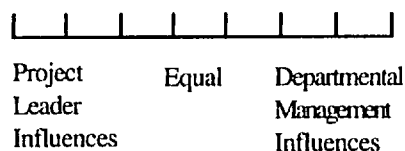
Appendix A
Team Member Survey

Please indicate (by positioning a (✓) **between** the short vertical lines (| | | | |) along each of the following scales) the relative degree of influence or involvement **exhibited by or which you would expect** from your project leader and the departmental manager most closely associated with that situation described in the left column.

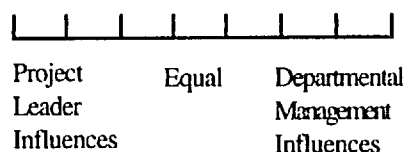
1. The decision to consider a new chemical entity as a candidate for development.



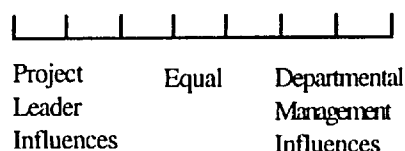
2. Initial choice of marketing claims (i.e. benefits statement) for the proposed new drug.



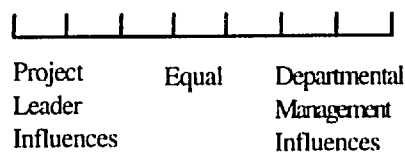
3. Initial choice of therapeutic indication(s) for the new drug.



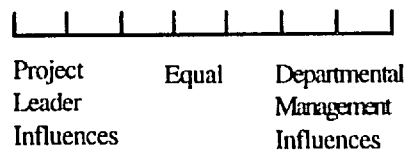
4. Decisions relating to the choice of dosages and delivery systems during preparation of the IND.



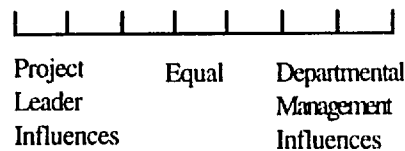
5. Decision to change the preclinical testing plan in response to discovery of possible toxicity or carcinogenicity in animal models.



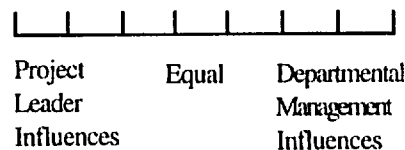
6. Decision to accelerate the project by concurrently conducting preclinical toxicology, pharmacology or other tests.



7. Decision to alter the project by adding or changing preclinical toxicology, pharmacology or other tests in response to an FDA request.



8. The decision to discontinue the project due to perceived toxicity, carcinogenicity, unfavorable therapeutic index etc. in non-human models.



9. The decision to submit the IND.

Project Leader Influences	Equal	Departmental Management Influences
1	1	1

10. The decision to take the proposed new drug into humans (i.e. to initiate Phase I clinical trials).

Project Leader Influences	Equal	Departmental Management Influences
1	1	1

11. Decision to accelerate or decelerate Phase I testing.

Project Leader Influences	Equal	Departmental Management Influences
1	1	1

12. Decision to change the Phase I testing plan due to an FDA request.

Project Leader Influences	Equal	Departmental Management Influences
1	1	1

13. The decision to continue or discontinue the development project between Phase I and Phase II trials.

Project Leader Influences	Equal	Departmental Management Influences
1	1	1

14. Decision to add more non-human model studies in response to perceived lack of adequate preclinical profiling.

Project Leader Influences	Equal	Departmental Management Influences
1	1	1

15. Decisions to submit clinical trial protocols to the FDA subsequent to the IND filing.



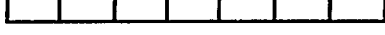



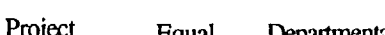

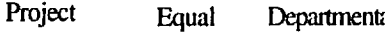
Project Leader Influences	Equal	Departmental Management Influences
1	1	1

16. Decision to alter clinical trial protocol in response to an FDA request.

Project Leader Influences	Equal	Departmental Management Influences
1	1	1

17. Decision to alter the clinical testing plan in response to lack of an adequate number of clinical trial subjects.

Project Leader Influences	Equal	Departmental Management Influences
1	1	1

- | | | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|-------|------------------------------------------|
| 18. Decision to change clinical testing plan due to possible lack of efficacy found during clinical trials. |  | | | |
| | <table border="0" style="width: 100%;"> <tr> <td style="width: 33%;">Project
Leader
Influences</td> <td style="width: 33%; text-align: center;">Equal</td> <td style="width: 33%; text-align: right;">Departmental
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Leader
Influences | Equal | Departmental
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Leader
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| 19. Decision to change clinical testing plan in response to possible toxicity or other side effect found during clinical trials. |  | | | |
| | <table border="0" style="width: 100%;"> <tr> <td style="width: 33%;">Project
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Leader
Influences | Equal | Departmental
Management
Influences |
| Project
Leader
Influences | Equal | Departmental
Management
Influences | | |
| 20. The decision to discontinue the development project due to possible lack of efficacy, toxicity, or side effect found during Phase II clinical trials. |  | | | |
| | <table border="0" style="width: 100%;"> <tr> <td style="width: 33%;">Project
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Leader
Influences | Equal | Departmental
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| Project
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| 21. Decision to scale up manufacturing capacity. |  | | | |
| | <table border="0" style="width: 100%;"> <tr> <td style="width: 33%;">Project
Leader
Influences</td> <td style="width: 33%; text-align: center;">Equal</td> <td style="width: 33%; text-align: right;">Departmental
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Influences | Equal | Departmental
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| 22. Decision to change project schedule due to difficulty obtaining adequate supplies of new drug. |  | | | |
| | <table border="0" style="width: 100%;"> <tr> <td style="width: 33%;">Project
Leader
Influences</td> <td style="width: 33%; text-align: center;">Equal</td> <td style="width: 33%; text-align: right;">Departmental
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Leader
Influences | Equal | Departmental
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| Project
Leader
Influences | Equal | Departmental
Management
Influences | | |
| 23. Decision to accelerate development by moving up the start of Phase III trials. |  | | | |
| | <table border="0" style="width: 100%;"> <tr> <td style="width: 33%;">Project
Leader
Influences</td> <td style="width: 33%; text-align: center;">Equal</td> <td style="width: 33%; text-align: right;">Departmental
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Leader
Influences | Equal | Departmental
Management
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| Project
Leader
Influences | Equal | Departmental
Management
Influences | | |
| 24. Decision to discontinue development for a therapeutic indication during clinical trials. |  | | | |
| | <table border="0" style="width: 100%;"> <tr> <td style="width: 33%;">Project
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Influences</td> <td style="width: 33%; text-align: center;">Equal</td> <td style="width: 33%; text-align: right;">Departmental
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Leader
Influences | Equal | Departmental
Management
Influences |
| Project
Leader
Influences | Equal | Departmental
Management
Influences | | |
| 25. Decision to test the efficacy of the agent for an additional therapeutic indication. |  | | | |
| | <table border="0" style="width: 100%;"> <tr> <td style="width: 33%;">Project
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Influences</td> <td style="width: 33%; text-align: center;">Equal</td> <td style="width: 33%; text-align: right;">Departmental
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Leader
Influences | Equal | Departmental
Management
Influences |
| Project
Leader
Influences | Equal | Departmental
Management
Influences | | |
| 26. The decision to continue or discontinue the development project between Phase II and Phase III trials. |  | | | |
| | <table border="0" style="width: 100%;"> <tr> <td style="width: 33%;">Project
Leader
Influences</td> <td style="width: 33%; text-align: center;">Equal</td> <td style="width: 33%; text-align: right;">Departmental
Management
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Leader
Influences | Equal | Departmental
Management
Influences |
| Project
Leader
Influences | Equal | Departmental
Management
Influences | | |

27. Decision to "unblind" a clinical study.

_ _ _ _ _ _ _						
Project Leader Influences	Equal	Departmental Management Influences				

28. The decision to cut off further data acquisition and submit the NDA.

_ _ _ _ _ _ _						
Project Leader Influences	Equal	Departmental Management Influences				

29. The decision to discontinue the development project during Phase III trials.

_ _ _ _ _ _ _						
Project Leader Influences	Equal	Departmental Management Influences				

30. Decision to alter the marketing claims (i.e. benefits statement) for the proposed new drug.

_ _ _ _ _ _ _						
Project Leader Influences	Equal	Departmental Management Influences				

31. Decisions relating to the choice of personnel from your department.

_ _ _ _ _ _ _						
Project Leader Influences	Equal	Departmental Management Influences				

32. Decisions on the assignment of specific tasks to project team members.

_ _ _ _ _ _ _						
Project Leader Influences	Equal	Departmental Management Influences				

33. Decisions relating to changes in task assignments.

_ _ _ _ _ _ _						
Project Leader Influences	Equal	Departmental Management Influences				

34. Decisions to hire new technical staff.

_ _ _ _ _ _ _						
Project Leader Influences	Equal	Departmental Management Influences				

35. Decisions relating to the selection of outside contractors, if necessary.

_ _ _ _ _ _ _						
Project Leader Influences	Equal	Departmental Management Influences				

36. Decisions relating to interactions with cooperating firms.

_ _ _ _ _ _ _						
Project	Equal	Departmental				
Leader		Management				
Influences		Influences				

37. Decisions to move budget from one task to another task within the same department.

_ _ _ _ _ _ _						
Project	Equal	Departmental				
Leader		Management				
Influences		Influences				

38. Decisions to reassign budget from the activities of one department to those of another department.

_ _ _ _ _ _ _						
Project	Equal	Departmental				
Leader		Management				
Influences		Influences				

39. Decisions to change the project schedule.

_ _ _ _ _ _ _						
Project	Equal	Departmental				
Leader		Management				
Influences		Influences				

40. Decisions to hire new technical staff for the project.

_ _ _ _ _ _ _						
Project	Equal	Departmental				
Leader		Management				
Influences		Influences				

41. A decision to seek additional funding for the development project.

_ _ _ _ _ _ _						
Project	Equal	Departmental				
Leader		Management				
Influences		Influences				

42. Decisions on the acquisition of equipment needed for the completion of the project.

_ _ _ _ _ _ _						
Project	Equal	Departmental				
Leader		Management				
Influences		Influences				










43. Decisions on promotions for project team members.







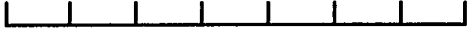
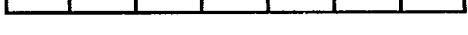

_ _ _ _ _ _ _						
Project	Equal	Departmental				
Leader		Management				
Influences		Influences				

44. Decisions on pay increases for project team members.

_ _ _ _ _ _ _						
Project	Equal	Departmental				
Leader		Management				
Influences		Influences				

On the following questions, please indicate the degree to which each statement accurately describes your project director.

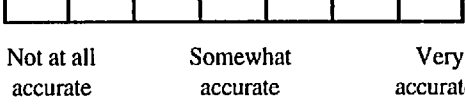
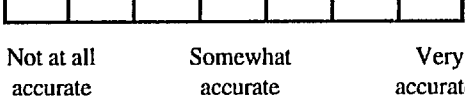
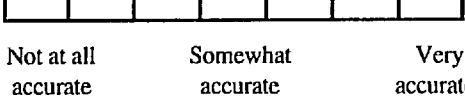
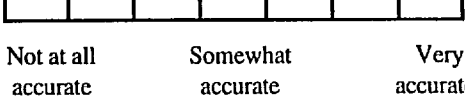
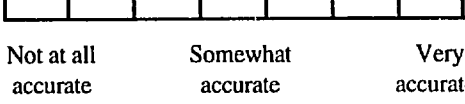
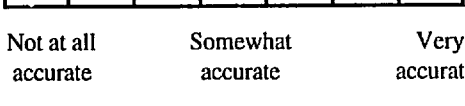
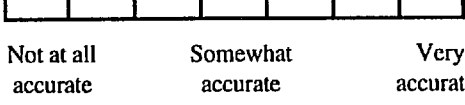
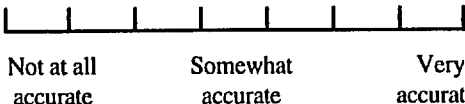
- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| 45. My project director has an excellent understanding of the technical aspects of <u>non-human</u> model testing issues in drug development. | 
Not at all accurate Somewhat accurate Very accurate |
| 46. My project director has an excellent understanding of the technical aspects of <u>clinical</u> testing issues in drug development. | 
Not at all accurate Somewhat accurate Very accurate |
| 47. My project director has an excellent understanding of the technical aspects of the work performed for the project by me and others in my department. | 
Not at all accurate Somewhat accurate Very accurate |
| 48. My project director keeps current and is well informed about the latest technical advances in his or her field. | 
Not at all accurate Somewhat accurate Very accurate |
| 49. My project director encourages team members to participate in important decisions. | 
Not at all accurate Somewhat accurate Very accurate |
| 50. My project director has an excellent understanding of the regulatory issues involved in drug development. | 
Not at all accurate Somewhat accurate Very accurate |
| 51. My project director is proactive when dealing with project issues. | 
Not at all accurate Somewhat accurate Very accurate |
| 52. My project director has the ability to recognize and mediate conflicts between groups or individuals. | 
Not at all accurate Somewhat accurate Very accurate |
| 53. My project director has considerable influence which is useful in obtaining resources necessary to carry out this project effectively. | 
Not at all accurate Somewhat accurate Very accurate |

54. My project director has significant influence within the overall organization. 
 Not at all accurate Somewhat accurate Very accurate
55. My project director has significant influence within my department. 
 Not at all accurate Somewhat accurate Very accurate
56. My project director has important and useful contacts with other R&D professionals outside this organization. 
 Not at all accurate Somewhat accurate Very accurate
57. My project director has important and useful contacts with other R&D professionals within this organization. 
 Not at all accurate Somewhat accurate Very accurate
58. My project director is an excellent sounding board for new ideas. 
 Not at all accurate Somewhat accurate Very accurate
59. My project director assigns me to jobs or tasks on which I am challenged professionally to perform well. 
 Not at all accurate Somewhat accurate Very accurate
60. My project director maintains high standards of performance. 
 Not at all accurate Somewhat accurate Very accurate
61. My project director is effective at providing appreciation and recognition for work well done. 
 Not at all accurate Somewhat accurate Very accurate
62. My project director has been very instrumental in my professional development and I have learned a great deal from him or her. 
 Not at all accurate Somewhat accurate Very accurate
63. How long have you worked in your department? _____ years
 How long have you worked on this project? _____ years
 How long working for this project director? _____ years
 What portion of your time is spent on this project? _____ %

In what department do you work? (Please specify.) _____

Approximately how many people (including yourself) in your department work on tasks related to this project? _____

What degree do you hold? BS, BA ___ MS, MA ___ MBA ___ PhD ___ MD ___

64. Goals for this development project are clearly defined and communicated to team members. 
65. Team members are committed strongly to a shared vision of the goals for this project. 
66. Within my department this project has very high priority. 
67. Team members are well informed regarding the critical path for meeting the project schedule. 
68. My role as a development team member is frequently in conflict with my role as a member of my department. 
69. Development teams have significant autonomy to plan and carry out their mission in this organization. 
70. There are clear criteria for assessing performance of development teams in this organization. 
71. The individual rewards I receive in this organization are linked strongly to the performance of this development team. 

72. Information needed by the team is readily obtained from sources within my department.

Not at all accurate Somewhat accurate Very accurate

73. Communications between the team and other groups within this organization are open and cooperative.

Not at all accurate Somewhat accurate Very accurate

74. Team members have adequate expertise in their functional areas to accomplish project tasks effectively.

Not at all accurate Somewhat accurate Very accurate

75. Members of this development team exhibit high morale.

Not at all accurate Somewhat accurate Very accurate

76. There is clear senior management support for this project.

Not at all accurate Somewhat accurate Very accurate

77. How would you assess the performance of this project overall?

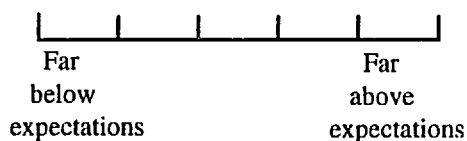
Poor Good Excellent

Thank you for your cooperation!

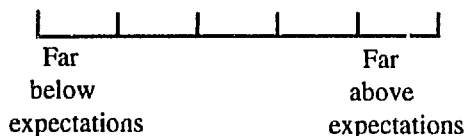
Appendix B
Senior Manager Survey

Development Project A

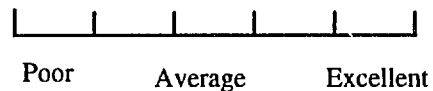
1. How would you rate the **schedule** performance of this development project relative to your initial expectations for the project?



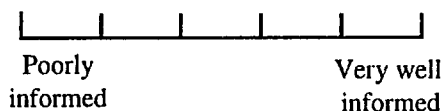
2. How would you rate the **overall** performance of this development project relative to your initial expectations for the project?



3. How would you rate the **project director's performance** on this development project to date?



4. Do you feel well informed regarding the progress of this development project?



5. What priority is this project?

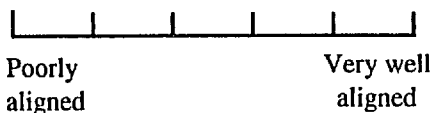
Highest priority _____

Average priority _____

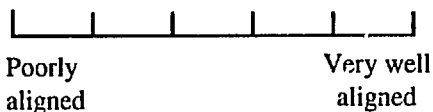
High priority _____

Below average priority _____

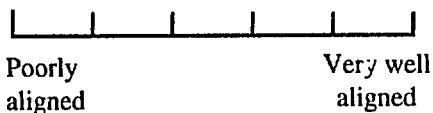
6. Is this drug well aligned with the overall R&D strategy of the firm?



7. Is this drug well aligned with firm capabilities?



8. Is this drug well aligned with market needs?



9. How profitable do you expect this drug to be if it makes it to market?

Not profitable _____

Moderately profitable _____

Slightly profitable _____

Highly profitable _____

Appendix C
Correlation Table

- - Correlation Coefficients - -

	ADF1	ADF2	ADF3	ADF4	ADF5	ADF6
ADF1	1.0000 (45) P= .	.0871 (45) P= .569	.4630 (45) P= .001	.5036 (45) P= .000	.0277 (45) P= .857	.1152 (45) P= .451
ADF2	.0871 (45) P= .569	1.0000 (45) P= .	.1643 (45) P= .281	.5002 (45) P= .000	-.1543 (45) P= .312	.5630 (45) P= .000
ADF3	.4630 (45) P= .001	.1643 (45) P= .281	1.0000 (45) P= .	.5509 (45) P= .000	.4083 (45) P= .005	.1442 (45) P= .345
ADF4	.5036 (45) P= .000	.5002 (45) P= .000	.5509 (45) P= .000	1.0000 (45) P= .	.2711 (45) P= .072	.3364 (45) P= .024
ADF5	.0277 (45) P= .857	-.1543 (45) P= .312	.4083 (45) P= .005	.2711 (45) P= .072	1.0000 (45) P= .	.0470 (45) P= .759
ADF6	.1152 (45) P= .451	.5630 (45) P= .000	.1442 (45) P= .345	.3364 (45) P= .024	.0470 (45) P= .759	1.0000 (45) P= .
ADF7	.1904 (45) P= .210	.4959 (45) P= .001	.1481 (45) P= .331	.3692 (45) P= .013	.0435 (45) P= .777	.8074 (45) P= .000
APF1	.0042 (45) P= .978	-.1541 (45) P= .312	.0067 (45) P= .965	-.0191 (45) P= .901	-.0626 (45) P= .683	-.1238 (45) P= .418
APF2	-.6018 (45) P= .000	.0894 (45) P= .559	-.4414 (45) P= .002	-.4618 (45) P= .001	-.2731 (45) P= .070	.0262 (45) P= .864
APF3	-.1754 (45) P= .249	-.1609 (45) P= .291	-.0523 (45) P= .733	-.1349 (45) P= .377	-.2375 (45) P= .116	-.2270 (45) P= .134
APF4	-.2910 (45) P= .052	-.0082 (45) P= .957	-.1152 (45) P= .451	-.0942 (45) P= .538	-.0210 (45) P= .891	-.1214 (45) P= .427

(Coefficient / (Cases) / 2-tailed Significance)

" . " is printed if a coefficient cannot be computed

- - Correlation Coefficients - -

	ADF1	ADF2	ADF3	ADF4	ADF5	ADF6
ATF1	-.4517 (45) P= .002	.0436 (45) P= .776	-.1784 (45) P= .241	-.2545 (45) P= .092	-.0113 (45) P= .941	-.0993 (45) P= .516
AE1	-.0800 (45) P= .602	.1541 (45) P= .312	.0477 (45) P= .756	-.2579 (45) P= .087	-.0614 (45) P= .689	.1474 (45) P= .334
AE2	-.0715 (45) P= .641	.2104 (45) P= .165	.0387 (45) P= .800	-.1470 (45) P= .335	-.1096 (45) P= .473	.1804 (45) P= .236
AE3	.0030 (45) P= .984	-.0783 (45) P= .609	-.0870 (45) P= .570	-.1298 (45) P= .395	-.1102 (45) P= .471	-.0371 (45) P= .809
AE5	.0018 (45) P= .991	.0348 (45) P= .820	-.0237 (45) P= .877	.0533 (45) P= .728	.0628 (45) P= .682	.1230 (45) P= .421
EARLATE	-.1072 (45) P= .484	-.2842 (45) P= .059	.0649 (45) P= .672	-.1698 (45) P= .265	.1451 (45) P= .342	-.2177 (45) P= .151
NUMGR	-.1784 (45) P= .241	-.3536 (45) P= .017	-.1552 (45) P= .309	-.4723 (45) P= .001	.1773 (45) P= .244	.0728 (45) P= .635

(Coefficient / (Cases) / 2-tailed Significance)

" . " is printed if a coefficient cannot be computed

- - Correlation Coefficients - -

	ADF7	APF1	APF2	APF3	APF4	ATF1
ADF1	.1904 (45) P= .210	.0042 (45) P= .978	-.6018 (45) P= .000	-.1754 (45) P= .249	-.2910 (45) P= .052	-.4517 (45) P= .002
ADF2	.4959 (45) P= .001	-.1541 (45) P= .312	.0894 (45) P= .559	-.1609 (45) P= .291	-.0082 (45) P= .957	.0436 (45) P= .776
ADF3	.1481 (45) P= .331	.0067 (45) P= .965	-.4414 (45) P= .002	-.0523 (45) P= .733	-.1152 (45) P= .451	-.1784 (45) P= .241
ADF4	.3692 (45) P= .013	-.0191 (45) P= .901	-.4618 (45) P= .001	-.1349 (45) P= .377	-.0942 (45) P= .538	-.2545 (45) P= .092
ADF5	.0435 (45) P= .777	-.0626 (45) P= .683	-.2731 (45) P= .070	-.2375 (45) P= .116	-.0210 (45) P= .891	-.0113 (45) P= .941
ADF6	.8074 (45) P= .000	-.1238 (45) P= .418	.0262 (45) P= .864	-.2270 (45) P= .134	-.1214 (45) P= .427	-.0993 (45) P= .516
ADF7	1.0000 (45) P= .	-.0662 (45) P= .666	.0768 (45) P= .616	-.1392 (45) P= .352	-.0682 (45) P= .656	.0042 (45) P= .978
APF1	-.0662 (45) P= .666	1.0000 (45) P= .	.4108 (45) P= .005	.7304 (45) P= .000	.7304 (45) P= .000	.2365 (45) P= .118
APF2	.0768 (45) P= .616	.4108 (45) P= .005	1.0000 (45) P= .	.5156 (45) P= .000	.6520 (45) P= .000	.5256 (45) P= .000
APF3	-.1392 (45) P= .362	.7304 (45) P= .000	.5156 (45) P= .000	1.0000 (45) P= .	.7645 (45) P= .000	.3666 (45) P= .013
APF4	-.0682 (45) P= .656	.7304 (45) P= .000	.6520 (45) P= .000	.7645 (45) P= .000	1.0000 (45) P= .	.5208 (45) P= .000

(Coefficient / (Cases) / 2-tailed Significance)

" . " is printed if a coefficient cannot be computed

- - Correlation Coefficients - -

	ADF7	APF1	APF2	APF3	APF4	ATF1
ATF1	.0042 (45) P= .978	.2365 (45) P= .118	.5256 (45) P= .000	.3666 (45) P= .013	.5208 (45) P= .000	1.0000 (45) P= .
AE1	.1978 (45) P= .193	.1079 (45) P= .480	.2704 (45) P= .072	.0772 (45) P= .614	.1758 (45) P= .248	.4072 (45) P= .005
AE2	.2403 (45) P= .112	.0840 (45) P= .583	.2497 (45) P= .098	.1055 (45) P= .490	.1836 (45) P= .227	.4276 (45) P= .003
AE3	.1055 (45) P= .490	.2494 (45) P= .098	.2667 (45) P= .077	.2207 (45) P= .145	.2640 (45) P= .080	.2028 (45) P= .181
AE5	-.1091 (45) P= .476	-.0448 (45) P= .770	-.2238 (45) P= .139	-.2956 (45) P= .049	-.2272 (45) P= .133	-.1524 (45) P= .317
EARLATE	-.1809 (45) P= .234	.0450 (45) P= .769	.1609 (45) P= .291	.3108 (45) P= .038	.2168 (45) P= .153	.1410 (45) P= .355
NUMGR	.1405 (45) P= .357	.2013 (45) P= .185	.3232 (45) P= .030	.1815 (45) P= .233	.2719 (45) P= .071	.4060 (45) P= .006

(Coefficient / (Cases) / 2-tailed Significance)

" . " is printed if a coefficient cannot be computed

- - Correlation Coefficients - -

	AE1	AE2	AE3	AE5	EARLATE	NUMGR
ADF1	-.0800 (45) P= .602	-.0715 (45) P= .641	.0030 (45) P= .984	.0018 (45) P= .991	-.1072 (45) P= .484	-.1784 (45) P= .241
ADF2	.1541 (45) P= .312	.2104 (45) P= .165	-.0783 (45) P= .609	.0348 (45) P= .820	-.2842 (45) P= .059	-.3536 (45) P= .017
ADF3	.0477 (45) P= .756	.0387 (45) P= .800	-.0870 (45) P= .570	-.0237 (45) P= .877	.0649 (45) P= .672	-.1552 (45) P= .309
ADF4	-.2579 (45) P= .087	-.1470 (45) P= .335	-.1298 (45) P= .395	.0533 (45) P= .728	-.1698 (45) P= .265	-.4723 (45) P= .001
ADF5	-.0614 (45) P= .689	-.1096 (45) P= .473	-.1102 (45) P= .471	.0628 (45) P= .682	.1451 (45) P= .342	.1773 (45) P= .244
ADF6	.1474 (45) P= .334	.1804 (45) P= .236	-.0371 (45) P= .809	.1230 (45) P= .421	-.2177 (45) P= .151	.0728 (45) P= .635
ADF7	.1978 (45) P= .193	.2403 (45) P= .112	.1055 (45) P= .490	-.1091 (45) P= .476	-.1809 (45) P= .234	.1405 (45) P= .357
APF1	.1079 (45) P= .480	.0840 (45) P= .583	.2494 (45) P= .098	-.0448 (45) P= .770	.0450 (45) P= .769	.2013 (45) P= .185
APF2	.2704 (45) P= .072	.2497 (45) P= .098	.2667 (45) P= .077	-.2238 (45) P= .139	.1609 (45) P= .291	.3232 (45) P= .030
APF3	.0772 (45) P= .614	.1055 (45) P= .490	.2207 (45) P= .145	-.2956 (45) P= .049	.3108 (45) P= .038	.1815 (45) P= .233
APF4	.1758 (45) P= .248	.1836 (45) P= .227	.2640 (45) P= .080	-.2272 (45) P= .133	.2168 (45) P= .153	.2719 (45) P= .071

(Coefficient / (Cases) / 2-tailed Significance)

" . " is printed if a coefficient cannot be computed

- - Correlation Coefficients - -

	AE1	AE2	AE3	AE5	EARLATE	NUMGR
ATF1	.4072 (45) P= .005	.4276 (45) P= .003	.2028 (45) P= .181	-.1524 (45) P= .317	.1410 (45) P= .355	.4060 (45) P= .006
AE1	1.0000 (45) P= .	.9085 (45) P= .000	.6508 (45) P= .000	-.4324 (45) P= .003	-.0408 (45) P= .790	.3330 (45) P= .025
AE2	.9085 (45) P= .000	1.0000 (45) P= .	.6651 (45) P= .000	-.4530 (45) P= .002	.0046 (45) P= .976	.2866 (45) P= .056
AE3	.6508 (45) P= .000	.6651 (45) P= .000	1.0000 (45) P= .	-.4129 (45) P= .005	.2259 (45) P= .136	.1691 (45) P= .267
AE5	-.4324 (45) P= .003	-.4530 (45) P= .002	-.4129 (45) P= .005	1.0000 (45) P= .	-.1644 (45) P= .281	-.2673 (45) P= .076
EARLATE	-.0408 (45) P= .790	.0046 (45) P= .976	.2259 (45) P= .136	-.1644 (45) P= .281	1.0000 (45) P= .	.2437 (45) P= .107
NUMGR	.3330 (45) P= .025	.2866 (45) P= .056	.1691 (45) P= .267	-.2673 (45) P= .076	.2437 (45) P= .107	1.0000 (45) P= .

(Coefficient / (Cases) / 2-tailed Significance)

" . " is printed if a coefficient cannot be computed