

**The Differences Between
Discovery and Development
Project & Portfolio Management
Come Down to the Level of Risk**

The Differences between Discovery and Development Project/Portfolio Management Come Down to the Level of Risk

Did you ever wonder why project and portfolio management in Bio/pharmaceutical Discovery is so different from Bio/pharmaceutical Development?ⁱ There are very good reasons for those differences and these stem from the different levels of risk inherent in projects in Discovery versus projects in Development.ⁱⁱ In this paper we will examine how this all comes about and then consider the ramifications. We will see why the solution to a project or portfolio management problem in Discovery could be different from a solution to the same project or portfolio management problem in Development.

Goal to Reduce Risk & Increase Value. The Project Management Institute defines Risk Management as “the systematic process of identifying, analyzing, and responding to project risk. It includes maximizing the probability and consequences of positive events and minimizing the probability and consequences of adverse events to project objectives.”ⁱⁱⁱ Fewer risks in a project mean greater probability of success (POS).^{iv} As the project team works to reduce risk, the total project cost increases, but because the POS increases, the potential value of the project and corporate commitment increases. [Figure 1](#) attempts to display these relationships pictorially. At each stage of Discovery and Development, work is performed to reduce risk and increase value. Even though, the work at any stage adds cost to the overall project, the latter stages of work are far more costly than earlier stages. Organizational commitment tends to increase as potential value increases.

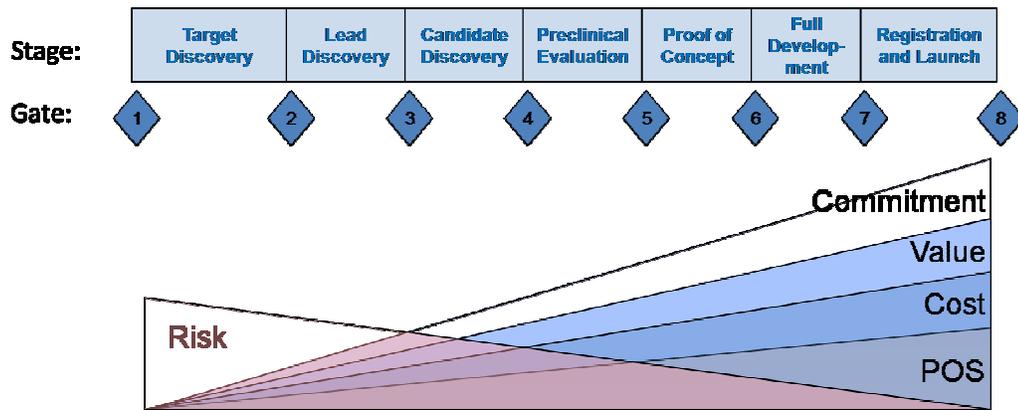


Figure 1, Relative relationship of Risk to POS, Value, Cost and Commitment^v

Risk in Discovery vs. Development. At the beginning stages of Discovery, there is scant evidence that a proposed therapy might work. Those blockbusters that command billions of dollars in sales today were in with the pack of wild ideas at the beginning of Drug Discovery. Risk that the proposed therapy might come to fruition is so pervasive in Drug Discovery, it is often not discussed as such – it’s seen as “work”. At the beginning of Discovery the risk of

failure in the clinic is part of the aggregate risk that the new project faces, even though work to reduce the clinical risk won't occur until a candidate is identified. Every experiment or trial performed along the way addresses a single component of the aggregate project risk.^{vi} In Development (esp. late stage), there is a mounting body of evidence that the proposed therapy might succeed. Risk is less obvious, so it needs special formal attention. But it can be tightly managed.

Value in Discovery vs. Development. Discovery is the start of the value chain, but given the low POS, quantitative estimations of value are meaningless. In Development (esp. late stage), because most of the risk has been dispensed and is more readily defined, determinations of Estimated Net Present Value (ePNV) are important. The potential value of the Discovery portfolio, however, is not ignored, and as we will discuss, can be dealt with in an appropriate manner.

Program/Project Authority versus Organizational Structure. The extent to which the project leaders manage the resources deployed to their projects can vary dramatically according to the impact of the projects on the corporation. Matrix Project Leader authority and effectiveness tends to vary from "Part-Time Coordinator" to a fully articulated professional "Project Management Office",^{vii} depending on the amount of risk, the relative value, cost and commitment the company foresees with any given project, Figure 2.

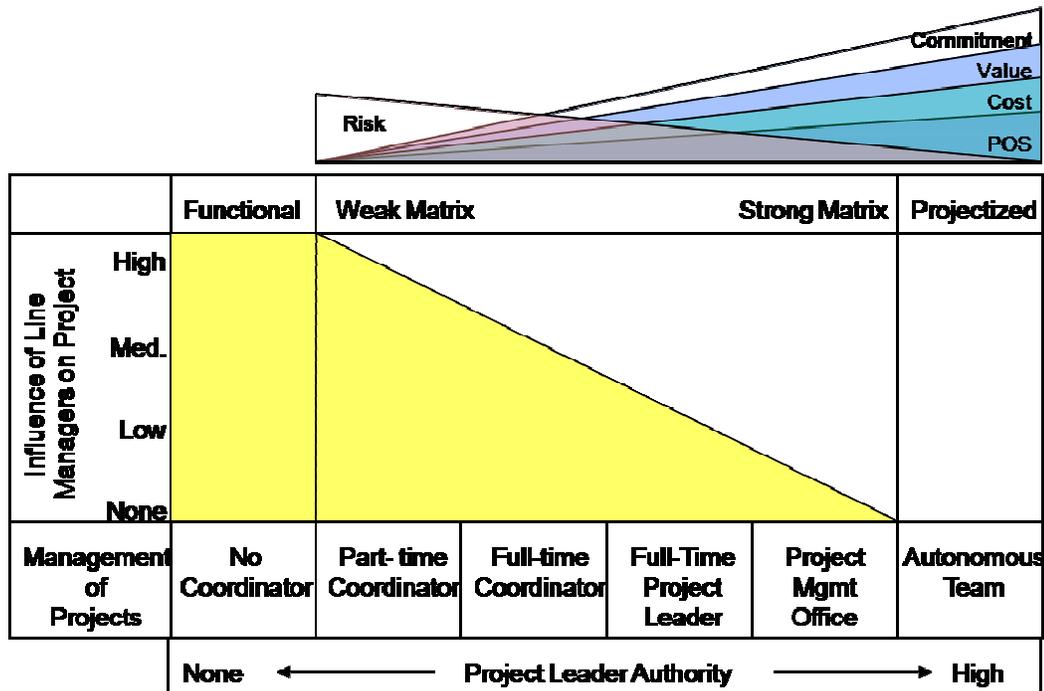


Figure 2, Variation of Project Leader Authority^{viii}

Thus, when aggregate project risk is high and potential project value is low, the staff that works on projects tends to reside within line departments, and the line managers are likely to have a

large influence on the conduct of the project. For this reason the project leader is likely to be a part-time coordinator. The work is considered to be performed in the line department on behalf of the project.

On the other hand, when the potential project value is high, and the aggregate project cost is high, the company is likely to take the outcome of the project very seriously and will likely commit resources to full-time professional project leadership of the project, and if there are many such projects the company will establish a project office to manage the projects. In extreme instances, the company may dissolve the matrix of line departments and assign all resource across the set of projects.

Discovery vs. Development. In Bio/pharmaceutical companies, project Leader authority and effectiveness tends to increase from early Discovery to final Drug Development,^{ix} Figure 3. Thus in early Target Discovery, there may be no formally recognized project team or project leader, but usually once there is a commitment to screening, a project is organized and a part-time project leader named. Project leaders in the Lead Discovery and Lead Optimization phases tend to be part-time or full-time coordinators but not professional project leaders. For the reasons described above, the line managers play a large role in the conduct of the Discovery project. Once candidate selection has occurred, the project is typically managed by a full-time professional project leader. The small set of projects that reach Full Development, especially those with block-buster potential, may be run as a project office, or possibly as autonomous teams, with direct reporting to the most senior managers.

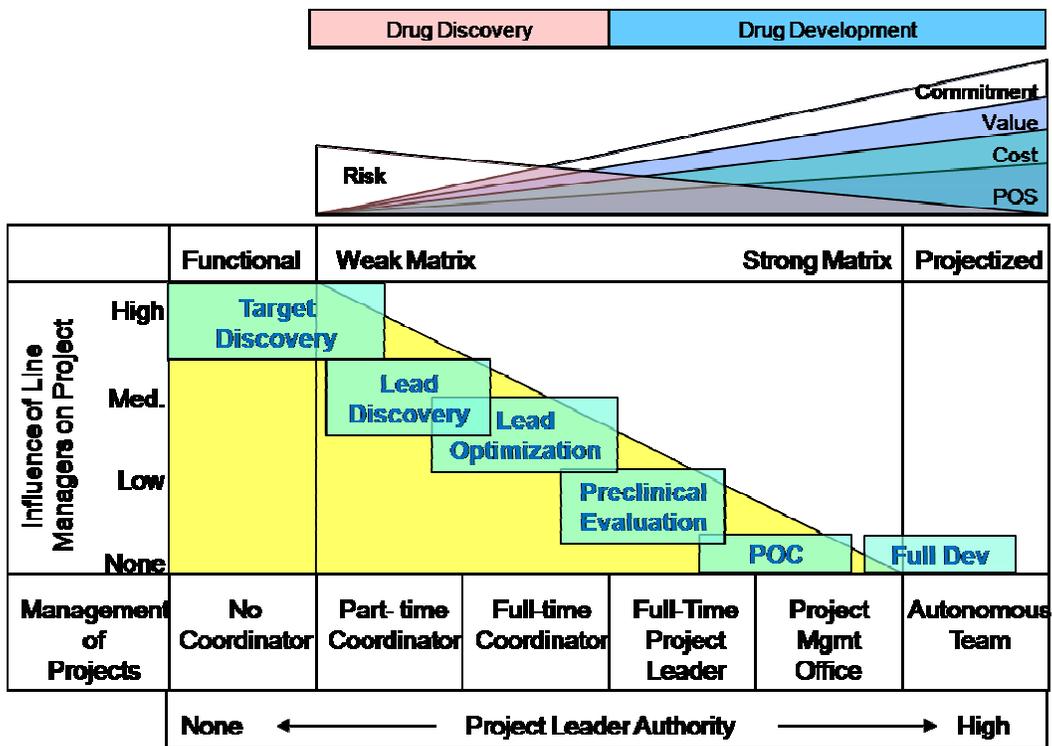


Figure 3, Variation of Project Leader Authority in Bio/pharmaceutical Companies

The level of training and certification of the full-time project leader are likely to vary among companies, some requiring professional certification from a group like the Project Management Institute, others seeing it as 'nice to have'. Here 'professional' means that the project leader position is recognized by the company as being filled by someone with the unique skill set of a project leader, distinguishable from any other scientific or business training the individual may have.

Inevitably, the style of project leadership is likely to vary from early Discovery to final Drug Development, as outlined below.

Discovery Project Leader

- Volunteer^x from line departments
- Averse to detailed project tracking & reporting – keep it simple (Gantt charts a tough sell)
- Line managers needs to value this work
- The PL will be beholden to the line managers for resource and delivery dates

Development Project Leader

- Professional project leader
- Appreciates the value of project tracking & reporting (Gantt charts a minimal necessity)
- Line managers will be influential in early Development.
- Project more important than line

Both need training in their jobs, especially to the specific needs of the company.

This fundamental difference in Project leader authority due to the different levels of Risk, POS, cost, value, and corporate commitment found in a Discovery project versus a Development project influences every aspect of project and portfolio management on both sides of the R&D pipeline.

Project and portfolio management is just as important in Discovery as it is in Development, especially since the Development portfolio is determined in Discovery. The fact of high attrition necessitates a larger Discovery portfolio than a Development portfolio. But we have just discussed some good reasons why project and portfolio management in Discovery do not mirror that in Development. It is likely that the solution to a project or portfolio management problem in Discovery will differ from the solution to the same project or portfolio management problem in Development.

If you would like to know more about the differences between Discovery and Development Project and Portfolio Management, and how current practice varies between the two sides of the R&D pipeline, we encourage you to visit our new website.

www.portfoliomanagementsolutions.com

This is set up as a blog so you can add your comments about Best Practice as you know it in your company.

If you would like to discuss how best practice can be brought to your project and portfolio management organization in your company, please contact us at

www.jamessamanenconsulting.com

We would be delighted to help bring best practice to your fit for purpose solutions to bio/pharmaceutical project and portfolio management!

ⁱ Bio/pharmaceutical here includes both small molecule and protein agent and is intended to include companies that pursue both types of agents as opposed to the so-called biopharmaceutical companies who specialize in therapies based on protein agents.

ⁱⁱ The Project Management Institute distinguishes between a project and a program as follows: “Programs have a larger scope (than projects) and provide more significant benefits (Section 1.3, The Standard for Portfolio Management, 2nd Ed. p. 6, Project Management Institute, 2008). Typically a single development project focuses on one clinical candidate, and one discovery program begets many clinical candidates. In this discussion, the differences between programs and projects are sufficiently few that in this discussion all such efforts will be considered projects.

ⁱⁱⁱ A Guide to the Project Management Book of Knowledge (PMBOK Guide) 2000 edition, Chapter 11, p. 127.

^{iv} The aggregate project risk differs from the risk per project phase – the risk addressed in one phase differs from another. Risk is what can go wrong; probability of failure is the likelihood it will go wrong. Both need to be considered in light of the impact or severity of the failure (see www.decisionability.com). It could be argued that the impact of risk in late stage clinical trials is greater than the impact of risk in early discovery experiments.

^v The wedges depicting decrease risk, increasing POS, cost, value and commitment are pictorial representations and not related to data.

^{vi} A potential outcome of any project risk is project failure - we do know about attrition in the portfolio (see www.portfoliomagementsolutions.com). But project success or failure is not proportional to project risk. Some risk never comes to fruition. Low risk projects can fail or be terminated for reasons not related to risk.

^{vii} Section 1.9.1 The Standard for Portfolio Management, 2nd Ed. P. 17, Project Management Institute, 2008.

^{viii} The wedge depicting the decreasing influence of line managers on a project with a weak matrix as opposed to a project with a strong matrix is a pictorial representation and not related to data.

^{ix} Any particular company may have its own reasons for increasing or decreasing project leader authority on any project in any phase.

^x The consequences of a volunteer scientist project leaders may include less training, less visibility and accountability (not sure of their role), more interested in exploring science than meeting timelines.