

Project Management

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Introduction

The word project originates from latin, *projectum*, something that comes before everything else happens. Projects may be big like building a bridge or small like writing a paper.

Projects are characterised by:

- *Objective*
- *Timeline*
- *Uncertain factors and risks*
- *Budget and resource consumption*
- *New experiences*
- *New results*
- *Cross disciplinary work*

A project is a unique task designed to attain a specific result over a specified time period.

The project foundation will include the overall purpose of the project and more concrete goals of the project together with a stakeholder analysis, a budget and a responsibility chart for activities.

A project may engage 1 person, a few persons or many persons in one or more organisations.

A more complicated project will require more formalized project control processes monitoring achievements (milestones), time estimations, cost and resource estimates. Organisation of the project means clarification of all roles and responsibilities, defining decision-making responsibilities, communication policy and maintaining flexibility in planning and execution.

In an ongoing project the extent of product features and product changes as well as the extent of production process changes allowed needs to be defined.

There are typically a number of project phases as planning, execution, continuous evaluation, completion and possibly a subsequent maintenance phase. These phases constitute the lifecycle of the project.

Two very different perspectives on project execution are outlined in agile project model and in the waterfall project model. The waterfall model focus on detailed planning of the entire project while the agile model focus on planning for shorter time horizons and maintaining more flexibility.

A responsibility chart shows who has the responsibility for the different tasks.

Responsibility chart

	Project manager	Team member A	Team member B	Line managers
Ressource forecast	X			
Budget	X			
Timeplan	X			
Technical assessment		X		
Production assessment			X	
Milestone report	X			
Financial updates			X	
Technical validation		X		
Ressource allocation				X

Main decisions gates for the project can be outlined in a project plan.

Main decision gates in drug development

Activity	Decision gate
Identify therapeutic target	Approval of therapeutic target
Identify lead chemical compound	Approval of lead
Pharmacology, toxicology, animal models	Approval of lead development
Preclinical studies	Go for First Human dose
Phase I	Approval of safety, tolerance & pharmacology data
Phase II	Approval of dosing choice
Phase III	Approval of Efficacy and safety data
Regulatory filings	If approved, approval of the marketing and launch plan
Marketing activities	Approval of the lifecycle strategy

In complicated projects, reporting and control are essential. Reporting is describing what has occurred and what the situation is. Control is doing something about what the report show.

Management styles may be described by Adizes model. The model describes a person's management styles and may be used to achieve balance among the management roles of the so-called PAEI:

- P) Producing results for which the organization exists
- A) Administering for systematized efficiency
- E) Entrepreneurship for proactive change
- I) Integrating the parts of the organization for long-term viability.

Milestones.

Milestones outline targeted completion of specified tasks which serves as a foundation for new subsequent activities. A milestone is a checkpoint. A goal should be presented in such a way that one could answer yes or no to the question: *Has the goal been achieved?* A goal related to the result of activities and not the activities itself. Goals form a hierarchy: those at lower levels are defined more precisely and elaborate the goals of the levels above.

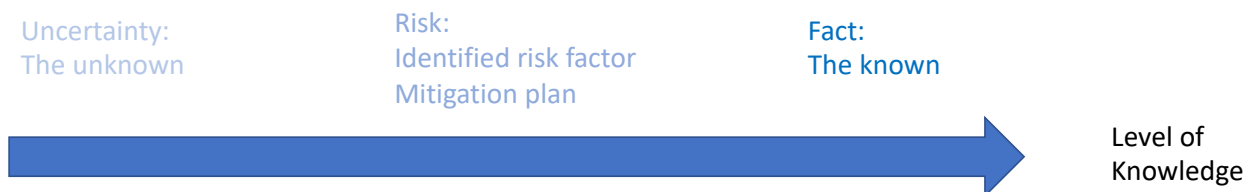
Goals may be SMART, thus they may be Specific, Measurable, Acceptable, Realistic and Time-limited.

Many organisations operate with Balanced Scorecards. Balanced Scorecards are used for assessments of the current status of defined activities, risks, stakeholders, quality, economy etc.

A Gantt (bar) chart outlines activities and their respective duration and is commonly used for planning purposes.

Risk assessment is also central in any project management activity. Risks may be outlined in risk grids focusing on the likelihood of the risk materializing and the severity of their consequences. In addition, uncertainties need to be assessed. They may relate to external and internal conditions. Both risks and uncertainties may be addressed by mitigation plans.

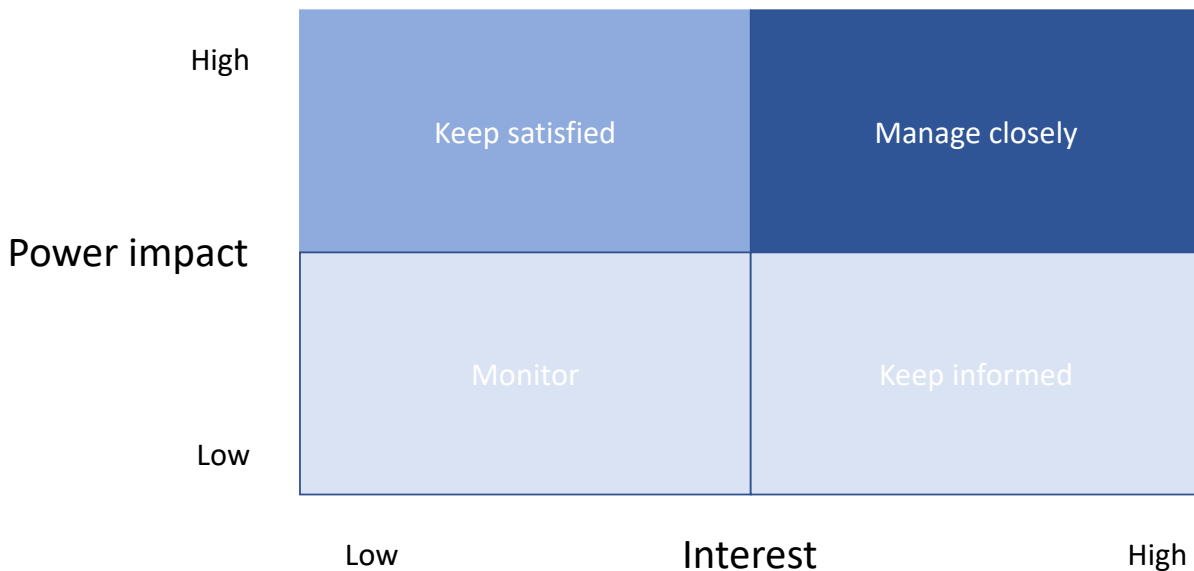
The level of knowledge to risks and uncertainties are different.



Stakeholders.

Stakeholders needs to be identified and their importance assessed. Internal stakeholders are individuals and groups who are actively involved in the project. External stakeholders are individuals and groups who are positively or negatively affected by the project. Common stakeholders are top management, users, competitors, suppliers, customers and media. The importance of stakeholders may be assessed in relation to the interest of stakeholders in the project versus the impact of stakeholder decisions in the project. Project managers aspire to get support from all stakeholders.

Stakeholder mapping



Project managers and project team members are often organized as a matrix organization. In such an organization, team members work for the project manager in one or more project but they refer to their departmental manager typically in a functional unit such as research, production, finance and sales. The departmental manager hire and fire people, decide on salary levels etc.

A project manager also needs a communication plan. The communication plan specifies what is the right information to the right people at the right time in a useful format. Formal and informal methods for distributing information needs to be considered.