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Risk Management in Project Planning for Life Science R&D: An Integration of the NTCP Framework

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Abstract. As with many industries, the early life science R&D drug discovery sector is facing growing pressure and higher demands on products in terms of cost, quality, and time-to-market. Additionally, the complexity of involved targets and systems, requirements for rapid, safe, and developable candidates are increasing. The drug discovery market, often regarded as rather conservative, relies more and more on advanced technologies. It is therefore a significant task for suppliers to create good solutions that meet customer requirements. The life science industry has a long tradition of using projects as the preferred method to manage these complex systems developments, such as the production of target proteins, screening of compounds, and follow-up of hit compounds. When applying the project approach, the level of uncertainty is usually high, and the risk of those uncertainties must be managed starting in the early planning phase. Thus, this paper focuses on the issue of how to manage risks in the early project planning phase. We first review state-of-the-art practices in risk management for complex systems project management and identify an important framework, Novelty-Technology-Cost-Pace (NTCP), and apply it to successful risk management for early life science projects. Through an in-depth case study in the life science industry, we demonstrate a systemic integration of the NTPC framework into project planning.

Keywords. Risk management, Project planning, NTCP framework, Complex systems development.

Introduction

Company. The company is a small and medium company that provides early-stage hit identification and other drug discovery services to biotechnology and pharmaceutical companies. The company, located in Buffalo NY had been operating in a global market for more than 5 years and had 26 employees with a revenue of nearly $4 million per year. Customers were typically Series A stage biotech companies, and large pharmaceutical interests. Projects ranged from relatively simple recombinant protein production with precedence in peer-reviewed scientific journals, to full drug discovery efforts on novel targets, which required significant scientific development efforts with technical feasibility concerns.

Background. As the company operates in a project-based industry, many processes involved with developing, configuring, and delivering complex systems solutions are managed by projects. Developing complex system solutions usually takes the form of deliverable milestones or development projects in the company. The former focuses on providing specialized materials or pieces of knowledge produced by the inspection of such materials, meeting customer and regulatory requirements. The latter is most often about developing new or improved features or solutions, whereby innovation is essential with this project type. Our study mainly focuses on the latter.

A project is a temporary effort (PMBoK, 2017), with a defined goal, time frame and budget. It is most often formed by multi-disciplined resources that are temporarily put together for the project work. The case company's matrix organization means the project resources work in different function-specific departments while being engaged in the project.

The Case. Most projects at the company involve activities performed by multiple functional groups, spanning different disciplines (i.e. Project leadership, Molecular Biology and Expression, Protein Purification, Structural Biology, and Biophysics). The company was organized in a matrix environment, which means that many projects are running concurrently with the same resources. This means that project teams may be different from project to project and that group experience and dynamics may differ. This way of organizing the project team is not novel yet has many benefits for this specific type of work. This organization allows the project to engage the necessary type of resources and experience when needed. However, there are some drawbacks. For instance, the resources needed may be oversubscribed or involved with higher priority work, and communication can become complex to organize when the same group of people are working on multiple projects, including process improvement and new technology development.

A development project is an investment into process improvement, new technology adoption/development, or team training, with the idea of enabling increased future profitability, either by cost reduction or new revenue generation. These investments present significant risks that need to be mitigated at the very front end of the project, due to the inherent uncertainty of future returns from investments.

Challenge. Every development project is different. Each has its challenges related to the novelty of the desired complex system(s). Different unknowns bring uncertainty to the project, in the forms of technology, market, user expectations, costs, time, etc. If the unknowns are not well managed, they might jeopardize the project success, such as cost and time overruns, which impact the justification of the project development and produce new risks.

One common way to handle the unknowns in a project is to undertake risk management (PMBoK, 2017; ISO 31000, 2018). This effort is usually a semi-structured way of identifying and mitigating the threats imposed by the uncertainties and nourishing the development opportunities. Risk management is a generic and powerful instrument for a project success, but it depends heavily on one condition that the project team understands the project. A skilled project manager with an experienced team is more likely to identify and handle the known unknowns well, compared to a rookie manager with an untrained team. However, the perfect manager and the ideal team does not exist. Even the most experienced team faces uncertainties, especially when taking on new types of unknowns, which are mostly likely to occur in development projects.

The risks related to unknown unknowns are often hard to plan for and to communicate. Despite this, managing risks related to unknown unknowns plays a vital part in the early planning phase for a development project. These risks are commonly understood by assuming some will emerge. and when they do, they will lead to some negative impact on the resource planning and timeline of the project. As a result, most projects simply plan for an arbitrary amount of excess schedule and funding. Thus, there has been a lack of a systematic method to aid the project planning through risk management in the case company.

Problem Statement. The case company's risk management is rather arbitrary and demonstrates gaps in systematic risk management, especially for development projects. This paper aims for a systematic method to aid the integration of risk management into project planning. By leveraging state-of-the-art at the intersection of risk management, project management as well as systems engineering, we will investigate the utility of technical tools, the NTCP in particular, and its possible integration into project planning for better chances of project success.

Literature Review

This section reviews the state-of-the-art with a focus on the issue around risk management in projects and project assessment. A lot of research is done within the project space, and many different aspects are covered thoroughly. There is consensus among researchers and practitioners about the key elements of project management – among them: planning, budgeting, goal(s), requirements, and uncertainty. The typical approach to achieving project success has been about reaching an acceptable level of quality (with the end results), within a defined timeframe, and budget. If even one of those objectives (i.e. quality, time, budget) is not met, the project would be conventionally regarded as more or less a failure. However, some studies have attempted to adjust this notion by suggesting that success could also reside outside these aspects (Shenhar and Dvir, 2007). For instance, elevating the team experience or entering new markets could be considered a success (for the company), even if the project itself did not fully reach its primary objectives.

Risk Management in Projects

Every project has some degree of uncertainty. As a key project activity, risk management has been subjected to studies in project contexts. Despite a conventional view of treating risks as threats, there exist actual opportunities within risks. The benefits that those opportunities represent are the main reason why a project exists. Project Management Institute (PMI) considers the project as "a temporary endeavor, unique, in line with the organization's strategy and conceived to create a product that has never been carried through before" (PMBoK, 2017). As the project is to generate a new or modified product (complex systems in our research), it usually involves risks during the steps to achieve the proposed objectives.

The concept of project risk is related to all events or conditions that can produce positive or negative effects on the project objectives (PMBoK, 2017). Risks can be classified as internal, where the project team can influence or control them, and external, where the project team is unable to control and influence them (PMBoK, 2017). Risks may emerge as events and non-events. As described in PMBoK (2017): "There is an increasing recognition that non-event risks need to be identified and managed". Such examples of non-event risks include "elements of the requirement or technical solution", and "inherent systemic complexity in the project". Petit (2012) reflected on the project risk being associated with events (only) and threats (negative effects), and the need to broaden the concept to project uncertainty. Uncertainty management allows for a deeper and more flexible understanding of the origin of the uncertainty and the impact it may have on the project.

Given the inherited uncertainties of a project, Christensen (1991) divided risk into operational uncertainty and contextual uncertainty. Every project, in the form of a temporary organization, shares some types of operational features, in which uncertainty resides. This operational uncertainty is controllable and based on factors known to the project from the start. During the project, it may face turbulence with its surroundings, including the market, management, or other key stakeholders. And the longer the project lasts, the more turbulence can occur. This may finally end up in a situation where the end product is evaluated to a different standard than when it was originally proposed. Christensen (1991) argued that this contextual uncertainty is out of the project's control and can only be regarded in retrospect.

Managing project risks is commonly associated with identifying, prioritizing, and mitigating threats to and within the project. Srinivas (2018) described risk management as a continuous process and emphasized the importance of starting risk management at the earliest project stage. This recommendation is also supported by Qazi et al. (2016), who pointed out the connection between project objectives and project complexity, and the risk induced by complexity. The need to start risk management early is also advocated by PMBoK (2017) and SEBoK (2017). Both highlighted the high level of uncertainty at the project start and less expensive of mitigating applicable threats at the earlier stages of the project in comparison to later stages (see Figure 1).

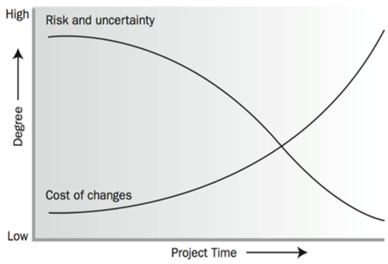

Figure 1. Project Uncertainty Vs. Cost of Changes (PMBoK, 2017)

Sols (2018) described a limitation in traditional risk assessment: “Traditional quantitative risk assessments have proven useful when the observations of past behaviour enable the inference of their probabilities of occurrence. Nevertheless, in complex and ambiguous risk situations, the probability distributions provide a limited perspective of identified risks. In these situations, the qualitative assessment of identified risks is more appropriate”.

The NTCP Framework for Project Assessment

Assessing the project in the early stage, based on its features, can be a plausible means to foresee the known unknowns. If the assessment is performed effectively, it will be able to move some of the unknown unknowns into the known. The NTCP framework, also referred to as the ‘diamond-model’, is one such means to help assess a project (Shenhar and Dvir, 2007). It is a conceptual framework to assess the project in the four main categories that allow us to address each category independently and to make a profile of the project. This profile is helpful for several reasons. The well-known one is that it can convey a shareable understanding of the size and impact of the project within the project team and in the company. NTCP can be applied to any level of the project and therefore can be used to convey the profile to involved contractors or partners. In our context, we argue it can help the project identify associated threats and opportunities with each four aspects, thus moving the unknowns into the known.

NTCP is an acronym, reflecting the four features, or dimensions: *Novelty, Technology, Complexity and Pace.* Each of these four categories is divided into three or four defined levels, from low to high implementation/impact. Every project can be assessed in each dimension and categorized depending on the impact of each dimension. These dimensions can be illustrated as four perpendicular axes (See Figure 2). Examples are mentioned below to help explain the different dimensions and levels.

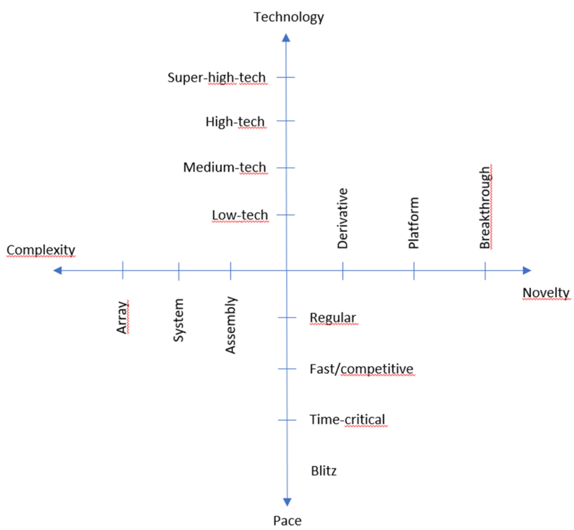

Figure 2. The NTCP Framework

Novelty is one important feature of the project, or rather the product or the outcome. It captures the maturity level of the product/result, as perceived by its intended market. The lowest level, 'Derivative', is an improvement of an existing product, with few unknowns for the new solution (e.g., facelift of an existing model in the automotive industry). The next level is Platform, which is a major upgrade of features, but still somewhat familiar to the market (e.g., EV-models in the automotive industry). The last is the 'Breakthrough' level, which is extremely rare. This is a solution never seen in that market before, sometimes referred to as a radical innovation (e.g., the emergence of LLM-based ChatGPT). The different levels help the project understand how much information to acquire from the market/customer (requirements/needs) and how much to give feedback to the market. If 'Derivative' is the assessed level, the market is familiar with the outcome and the information needed (both ways) will not be as much as for the 'Platform' level, which will take extensive stakeholder analysis and requirement management. For the 'Breakthrough' level, it flips around as market analysis is almost useless if the market does not understand or has no idea what the (proposed) solution is. The higher the *Novelty* level means the higher the uncertainty.

The *Technology* dimension is about the uncertainty regarding the solution applied to the project, in terms of knowledge and resources. At the lowest level, 'Low-tech', everyone in the team is experienced with the solution and all the elements in the design are available for the team. An example alike can be building construction. 'Medium-tech' is where experience must be elevated and/or elements and means of production are new to the team. 'High-tech' means there is a need for expertise that doesn't exist within the team or some elements in the design must be brought from other markets/industries. If super high-tech experiences or elements do not exist, they must be developed. It is also related to the field of production and tooling, as the requirement of high-level technology usually needs more development resources in manufacturing. Like Novelty, the higher level of *Technology* means higher uncertainty.

The *Complexity* dimension in our context (i.e. complex systems) is mainly about interdependencies, within the solution (architecture), and the organization. It can be understood as 'system complexity', growing as the number of elements grows, thus adding to the integration and coordination issues. At the lowest level, 'Assembly', a mere production of relatively few elements takes place. It can be hardware and software, but the dependencies between the elements are relatively few (e.g., a joystick device). The development can be managed by a team of experienced actors. The next is the 'System' level, where a compilation and configuration of units form a higher level of function. It may involve subcontractors, as it usually produces more artifacts and services, like spare parts, documentation, and training, and takes more coordination (e.g., a construction project). The highest level, Array, can also be referred to as a System of Systems and is often run as a program, involving multiple locations, disciplines, and sometimes even political and environmental issues (e.g., a new airport). The higher level of *Complexity* is usually associated with more bureaucracy and more formal governance.

The last dimension, *Pace*, is about the time available for developing and deploying the solution and gaining clues on its impacts on the project. 'Regular' means there is no real deadline, as the result will be ready once the job is done. 'Fast/Competitive' is when the project must reach a defined deadline. Failing to do so means a loss of market shares. 'Time-critical' is to meet a hard deadline. There is no market after this deadline (e.g., Y2K-issue in the late 90's). 'Blitz' is usually about incidents that involve health or safety issues. The higher level of *Pace* requires more autonomous leadership and a higher degree of support from business.

When assessing projects in each different dimension, the different levels provide an NTCP profile. Drawing a line between the different levels creates a diamond-shaped footprint for the project, which is why the NTCP is often referred to as the 'diamond-model'. The smaller the area, the lower the uncertainty identified with the project. The opposite is true as well. The larger the area, the higher the level of identified uncertainty. This representation emphasizes the risk of having multiple dimensions of high uncertainty, because the area of the diamond increases geometrically rather than linearly. The given examples (Figure 3 & Figure 4) are from our case company and many projects share common features, such as the need for organizing, planning, budgeting, and control. But they also differ in many aspects, including size, timespan, market, and technology (Shenhar, 1998). Shenhar and Dvir (2007) argued that most handbooks on project management treated projects in general terms and did not distinguish among different kinds of projects with different operational and strategic problems. Others (Tatikonda and Rosenthal, 1996; Vidale and Marle, 2008) also suggested dividing project uncertainties into categories. One critical feature of the NTCP assessment is that it does not regard uncertainty in the form of events, but focuses on the project's inherent uncertainty, especially concerning both internal management and external market and technology involved.

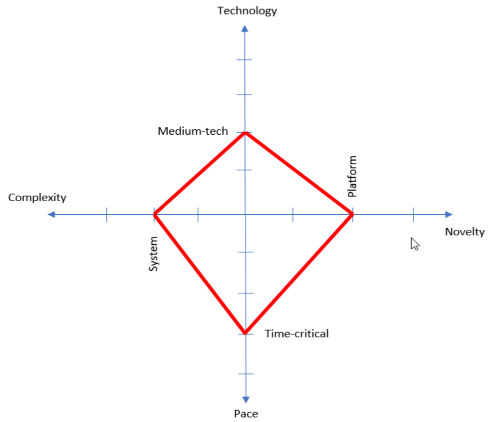

Figure 3. Example of NTCP-profile (e.g. Crystal Structure Repetition)

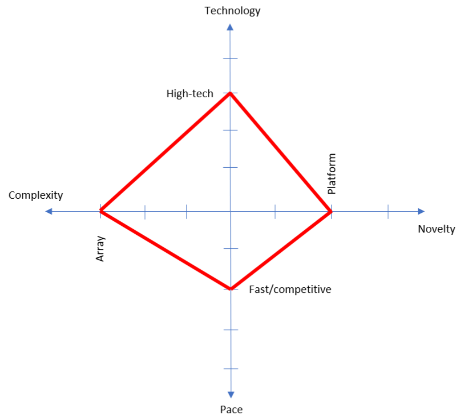

Figure 4. Example of NTCP-profile (e.g. Unprecedented Protein Production Service)

Assessing a project for its applicable risk levels in each dimension of NTCP enables the project risk management in the very beginning. It also can help the firm to appoint the right project manager, select the appropriate team members, and adopt a convenient project organization and managerial approach (Sols, 2014). As Shenhar (1998) pointed out, each project calls for a different management style and the practice must be adapted to the specific type of project. Similarly, the Systems Engineering Body of Knowledge (SEBoK, 2017) also exclaimed the team in project management: "Project teams […] depend on factors such as the nature, size, and scope of the project, […]". In this lies an assessment, one way or another, of the various aspects of the project, preferably before the team is formed. This implies that the team itself is not supposed to assess these aspects, but rather these factors determine who goes into the team.

Given the importance of risk assessment, ISO 9001 (2015) requires the organization to adopt models for assessing project contexts when managing risks. The proper integration of NTCP for such purpose is critical. One common mistake has been the implementation of a smaller footprint in the form of plans, budgets, and activities, rather than the NTCP assessment of the project risks. In turn, the bad planning leads to cost overruns, delays, and otherwise faulty results. One possible explanation for the smaller assessed footprint (than the actual required) can be over-optimistic project management or suppressed cost- and time- frames to receive project funding and acceptance. Besner and Hobbs (2008) has found in their empirical examination of project management practices with 750 different projects that risk management documents were the least used tool of "the most extensively used tools". And feasibility study, contingency plans, and stakeholder analysis were, on average, found to have limited usage. This limited usage is related to a practical question of 'who' should use them in risk assessment. As ISO 31000 (2018) stated "the risk analysis may be influenced by any divergence of opinions, biases, perceptions of risk and judgments". The usage of NTCP in risk assessment requires the right people to perform the right risk analysis at the right time. In sum, there is a need for a systemic way to integrate NTCP in assessing project risks of complex systems developments from the beginning. Then conventional planning methods such as Gantt, PERT, CPM, etc. can be in place. For instance, Gantt can be useful for the lower levels of planning and all levels in *Pace* (related to time), except "Blitz", where planning is of limited utility due to rapid changes in the plan. PERT can be applicable for the higher levels of *Novelty* and T*echnology*, and CPM for the higher levels of *Complexity*.

Data and Methods

We employ a case study as our main research methodology. Based on the systems engineering problem-solving process (INCOSE, 2015; SEBok, 2017), we first identified the stakeholders in this case study and collected their needs through interviews. Then we captured the As-is (descriptive) situation of risk management in complex systems development projects and the To-be (normative) situation in the case company. Through a deeper analysis of the actual risk management practices, we identified the best practices and derived an integration solution as intended. The solution is validated at the end of the case study. Our research methodology is outlined in Figure 5.

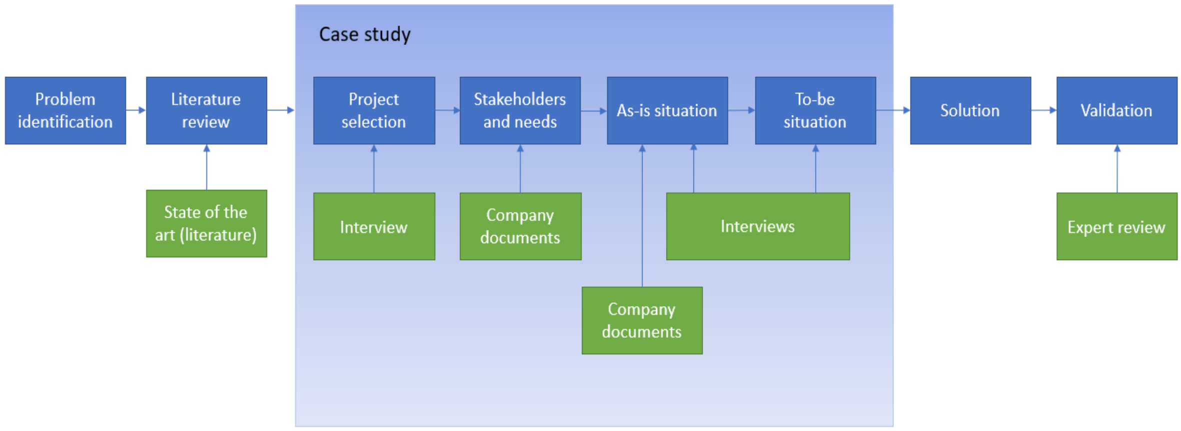

Figure 5. Research Methodology

With a good understanding of the problem and the relevant literature, the case study focused on examining the actual risk efforts of the case company. To identify appropriate projects, we conducted an interview with the Chief Scientific Officer (CSO). As a result, nine key complex systems development projects were included in this study. They were of different sizes and maturity. Some projects were more complex than others, involving novel technologies or especially difficult drug targets. Some were in progress, and others were already completed. These projects were all varied in terms of budget, time frame, and scope. The selected projects broadly reflected the most common types of projects undertaken by the company.

To capture the As-is situation, we collected data from the existing process documents, as well as the Risk Procedure and Project Guideline. We also obtained the data from the project documents of the nine selected development projects, such as charters and risk registers, as well as the series of interviews with key project members. In addition, we conducted the interviews (after studying key features of the projects, described in the charter) to capture the in-depth project data regarding the current practices and the expected To-be situation. For all projects, the Project Scientist and the Project Leader were interviewed one-on-one online (with Teams video-chat) due to the COVID-19 pandemic situation at the time. We started with a pilot of the first project interview to gain experience and determine what data to obtain and what questions to ask. Then we use the refined findings from the pilot to perform the rest interviews for other projects. At the last, we ran the first project interview again for the same type of data across every project. The interviews were performed with a pre-formed set of qualitative questions to capture the actual risk effort, mainly concerning the company's formal risk processes and the aspects of the NTCP framework. Since the NTCP framework was not implemented in the case company, at least not explicitly, these interviews did not aim to assess any direct NTCP effort, but to uncover how, if at all, the project activities covered the aspects included in NTCP to any extent.

Case Analysis and Findings

Stakeholder Identification

Direct stakeholders are identified by reviewing roles and responsibilities within the company's processes. These actors are well-defined and appear within the project space, mainly as individuals. Actors with direct interests in the project governance are the practitioners, i.e. the project team, Project Scientist and Project Leader. Other direct stakeholders, those who are affecting or being affected by the result, include the Product Owner, Resource Owner and Sponsor. Other, in-house stakeholders include Management, Sales, Training, Logistics, and Service. There are also actors outside the company interested in the project or, at least, the end results. Among them are customers and sub-contractors. The stakeholder overview is mapped in Figure 6.

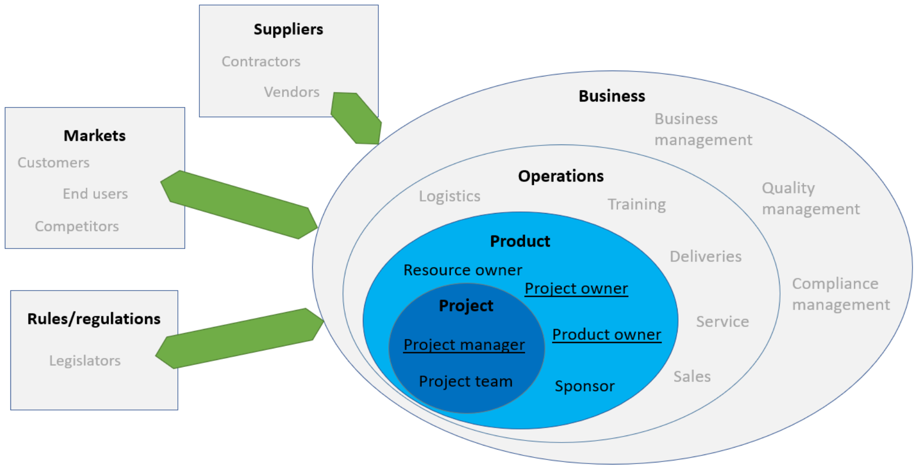

Figure 6. Stakeholders Overview

Based on the company's documents and the interviews with the Project Scientists, Project Leaders, and Product and Quality Management, the key stakeholders and their needs are elicited (shown in Table 1).

Table 1. Key Stakeholder Needs

Key Stakeholders	**Description of Needs**
Project Scientist	-Carrying the operative, day-to-day responsibility for the progress, resources, and product of the project -Responsible for successful project execution within the frames and conditions given
Project Leader	-Receiving the resulting product; responsible for the end-product is satisfying the product owners and other stakeholder's expectations and requirements -Responsible for project success and establishing the conditions for the project to be successful
Product Owner	-Responsible for ensuring that the product solves the user's needs; owning the product backlog and is continuously maintaining it -The role often held by the product manager or delegated to others acting on his/her behalf

As-Is Situation Analysis

The current project governance and risk management are described in different types of company documents: 1) Processes for business management, project management, and risk management, 2)

Procedures for risk identification and handling, and 3) Checklists to guide the project (team) though the various phases and aspects with the project. In our case study, we reviewed and assessed the documents concerning the risk management aspects.

Project (Management) Process. A generic project comprises the following four steps: Mandate review, Project planning & Kick-off, Project execution, and Project closure. For instance, the Mandate review usually consists of the following project features: objectives, resources, milestones, risk assessment, governance, and budget. All features are described by involved actors, activities and (minimum) expected input and output.

The generic project process describes Risk Assessment as an activity performed by the Project Scientist, Project Leader, and Product Owner, and emphasizes the need for an active Project Leader. This implies a certain level of expertise and involvement from the Project Leader's side. The Project Leader is also involved with the project assessment, before entering the next phase.

Risk Handling. The process of identifying and assessing risk is described in Figure 7.

Figure 7. The Company's Risk Assessment Process

The risk assessment process (Figure 7) is in line with the state-of-the-art of the risk assessment process described by PMI. The company acknowledges the high degree of uncertainty at the commencement of the development project and has, as a major risk-mitigating step, established decision gates before each of the three phases making up the total project process. This is a means to make sure the project (team) is on the 'right track' during the project. This resonates well with the state-of-the-art risk management processes (SEBoK/PMI). Associated actors with these decision-gates are the Project Scientist, Project Leader and Sponsor. However, the type or method of assessment to proceed with the green lights for the next phase is not well described.

The risk assessment process describes risk identification with activities like "brainstorming" and "interviews". No methods or tools are described to help identify typical risks that reside within the context of the project, whether internally or externally. Such context is mentioned in the risk documents, shown in Table 2. However, little is done to describe how to identify and assess the context, or how it may affect the project. More specifically, risk management within the company is generic and not adapted to complex systems projects.

Table 2. The Company's Definition of (Project) Context

Risk Context	Affected by the constantly changing external and internal environment. We must monitor both the environments and effectiveness and adequacy of existing controls, risk actions and their implementation.
Internal Context	Including objectives and strategies, governance, structure, roles and responsibilities, capability of people, systems and processes, changes to processes or compliance obligations and the risk tolerance and appetite of the business.
External Context	The environment in which the business operates and seek to achieve the objectives, including the business, social, regulatory, cultural, competitive, financial, and political environment.

(Product) Development Process. The document describes the development process as three consecutive projects (3 x generic project process), called Phase 1, Phase 2 and Phase 3. The rationale for this construction of the development process is to have checkpoints (decision gates) between the phases. This provides a means to assess the project's progress and status, and based on the output of the preceding phase, give a go or a no-go for the next phase. The overall goal of this structure is to provide "increased maturity level" and "decreased level of business risk" throughout the three phases (see Figure 8 & Table 3). Defined actors with the decision gates for each phase are the Project Scientist and the Project Leader. Milestones within each project shall be established and approved by the Project Leader.

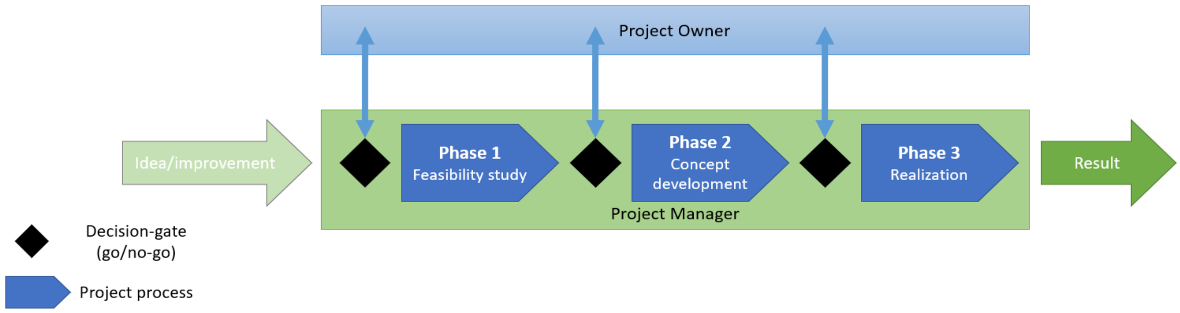

Figure 8. The Principle of the Product Development Process

Table 3. The Phase Descriptions

Phase	Description	Goal	Activities
1	Feasibility study	Evaluate ideas attractiveness and establish feasible concepts for further studies and possible implementation.	-Describe System context, stakeholder needs and potential solution alternatives -Outline concepts -Plan development methodologies -Establish business case
2	Concept Development	Detailing concepts for robustness and prepare for implementation.	-Detail the business case for a concept -Ensure context and stakeholder needs -Detail the architecture and design for the concept -Prepare for implementation
3	Realization	Implement and industrialize decided concepts	-Implement the specifications, ensure the product's functional safety and quality level -Establish and secure the product's commercial part

As the development process, in principle, is made up of three consecutive projects (phase 1, 2 and 3), there exists some ambiguity on whether to manage the risk as per phase, or as an overall project. Risk management is currently described as a part of the project process.

Project Mandate. It describes the project, in terms of budget, time frames, goals, impact analysis, initial risks and roles. It defines the actors as Project manager, Project Leader, Project Sponsor, Project team, Reference group and Steering group.

The company's Risk Management categorizes risks in the following areas: 1) Cost, 2) Schedule, 3) Quality, 4) HSE, 5) Reputation, 6) Strategic and 7) General. These categories describe which aspect of the project (or the business) will be impacted or should the risk emerge/occur, but not where the risks reside or originate from. Categories 1), 2) and 3) are regarded as the main operational aspects, common for any type of project. Category 4) are the aspects that may cause harm to the project or its environment, with issues typically emerging during development and travel, but mostly during installation/deployment. Regarding the three latter categories, they are more in the strategic domain of the business. They consist of issues that resonate well with the NTCP framework, with examples like "New products", "New customers" (Novelty), "Needs for technical development" (Technology), and "Organizational communication issues" (Complexity). Although the issues listed within 5), 6) and 7) are to be managed by the project, their characteristics imply they should be identified and prioritized by or at least together with Project Leader/Business Management.

The mandate describes the scope and goal of the project, and the biggest initial risks identified, before the phase commencement. The risk register provides a list of risks identified during the project, and how the risks were assessed and (suggested) mitigated. If the information in these documents were ambiguous or unclear, a set of interviews with key actors from each selected project would provide in-depth knowledge about the who, when, what, and how.

The Undesirable Practices. A development project working with complex systems is involved many different activities and produces a lot of documents, from start to end. Our research is to understand how the development project assesses its uncertainties and how it came to identify the initial project risks. This is done by reviewing two types of project documents in particular: Project Mandate (charter) and Risk Register. Based on our in-depth interview data, we found the key undesirable practices and summarized them in Table 4.

Table 4. The Undesirable Practices

1	Almost all assessed projects had a cost and time overrun about 30% or more, which were not explicitly connected to the actual Risk Management.
2	None of the assessed projects performed the Phase 1 ("Feasibility Study"), but performed the Phase 2, either exclusively, or combined with the Phase 3.
3	The risk were viewed as events to the project, rather than the objectives or chosen concepts (solutions).
4	Most of the identified risks are in the operational categories, related to schedule and cost, but some are in the strategic areas, which are not addressed with the managment.
5	Most project's risk assessment did not involve Project Scientist or Product Owner.
6	Strategic risks were identified without the involvement of management.

Best Practices. Based on the interview data, we identified the best practices of What, When, Who and How.

What - The first phase of the development process mainly includes evaluating an initial idea, describing the context and capturing stakeholders needs. This is in line with SEBoK by assessing the issue at hand, capturing the As-is situation and forming a concept. A business case is established. The second phase is about ensuring context and stakeholders' needs, reinforcing both the concept and solution, and planning for implementation. The third phase is the realization of the solution. This method of dividing the project into phases is in line with PMBoK.

When - Among the first activities in each phase is the risk assessment, and managing the risks takes place throughout the entire project. A risk register is established at the first risk assessment and updated either regularly or upon major findings. The stage-gates, before the first phase and between the phases, are the major decision points. The Project Scientist presents the work done in the preceding phase and receives the go-ahead to the next phase if the status of the work is according to plan. If not, the entire project can be stopped, or more commonly, the Project Scientist gets a new chance to improve the work. This stage-gates-effort endorsed by the PMBoK is a method to reduce overall business risk.

Who - The Project Scientist is responsible for day-to-day operations like planning, budgeting, and managing stakeholder requirements and risks. The Project Scientist reports to the Project Leader who is responsible for the end product satisfying the Product Owners and other stakeholders. Both are responsible for making the charter (mandate) for each project phase and should, together with Product

Owner, assess the project risks. The three of them, along with a steering group assessment of performed phase work at the stage-gates.

How - Initial risk identification is performed by the team by brainstorming and collecting experiences from earlier projects with similar features. Identified risks are categorized, based on where the risk is likely to impact (the project or business) and weighted, in terms of probability and consequence. Threats get a negative consequence-weight and possibilities get a positive consequence-weight. As risks are managed (mitigated or transferred) the probability and/or consequence weights are reduced. The focus is on the risks with the highest weights.

To-be Situation

Although the current risk assessment resonates with the state-of-the-art in the literature, we identified the three practical needs for complex systems development projects: 1) To improve risk identification by implementing a structured project assessment tool into today's risk management; 2) To keep the three-stage/phase development process but emphasize the importance of performing an early project assessment; 3) To secure the solution and associated risks with (more) involvement from Project Leader and Product Owner.

Derived Solution

Based on the literature review and the case study, it is ascertained that complex system development projects benefit from a more structured method of identifying the unknowns and mitigating the risks. Based on the identified best practices, the To-be situation can be achieved by implementing the three steps:

Step 1. Introduce the use of the NTCP framework in risk assessment to the project actors. The NTCP framework needs to be introduced in assessing the risk of a development project. It is critical to illustrate how different levels with each NTCP dimension have an impact on risk levels, and how the different NTCP profiles make a difference in various aspects of the project, such as management style, design freeze, market communication, and planning method, etc. NTCP as a tool should be explained to all actors within the development project space.

Step 2. Update the current 3-phased development project process with the NTCP assessment. The NTCP assessment should be performed before each phase and the Project Mandate should reflect the result of the assessment. By integrating the NTCP assessment into the Project Mandate, the steering group and the reference group are also informed about the assessed levels. The assessment should be carried out by the Project Leader and Project Scientist, in cooperation. The assessment needs to be adapted to better reflect the levels of technology and novelty that the company is usually involved with.

Step 3. Strengthen the Project Leader's role in the development project process. The Project Leader should play an active part in the project. The Project Leader, supported by Product Owner, should be in charge of the NTCP assessment and the project team should not perform such an assessment alone. In this way, there is a shared understanding between the Project Leader, Project Scientist, and the project team. Such involvement helps ensure the risk assessment reflects business and strategic aspects, as the Project Leader can convey risks between the project and management.

Validation

We presented a derived solution to three experts with ample Product, Project, and Quality management experiences. All agreed it is an actual and important issue to be addressed by the derived solution. For Product and Project Management, assessing the project risks helps better planning and budgeting. One key goal is to avoid overruns for the ongoing project, which may affect parallel and succeeding projects. Quality Management highlighted the findings underpinned two needs: 1) for an initial project assessment in the first phase, which should be emphasized and even strengthened with implementations of the NTCP framework; 2) a more committed Project Leader to communicate risks across the project and management.

Conclusion and Discussion

This paper started with a problem statement, indicating that the company could benefit from a structured method when assessing projects early in the context of complex systems development. Our proposed method, to integrate an NTCP framework, is supported by the relevant risk management and project management literature at project commencement in the early stage. The three-phased development process in our case study emphasizes the need for an early risk effort. In our case study, we identified one major issue that the Phase 1 is omitted in the actual work of the assessed projects against the company's best practices. This finding reveals the need to implement the NTCP framework and to perform an early-stage project assessment in general.

Despite no clear evidence of causal relationships between the risk assessment and project performance in our case, the risk effort is essential according to the company's best practices and state-of-the-art in the literature. The fact that most of the assessed projects had cost- and time-overruns could be associated with the ignorance of Phase 1 of the project. The risk assessment in most cases was carried out only by the project team and not involving the Project Leader or Product Owner. One reason for such ignorance could be that the project team is (over-) confident and underestimates the level of uncertainty that they sense no need to perform a feasibility study given the permission to start the project. In other words, the project team could view 'the project' as the execution phase, and the preceding phases are perceived as non-productive activities that only delay problem-solving.

Due to the limited timeframe, this study has no (quantitative) verification that calls for action, like 'do this much and save that much'. For instance, pilot projects can be run, where the quantitative measurements are handled while implementing our solution. In spite of the well-known utility, the NTCP framework itself cannot identify any specific risks. This research contributes to a systemic way of using it to assess the project by involving the stakeholders. It is not about absolute metrics but the perception of various amalgamated project features. We found the assessment must be performed as cooperative efforts among key personnel of the project, including but not limited to the Project Scientist and Project Leader. It may also be wise to include Product and Quality Management for bigger projects. Comparing different projects' NTCP assessments should therefore be done carefully.

We acknowledge this study does not cover every development project in the company. Yet, the population of the selected cases reflected most types of projects in this context, ranging from small to large, from assemblies to a system of systems, from facelifts to ground-breaking. This classification method helps to understand and convey how much effort is needed in the project as well as the applicable management and organization for the work. There exists no such classification for the development projects in the company today, and our study points to that as an improvement area. Since development projects are subjected to a higher degree of uncertainty, the NTCP framework should have more impact on this type of project.

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