



Evaluation of Project Management in Early-Drug Discovery in Pharmaceutical Industry: Understanding the Cost and Benefit of Early Assignments of Project Managers

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Evaluation of Project Management in early-Drug Discovery in Pharmaceutical Industry:
Understanding the cost and benefit of early assignments of Project Managers

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A Thesis in the Field of Bioengineering & Nanotechnology
for the Degree of Master of Liberal Arts in Extension Studies

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Abstract

The main purpose of this study is to evaluate the Project Management in early-Drug Discovery in the Pharmaceutical Industry and to examine the cost and benefit of early assignments of Project Managers. This study focuses on how Project Managers can improve Business Processes and Team Communications in early-Drug Discovery projects. It also aims to determine the important characteristics/skills Project Managers must possess in order to successfully lead early-Drug Discovery projects and how Project Manager's competencies and their leadership skills can help increase R&D productivity. In the first part of this thesis, a background on Project Management methodology, and the past and current Project Management practices in the Pharmaceutical Industry are described. The final part of this thesis provides empirical evidence with an in-depth analysis of current status of Business Processes and Team Communication, as well as Project Manager's skills needed for effective team management. The results point to Project Management practices as a valuable asset to project teams in early-Drug Discovery and the value an early assignment of a Project Manager can bring in terms of improving Business Processes and Team Communication. The results from this study also show that communication, effective leadership, commitment, motivation, and ability to coordinate are the most significant managerial skills a Project Manager must possess in order to effectively lead early-Drug Discovery Projects.

Dedication

This thesis is dedicated to my husband, Brian Daniel Santos, who encouraged me to start and finish this project, and achieve my dream. Thank you, Brian, for your love, patience, and support. To my amazing, smart, beautiful daughter, Mila, who always puts a smile on my face and who gives me the strength and motivation to always strive to be and do better than yesterday. Mama loves you to the moon and back and all the stars in between. My sweet child always know that you can achieve anything as long as you put your mind and hard work in it, so: “Shoot for the moon. Even if you miss, you'll land among the stars.” - Normand Vincent Peale

Also to my parents, Mira and Dusan Cvetinovic, thank you for all your unconditional love and support, and for all the sacrifices you have made to give me a good life. Without you, none of this would be possible.

To my best friend, Isabelle Joseph, thank you for being my person and for always being there to share all my ups and downs with. We did it!

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Chapter I.

Introduction

Success of a pharmaceutical company depends on driving a product to market safely and quickly, while keeping the cost of development low. In recent years, the pharmaceutical market has become more competitive than ever, and fewer companies are able to keep their businesses successful (Cohen, et al. 2015). The United States pharmaceutical industry R&D spending reached \$33.2 billion in 2003 (doubling from the previous decade) and with the steady increase since then, reached almost \$80 billion in 2015 (Cohen, et al. 2015; The Statistic Portal, 2018). With this increase in spending, combined with a decrease in the number of drugs reaching the market (only one in thirteen compounds put in preclinical trials reaches the market today, compared to one in eight in the 1995-2000 period), it is easy to see why fewer companies are able to keep their businesses successful (Cohen, et al. 2015; PhRMA website). Two biggest challenges that pharmaceutical firms are facing today are time and cost, which in turn negatively impact their productivity (including the quality of the product) and overall success.

Drug development process is very complex, costly, and involves many uncertainties from the very early stages of drug discovery until launch to the market (Cooke-Davis, et al. 2002). A typical process for developing a drug begins at the target identification and validation step. This is followed by: developing numerous assays aiming to identify the lead compound, testing the lead compound in animal studies, and subsequently gaining a FIH (first in human) approval from a government regulatory agency (i.e. Food and Drug Administration (FDA) in the United States) to begin with

human trials. This step marks the Phase I of clinical trials. After a successful completion of Phase I trials, and after providing evidence of low safety risks, efficacy, and establishing a proof of concept (PoC), the development process moves to Phase II and Phase III clinical trials, which are larger scale clinical studies consisting of randomized and placebo-controlled arms to ensure safety and efficacy (Posey Norris, et al. 2014). Finally, if Phase III is successful, the pharmaceutical company is able to submit a new drug application (NDA) to the regulatory agency for the approval to market for their drug. After the NDA approval, commercialization of the drug begins for each approved global market where the company intends to sell their new therapeutic drug (Babler, 2010).

Each one of these stages requires deep scientific expertise and increasing commercial oversight in order to stay competitive; and each stage carries a level of risk to terminate the project early based on data, to not deliver on time or within the budget, and face the project failure. Therefore, a careful and strategic planning, knowledge of the industry and competition, transparency, and willingness to implement changes are crucial for successful launch of a high-quality products that can improve patients' quality of life. These can be achieved by having specific set of rules implemented into daily cross-functional business operations, also known as Project Management (PMgmt) principles, and by having dedicated individuals overseeing these implementations, also known as Project Managers (PMs).

Most organizations using PMgmt to manage their business have a dedicated group or department known as Project Management Office (PMO) that defines and maintains standards for PMgmt within the organization. The PMO is the source of documentation,

guidance and metrics on the practice of project management and execution (Project Management Institute, 2013; Raemdock and Burus, 2010). Pharmaceutical companies have started implementing PMgmt more widely over the past decade or so (Bateman, 2012) in order to bring more structure and focus to their drug development process. According to Project Management Solutions, their 2000 survey found only 47% of companies surveyed had a dedicated enterprise PMO, where, in 2014, 90% did (Martin, 2017). In addition, of those who did not, 30% of those without a PMO planned to implement one within the next year. This change in the drug development operations was the result of the rapid pace of scientific advancements in our understanding of diseases at the molecular level, which in turn led to the scientific, technological, and regulatory challenges to the drug development that began at the end of the 20th Century (PhRMA website). To add to these complexities, the consumer market expanded and the competition became global (Babler, 2010).

PMgmt is very different in Pharmaceutical Discovery from the PMgmt in Pharmaceutical Development (Samanen, 2013). This difference stems from different levels of risk inherent in projects in Discovery versus in Development. According to the Project Management Institute's "The Standard for portfolio management", 3rd edition, probability of success (PoS) increases as the project enters the Development stage, whereas the PoS is very low in the Discovery stage (Project Management Institute, 2013). This increases the value of the Development phase; and, thus more effort and resources are applied at this stage. Therefore, the PMgmt methodology, along with its principles applies mostly, if not entirely, to the Development stage rather than to both, Discovery and Development. While applying PMgmt in the Development is inherently obvious for

successful project, not applying this in the Discovery stage can impact time, cost, and quality of the product going into development due to lack of structured planning.

This study aims to evaluate whether applying PMgmt methodology and assigning a PM to projects in early Discovery stages can improve project performance in terms of business processes, team communication, and stakeholder management. In addition to the above, this thesis also aims to determine the set of skills a PM should possess when managing early Discovery stage projects. It is believed that assigning a PM to early Discovery stage projects and thus implementing PMgmt methodology will bring value to early Discovery projects by providing more structure and improve planning, which in turn can improve project execution. The hypothesis is based on personal knowledge of industry, as well as literature reviews that confirm that by carefully planned and organized activities, companies are able to foresee and identify any risks ahead of time and thus implement risk mitigation early on should it be needed.

To determine if there is a correlation between the PMgmt implementation in early Discovery projects and their success rate, the author conducted extensive literature review on current processes within the pharmaceutical industry, as well as processes of EMD Serono Research and Development, Inc. (further referred to as EMD SRDI in this study) to determine how Discovery projects are managed and how allocations of time and resources are performed. In addition, a survey comprised of questions related to PMgmt methodologies and its implementation into projects, including early assignment of a PM to projects, was sent out to selected EMD SRDI employees who have experience in project setting, including but not limited to being a functional member of a project team.

The significance of this study is two-fold:

- The first being that if this study proves that implementing PMgmt methodology and assigning a PM to a project in early-Discovery can improve project and project team performance, then one could argue that the scientific creativity can benefit from a more structured and organized approach, without creating boundaries; and thus implementation of PMgmt should occur as early as Hit Optimization stage (HO) where, as the name suggests, potential hit molecules are identified and are being optimized.
- The second is the larger implication on the PMgmt use, as one size does not fit all when it comes to PMgmt in pharmaceutical industry, especially in terms of demands for early-Discovery projects versus Development projects; thus, depending on the stage a project is in, further optimization of the PMgmt methodology may be needed to meet these demands.

Definition of Terms and Abbreviations

“Development Stage”: stages of drug development – DP0 (pre-clinical phase), Phase I clinical development assessing tolerance and pharmacokinetic parameters in healthy human volunteers/patients (depending on the TIP), Phase II clinical development assessing preliminary efficacy and side effect profile in patients, and Phase III clinical development confirming the therapeutic efficacy through large-scale clinical trials (Pacific BioLabs website).

“Discovery Stage”: stages of drug discovery prior to pre-clinical phase – Hit Discovery (HD), Hit Optimization (HO), Lead Optimization (LO), Exploratory Development (ED).

“EMD SRDI”: EMD Serono Research and Development Institute.

International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH): Organization tasked with bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration.

“Pharmaceutical Research and Development (R&D)”: a process of discovering, developing, producing, and bringing to market the drugs for use as medications (Tanzeena, 2012).

“Probability of Success (PoS)”: a statistic concept used in the pharmaceutical industry to support decision making (Project Management Institute, 2013).

“Project”: work with a predefined beginning and end, having a specific outcome that needs to be achieved, typically with appropriate resources and in a predetermined timeframe (Carayannis, et al. 2005).

“Project Management (PMgmt)”: multifaceted discipline used in managing projects in various fields, including medicinal drug development. Its principles involve: scope management; project planning, execution, and monitoring; timeline and budget planning and management; stakeholder management; management of regulatory and compliance strategies; environmental safety; risk management; and team management (Pattanaik, 2014; Chauhan and Srivastava, 2015).

“Project Manager (PM)”: an individual who is in charge of a specific project(s) and whose job is to plan, budget, oversee, and document all aspects of the specific project they are working on, as well as ensure the quality of all documents, project managers may work closely with upper management to make sure that the scope and direction of each project is on schedule, as well as other departments for support (PMI, 2017).

“Return on investment (ROI)”: also known as cost-benefit analysis; calculates the benefit to a business after taking in consideration the amount invested. Formula to calculate ROI: $(\text{Net Profit}/\text{Cost of Investment}) \times 100$.

“TIP”: Translational Innovation Platform. This a highly interdisciplinary branch of the biomedical field supported by three main pillars: benchside, bedside, and community. The main goal of TIP is to combine disciplines, resources, expertise, and techniques within these pillars to promote enhancements in prevention, diagnosis, and therapies in specific therapeutic indications (Cohrs, et al., 2015).

Chapter II.

Background

The following sections in this chapter will present the background information for the research presented in this thesis. Literature on the Project and its components, Project Management and the Project Manager, the organizing of the project team and success factors related to the projects, and the difference in Project Management in early Drug Discovery versus late Drug Discovery is carefully selected and reviewed in order to provide the best theoretical perspective to go along with this study. This chapter will conclude with author's study aim and the hypothesis driving this thesis.

What is a Project and its Components

Historically, projects have been defined as work with a predefined beginning and end, having a specific outcome that needs to be achieved, typically with appropriate resources and in a predetermined timeframe. But, as Carayannis et. al. suggests, "does not just about everything we do fall into this definition in one way or another?" (Carayannis et. al., 2005). The answer to that is yes and no. Yes, because the basics to all projects fall into the definition above; and no, because each project has unique demands as far as time, cost, and quality; and these demands are constantly changing due to competition and customer demand. It is not good enough to do things the way we did last year, we must do them with higher quality, less resources, and in shorter timeframe in order to maintain competitive advantage. (Carayannis et. al., 2005). To do this, teams and businesses must

organize their operations in a way where projects re carefully planned and monitored, risks assessed and managed, and changes are made as needed to ensure success. This is where Project Management is imperative to a business.

What is Project Management

Project Management (PMgmt) is a multifaceted discipline used in managing projects in various fields, including medicinal drug development. There are eight principles that define the scope of PMgmt (Pattanaik, 2014; Chauhan and Srivastava, 2015):

1. Scope management
2. Project planning, execution, and monitoring
3. Timeline and budget planning
4. Stakeholder management
5. Management of regulatory and compliance strategies
6. Environmental safety
7. Risk management
8. Team management

Managing a project requires initiating, planning, executing, controlling, and supporting the right decision at the right time to achieve specific goals while meeting specific constraints/success criteria, such as meeting predetermined deadlines, staying on budget, and delivering high quality product (PMI, 2017). These three parameters are known as the project scope triangle, shown in Figure 1. Managing a well-balanced project requires

constant organizing and managing of resources in a way that project is completed within defined scope and with ever-changing demands.

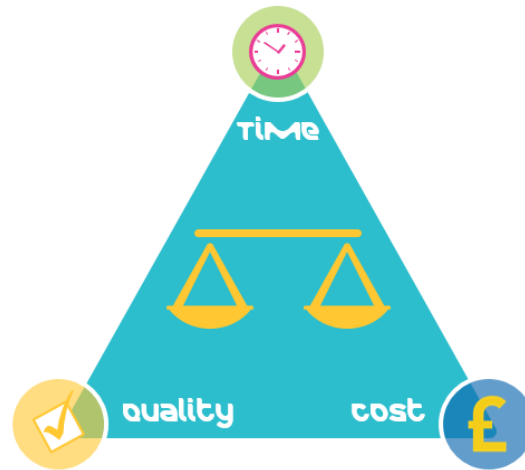


Figure 1. Project Scope Triangle.

“These constraints form an interdependent set - a change in one constraint can require a change in another constraint in order to restore the equilibrium of the project. In this context the set of three parameters form a system that must remain in balance for the project to be in balance” (Wysocki, 2009). Figure source: EMD Serono Research and Development Institute, Inc.

To successfully manage projects, PMgmt draws on knowledge of the following ten areas (Chauhan, D. and Srivastava, P., 2015; PMI, 2017):

1. Integration
2. Scope
3. Time
4. Cost
5. Quality
6. Procurement

7. Human resources
8. Communications
9. Risk management
10. Stakeholder management

While all management needs to consider all knowledge areas listed above, focus of specific PMgmt is usually shaped by goals, resources, and schedule of each project and business (Carayannis, 2005). This is where the “art” of PMgmt comes into play and processes are customized to meet the specific needs of business and its customers.

While it is unclear when this discipline was first implemented in the business world due to conflicting reports, majority of PMgmt principles used today were greatly shaped by the construction industry following WWII (Cooke-Davis, T.J. and Arzymanow, A., 2002). Today, almost all industries utilize PMgmt principles at least to some extent in order to keep track of their daily business operations, as well as to project their long-term outlooks.

Pharmaceutical R&D and Introduction of PMgmt to Pharmaceutical Industry

Pharmaceutical R&D is a process of discovering, developing, producing, and bringing to market the drugs for use as medications (Tanzeena, 2012). Typical drug development process in the Pharma industry follows the five steps set by the Food and Drug Authorities (FDA) (Strovel et. al., 2016; Pacific BioLabs website):

1. Discovery and Development
2. Preclinical research
3. Clinical research

4. FDA review
5. FDA post-market safety and monitoring

Figure 2 represents general drug development process, including Decision points (DP) and milestone (MS) requirements for each process:

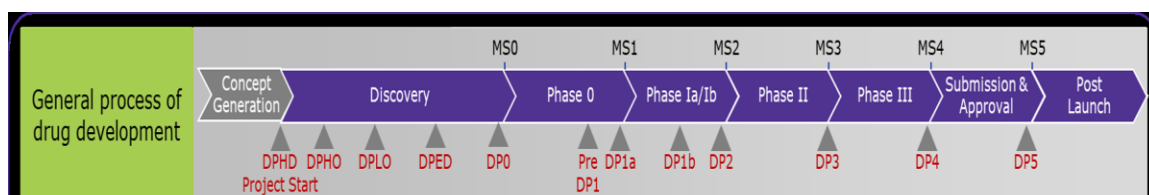


Figure 2. General process of drug development.

Source: EMD Serono Research and Development Institute, Inc.

During drug discovery stage, hits series are identified, and target is validated. The objective for NCEs (new chemical entities) and ADCs (antibody-drug conjugates) is to select a patentable lead, and for NBEs to select an optimized lead which meets the essential attributes (i.e., feasibility of manufacture, storage and formulation). This discovery step requires a significant amount of resources and scientific creativity plays the most important part. As a consequence, spending is not well controlled, if at all. In the Discovery stage, multiple functions are running experiments to assess structural and binding confirmation, assess potency and investigate biomarkers to identify the best lead candidate. More hours are spent on assay development and validation, more employees support these efforts, and some new assays may require purchasing new equipment – all of which results in increased spending and increased budget requirements. As a project moves into the Development stage (DPED onward), PMgmt is introduced and more

concrete plan regarding costs, timelines, and risk management is put in place. This timing of official PM assignment is somewhat unique to EMD Serono as other pharmaceutical/biotech companies officially assign PMs at the LO stage.

PMgmt practice has only been utilized in the pharmaceutical industry for the past two decades or so (Babler, 2010; Bateman, 2012). The reason for this change in processes came from an increase in competition, as well as stricter demands and requirements from global regulatory authorities, such as FDA (in U.S.A.) and EMA (European Medicines Agency) (Boogert et. al., 2015; Martin, 2017). Rapid increase in understanding of diseases at the molecular level is creating scientific, technical, and regulatory challenges that make drug development more difficult and riskier than ever (Martin, 2017). According to the latest statistical data found on the International Council for Harmonization of Technical Requirements for Pharmaceutical for Human Use (ICH) website, any new drug entering clinical testing is only 8% likely to be approved (Martin, 2017).

According to a study conducted by the Tufts Center for the Study of Drug Development in 2014, it takes at least 10 years for a new medicine to go from bench to market (starting from the initial Discovery stage), resulting in an average cost of bringing a new drug to market at about 2.5 billion US dollars (Martin, 2017). With this amount at stake and inherent uncertainty of success, it is imperative to create a solid plan and closely monitor every step of drug development process, and if a need/demand arises, change the plan accordingly without an impact on business. Another important aspect is being able to stop some assets early on based on clear No-Go criteria.

With this in mind, it should be made clear that the PMgmt in drug development is a highly specialized practice. It differs from project management in other industries in that, considering uncertainties of the pharmaceutical industry and no pre-defined end products (i.e. motor industry). A PM in drug development needs to possess skills and qualities around communications, decision-making, delegation, and risk taking. In addition, it is important that this individual is trained and qualified to deal with day-to-day challenges based on continuous changes coming from individual functions, senior leadership, and regulatory agencies (Martin, 2017; Tanzeena, 2012).

Project Management in early Drug Discovery

Discovery stage is where scientists' knowledge and creativity come together to create a potential drug molecule. During this stage, many ideas are considered, many new assays created and old assays optimized, and a lot of time is spent looking into every possible molecule structure and combination.

The Difference between Discovery and Development Project and Portfolio Management

It is a very well-known fact that project and portfolio management in Discovery is very different from project and portfolio management in Development. According to previously published literature, this stems from different levels of risks inherent in projects in Discovery versus projects in Development (PMI, 2018). 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” (PMBOK, 2000). Fewer risks in a project means greater probability of success (PoS). (Samanen, 2013).

The Inherent Risk in Discovery vs. Development

In early stages of Discovery, uncertainty that a proposed molecule will work is great and thereby the inherent risk of failure is high, resulting in a very low PoS. According to Samanen, at the start of a project, the risk that any aspect of it will succeed is unknown. Thus, all of the potential project risks are loaded at the beginning as aggregate project risks. every experiment is designed to answer one question about whether the target and related compounds will work against a disease and there is a risk that any experiment will fail. If the experiment is a success, that particular risk is eliminated and the probability of success is increased. In Development, the number of inherent risks is lower as the body of evidence that the proposed molecule might succeed is mounting and thereby the PoS is increased significantly, and with that so is the project value, cost, as well as the business commitment to the project (Samanen, 2013). Figure 3 attempts to display these relationships pictorially. The reader should be aware that Figure 3 shows the difference only in the number of risks. Although there are fewer risks in Development, the weight of these risks is high resulting in low approval rate of drugs to market.

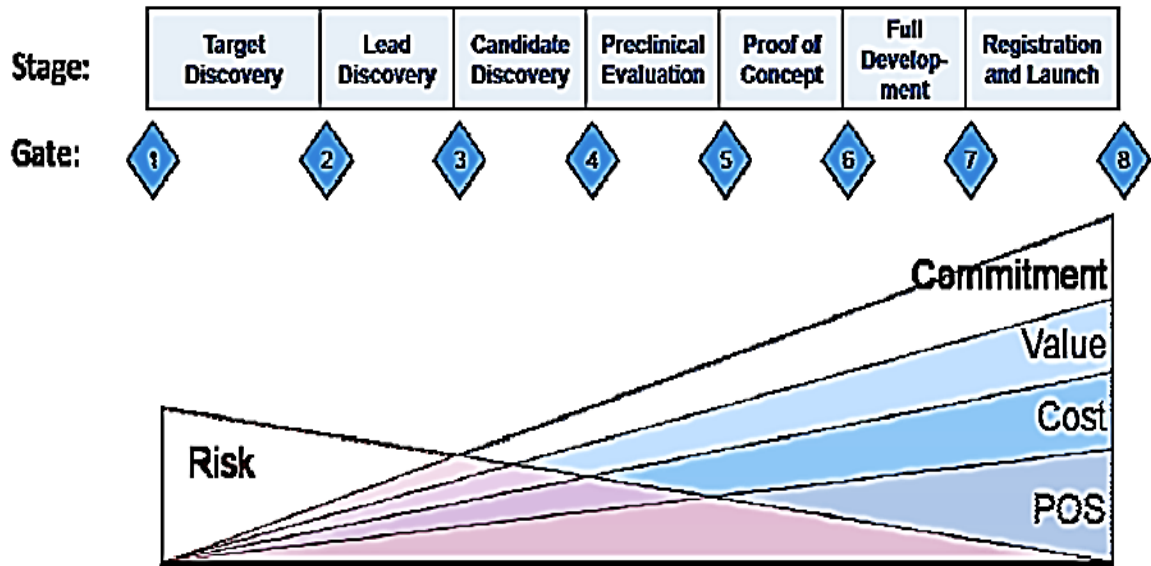


Figure 3. Relative Relationship of Risk to PoS, Value, Cost, and Commitment.

Source: Samanen, 2013.

As the value of the project increases, influence of management of projects moves from informal management by line functions to official PMgmt. Figures 4 and 5.

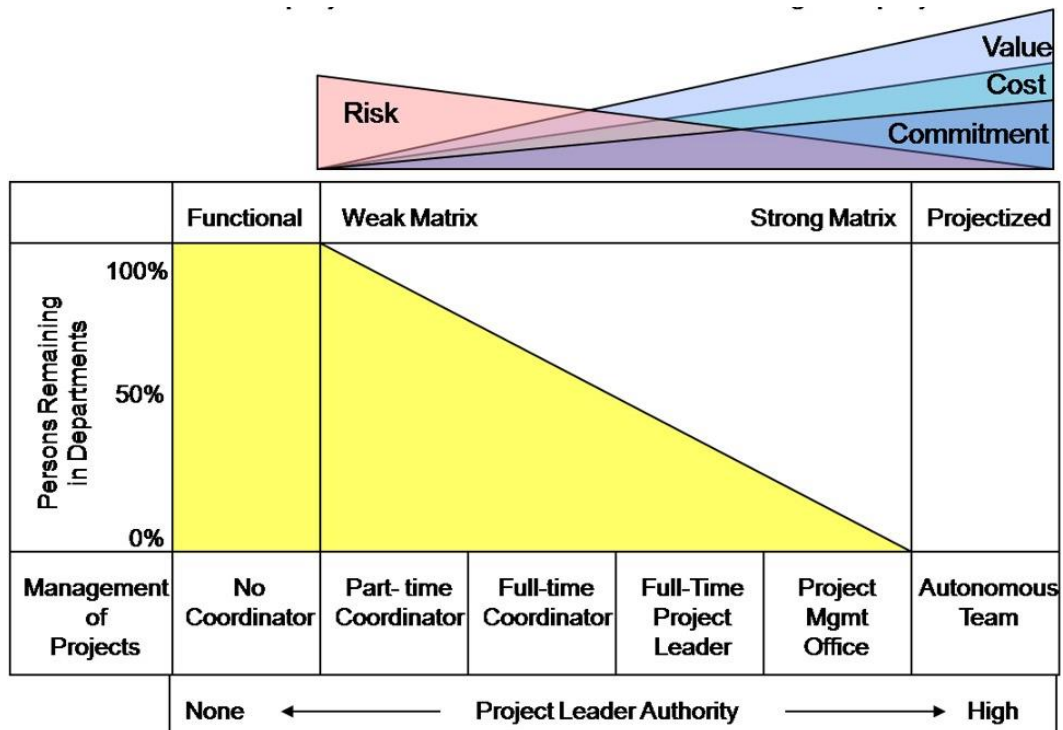


Figure 4. Variation of Project Leader Authority

Source: Samanen, 2013.

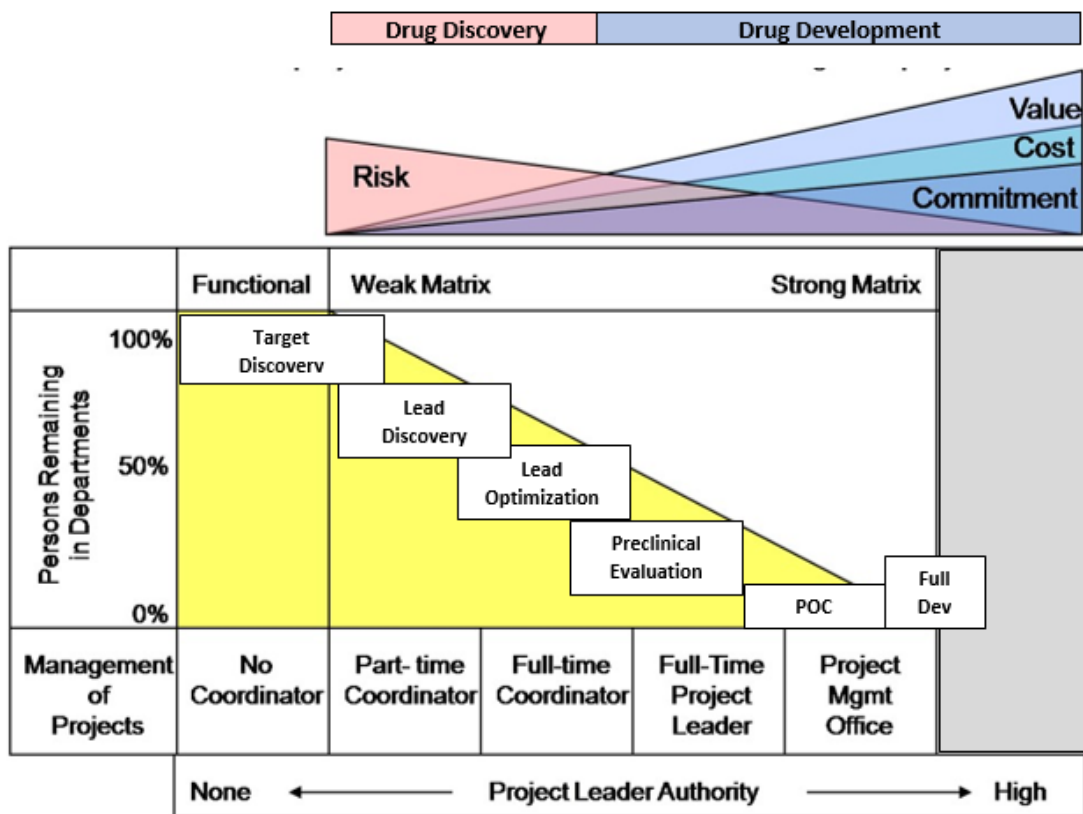


Figure 5. Variation of Project Leader Authority in Pharmaceutical Companies.

Source: Samanen, 2013.

As depicted above, in early Discovery (Target Discovery), the project is organized and managed solely at the discretion of functions and no formal project team is established. Once a commitment to screen is in place, the project is overseen by a functional lead and a small project team comprised of functional representatives is established (Samanen, 2013). At EMD SRDI, a Discovery project team is established with a Discovery Project Team Lead (DPTL) driving the project from DPHD to DP0.

There is no team in place pre-DPHD. In some cases, other organizations have platforms that make for a very different approach and establish teams pre-DPHD.

The purpose of the Discovery project team is to establish a workflow, communication, and data sharing. Timelines and budget at this stage are not formally managed until just before the project enters a pre-clinical stage (aka Preclinical Evaluation, DPED). At this stage a Global Project team (GPT) comprising functional representatives, a Project Leader and a Program Lead is established. With this in mind, it is inevitable that the style of project leadership varies from early Discovery to final drug Development. This is seen Samanen's list of leadership styles below (Samanen, 2013):

Discovery Project Leader (DPTL):

- A scientist from a line department with group responsibility in Research.
- Averse to detailed project tracking and reporting – keep it simple (Gantt charts a tough sell)
- Line managers need to value this work
- The PL will be beholden to the line functions for resources and delivery dates

Development Project Leader:

- Professional leader with formal PMgmt experience and training
- Appreciates the value of project tracking and reporting (Gantt charts a minimal necessity)
- Line managers will be influential in early Development
- Project more important than line

Current Knowledge on PMgmt in Drug Discovery and Current Gaps

A review article found on Project Management Institute (PMI) website clearly lists challenges encountered by project managers, and projects, in the pharmaceutical industry (PMI, 2017):

- Resource limitation
- Cross-functional team management
- Institution processes
- Cultural differences
- Customer management

Drug Discovery organizations utilize PMgmt processes to varying degrees to advance their pipelines, yet, exactly how PMgmt practices are implemented across organizations – and how effective they are – does not appear to be information that is available (Locuson, C.W., 2016).

Locuson's paper *Project Management in Drug Discovery: Current Practices and Opportunities* attempted to analyze the current state of PMgmt practices through a survey of drug Discovery scientists from the pharmaceutical industry. According to Locuson's findings, team scientists had a limited role in planning and managing spending, and majority of respondents answered that their research budget was adequate. However, with the respect to meeting project team goals within the allotted timeframe, the majority of respondents answered that their teams were only sometimes given adequate time (Locuson, C.W., 2016). Also, according to Locuson's survey, although responses were split on whether having more project management resources would be beneficial in

achieving project success, all respondents agreed that having access to up-to-date project management information by project team members (not just the project manager) was helpful. Respondents stated that access to such information as critical activities, budgets, and Gantt charts were not consistently available (Locuson, C.W., 2016).

Findings from Locuson's short study suggested that PMgmt practices in drug Discovery are a valuable asset to project teams and enhancement to the effectiveness of PMgmt would benefit the industry in cutting costs and allow for more informed teams (Locuson, 2016). Having more informed teams would increase the level of team members' engagement and with that, increase team productivity.

Study Aim and Hypothesis

To this date, there are no reports of successful implementation of formal PMgmt in the Discovery stage of drug development. As seen in previous literature review, the probable reason for this is the lack of interest due to a low PoS, as this stage is more focused on basic research, and due to the high attrition rates for Discovery stage as opposed to Development.

The findings above lead to the conceptual work of this thesis. The goal of this study is to evaluate whether, and to what extent early Discovery projects can utilize PMgmt and to understand the cost and benefit of early assignment of PMs.

Based on the current practice and limited knowledge in regard to PMgmt implementation in early Discovery projects, the questions driving this thesis in an attempt to address the key factors that impact project success are stated below:

Key factor #1: Business processes

- Question 1: Would applying the PMgmt principles, all or some, strengthen the way projects progress from early Discovery stage by bringing more structure, and by improving the planning of efforts, time, and risk management?

Key factor #2: Team communication and the role of project managers in a project

- Question 2: What set of skills does a PM need to possess to successfully manage Discovery projects and does it differ from PM skill set needed for Development project management?

Based on available literature and author's extensive professional experience in the pharmaceutical industry, hypothesis for this thesis is: applying PMgmt principles would improve the planning of cross-functional activities and communication with team members and their respective functions. It would also allow for teams to set informed critical experiments and clear Go/No-Go criteria for projects in the Discovery stage.

Findings from this thesis could establish a baseline for Drug Discovery PMgmt practices and may serve as a foundation in designing larger case studies aimed to analyze PMgmt impact on projects and project team effectiveness in real time.

Chapter III.

Research Methods and Limitations

Following sections will describe the research methodology used by the author in this study and address its limitations.

“There are different ways of drawing information from data: these are called methods. A method is a particular, systematic and orderly approach taken towards the collection and analysis of data in such a way that information can be obtained from those data” (Jankowicz, 2013).

In conjunction with the literature review, the research process is used to make an argument and thereby generate knowledge. The following list presents the research process of this thesis:

1. Define research problem and plan out the work.
 - This was done during the Research Proposal phase for this Master’s Thesis.
2. Choose the study design, method, and technique.
3. Gather information, including collection of secondary data, literature review, and formulization of questions for interviews and survey.
4. Conduct face-to-face interviews and send questionnaire to survey participants.
5. Collect and analyze data from the interviews and the survey.
6. Write the thesis.

Interview Method

This study is based on evidence gained from EMD SRDI, a biopharmaceutical company. The author is an employee and is personally involved in the Project Management organization in EMD SRDI. PMgmt processes in Drug Discovery within EMD SRDI are used as evidence to evaluate PMgmt practices and to test whether early-Discovery projects can benefit from early assignment of PMs.

This is a small, in-company focused study, but its findings can help other Pharmaceutical R&D companies interested in evaluating their Drug Discovery PMgmt in serving as a baseline for designing larger, real-time case studies that analyze their Drug Discovery PMgmt practices.

Semi-structured face-to-face interviews were conducted with four key informants from EMD SRDI. Key informant technique means that people with specialized knowledge about the research question are selected for the interview (Jankowicz, 2013; Mandson and Selnes, 2015).

The author used triangulation to cope with the information gathered and determine the parallels and/or gaps in this information. Triangulation means several techniques are used in combination in a search for a consistent pattern of results, thereby increasing confidence that an appropriate understanding of the issue being researched has been achieved (Jankowicz, 2013; Steingrimsdottir, 2017).

Survey Method

The purpose of the survey is to enhance data collection from the internal employees who are involved in Drug Discovery projects and to support the argument being presented in this study.

Purposive sampling was used as the author selected survey participants based on their position/role in the organization (Jankowicz, 2013; Mandson and Selnes, 2015). All survey participants were involved in Drug and Development projects of the EMD SRDI R&D unit. To make sure that the survey participants would answer honestly, their anonymity and confidentiality is preserved, and their participation is voluntary.

Action Research

According to Jankowicz, action research starts from the researcher community and draws on the academic community as well (Jankowicz, 2013). Since the author is an employee of the company and involved in the processes being studied, action research is also used as it is impossible to separate the researcher from the subject matter, as required by the positivist approach. However, in terms of data, the author has no prior knowledge regarding the questions being asked in this study and therefore the data analysis and interpretations was done with no bias toward either outcome.

Study Design

“The research design is about the way data are collected and analyzed to answer the research question put forth. The research design needs to fit the research objective. Research designs that are most useful in business and management research can be categorized into three types: exploratory design, descriptive design, and casual design” (Jankowicz, 2013; Steingrimsdottir, 2017):

- Exploratory design: any research design exploring which variables pertain, or which issues are important, the better to flesh one’s research question (Jankowicz, 2013; Steingrimsdottir, 2017).

- Descriptive design: any research design in which the issues or variables are known and the intention is to describe the relationships between variables, or the details of the issues, systematically, precisely and in detail (Jankowicz, 2013; Steingrimsdottir, 2017).
- Casual design: any research design in which an attempt is made to establish patterns of cause and effect in the situation being researched (Jankowicz, 2013; Steingrimsdottir, 2017).

For this study, the author chose to use exploratory design, as one of the goals of this type of research is to gain a better understanding of the existing problem and come up with ideas which can be used for future research (Jankowicz, 2013). Such a research is usually carried out when the problem is at a preliminary stage and is often referred to as grounded theory approach or interpretive research as it is used to answer questions like what why, and how (Jankowicz, 2013; Steingrimsdottir, 2017).

Study Techniques

Research techniques are step-by-step procedures through which data are collected and which tell you how rather than why something is done (Jankowicz, 2013; Steingrimsdottir, 2017).

- Semi-structured, primary data techniques: research conversations and storytelling, semi-structured individual interviews, key informant interviews and focus groups (Jankowicz, 2013; Steingrimsdottir, 2017).

- Fully structured primary data techniques: structured observation, structured questionnaire and structured interview (Jankowicz, 2013; Steingrimsdottir, 2017).

This study is based on the qualitative data gathered using semi-structured techniques. Empirical research is research using empirical evidence from the survey questionnaire. The empirical evidence will mainly be analyzed qualitatively (Steingrimsdottir, 2017).

Data Collection

In this study, data was collected using primary and secondary data sources. Primary data was collected through semi-structured interviews and survey questionnaire. The interview and survey participants were internal EMD SRDI employees familiar with the PMgmt processes in Drug Discovery and Development.

The data was collected from November 2018 to February 2019. “Secondary data are historical data structures of variables previously collected and assembled for some research problem or opportunity situation other than the current situation. Primary data are raw data and structures that have yet to receive any type of meaningful interpretations” (Mandson and Selnes, 2015).

Secondary data used in this study are: organizational charts, company’s project/portfolio records, internal presentations and flowcharts, and project meeting minutes, decision committees’ meeting minutes.

Primary data are data that are especially gathered for the research (Mandson and Selnes, 2015). The author gathered the primary data by interviews and survey. Participant

were selected based on their position/role within the Drug Discovery and Development unit of EMD SRDI.

Key Informant Interviews

The information was gathered through semi-structured face-to-face interviews with four EMD SRDI employees from four different functions and with different roles currently involved in Drug Discovery and Development projects: finances, TIP, and research. The semi-structured interviews were conducted from November 2018 to January 2019. All interviews were conducted on confidential basis; no names or personal details are mentioned in this report. A semi-structured interview guide was developed before the interviews, which can be seen in Appendix 1.

Survey

The author used the semi-structured interview method to familiarize themselves with issues being researched before creating the survey using structured technique.

An anonymous survey questionnaire was created in a tool called SurveyMonkey and was deployed for three-week period from January 02nd to January 30th, 2019. The survey questions were grouped into three main categories and an additional open-ended question category: Business Process, Team Communication, the Role of Project Managers and Stakeholders, and In Your Own Words consisting of a total of 35 questions including closed and open-ended questions found in the Appendix 2. The questionnaire was split into two sections, pre-LO/LO and post-LO, and respondents were automatically taken to questions in the appropriate section based on their answer to a question in the Participant Information section on whether they had been involved in pre-LO/LO

projects. Both sections were composed of the same set of questions and the split merely served as a comparison reference for the author to ensure information is gathered from a wider perspective from employees with experience in both early-Discovery projects and late-Discovery/early-Development projects, and to try to identify gaps/parallels in their experience with PMgmt process in these projects.

The survey respondents were not able to see nor answer questions from the other section that was not relevant to them. The Survey questions were formulated so that they could be answered in a general matter and respondents could refer to their overall experience on any project regardless of a therapeutic or disease area. The respondents to the survey represented a diverse array of job titles and roles, which helped the author gain information from diverse and wider perspective.

The survey results were analyzed and compared to the interview findings to gain insights from several relevant factors. Those factors were compared to findings from the company's internal document review in an attempt to establish a trend and see if there is a parallel in these three sources of information. Findings from these provided stronger foundation for this thesis and helped the author formulize a possible solution to this thesis' questions and propose a design for future studies of this topic.

Data Analysis

There is no standardized procedure to analyze qualitative data due to their diverse nature (Mark et al. 2009). Still, usually three processes are applied: summarizing, categorizing, and structuring of meanings (Mandson and Selnes, 2015).

This study is based on four interview subjects and in total of 18 out of 48 (37%) survey respondents who answered all questions in the survey. The amount of data which

were collected through the interview and the survey might be considered too small for making solid statistical generalization. However, to determine a difference in survey responses between pre-LO/LO and post-LO groups, the author ranked the top two answers (i.e. strongly agree, agree) as positive, and the rest of answers (i.e. somewhat agree, disagree, strongly disagree, don't know) as negative. Since the two groups had unequal number of respondents, the weight of each response was preserved by using percentages rather than the number of responses to calculate the delta ($\text{delta} = \% \text{positive} - \% \text{negative}$) between the positive and negative answers. Calculated deltas from the pre-LO/LO group were then compared to deltas from the post-LO group for each answer to determine in which PMgmt areas the pre-LO/LO projects could use improvement.

Assumptions and Limitations

Like any research study, this study has certain limitations that must be considered when interpreting results. It is assumed that the selected sample of individuals represent the characteristic of the actual organizational team members and stakeholders. It is expected that individuals chosen to answer the questionnaire will do so in time for the author to analyze the data. Additionally, the author assumes that all individuals will answer truthfully to the questions asked.

All interview and survey participants are sharing experience from the same company. If participants from other companies were involved, it would have been possible to use the comparative study method, as comparative case study is used to compare the company or department being studied with others in a systematic way (Jankowicz, 2013; Steingrimsdottir, 2017).

At the same time there were limitations in finding enough relevant people to talk to within the boundaries of time that is set for this task, since people sometimes did not have sufficient time to meet and participate in the interview. Also, there were limitations in having enough people to respond to the survey in time. In order for the survey to be valid, all questions had to be answered and no changes could be made once the survey was completed. However, the author observed that the survey was opened and closed several times without completing all questions. If all respondents completed all questions, information from this survey could have been more reliable.

Another limitation was the boundaries of time the author had to fulfil this thesis report to its necessary extent. The question of this thesis makes this project very large, and several more aspects could have been counted for within the thesis, including performing a real-time case study on an active project; but, this would require years of monitoring to gain a meaningful conclusion in terms of the PM and PMgmt value in early-Discovery. Therefore, previously mentioned concepts were chosen because of the time constraint.

“The information received from the conducted survey and interviews are only as good as the questions asked” (Mandson and Selnes, 2015). Since the questions asked may not have covered everything that should have been captured, there might have been information that was missed if the author had not thought of it beforehand.

Chapter IV.

Findings

The following chapter will present the findings from the secondary data, empirical data, as well as data analysis and discussion. The secondary data is based on the company's material from EMD Serono's internal database such as: project documents, project/portfolio financials, annual reports, and internal presentations and flowcharts. The primary data is based on the semi-structured interviews with key informants from various functions involved in R&D projects. The four interview participants were: a project controller, a TIP lead, and two functional representatives: one for NBE and one for NCE. The empirical data is based on a survey questionnaire that was sent out to 48 current EMD SRDI's employees who were chosen based on the author's knowledge of their involvement in project teams.

Secondary data and Empirical Data Findings

This section of the chapter will present the relevant factors from the qualitative interview, the findings from the quantitative survey, and secondary data from EMD Serono's internal document repositories. The results will focus on the three essential subjects: business processes, team communication, the role of projects managers and stakeholders. Findings are presented in sequential order.

Key Informant Interviews and Internal Data Review

One of the methods used to gather information for this research was to conduct interviews with four EMD SRDI employees from different functions involved in early- and late-Discovery projects. The goal was to gain a deeper insight into how project teams operate and what improvements can be made to the way early-Discovery project are currently managed, and whether PMgmt is a solution. Projects and their teams, from a business operational perspective were discussed in semi-structured interviews, which focused on three essential subjects:

Business Processes

Team communication

The Roles of Project Managers and Stakeholders

Business Processes

The business processes were more clearly understood in teams that were involved in late-Discovery projects. Team members were involved in almost all project planning activities and were generally satisfied with the level of their involvement. Having a PM assigned was seen as a benefit as this individual was responsible for overseeing and making sure that all activities are aligned with the project objectives and ensuring that any deviation in either a timeline, budget, or change in processes is quickly addressed with the team and beyond. According to the interviews, team members involved in early-Discovery projects see the same benefits for having a PM assigned. The early-Discovery teams are not as involved in the business processes, and one of the gaps seen in project teams at this stage is not having a clear understanding of their expectations and what is needed to reach the next stage/milestone in the project. This is especially true when it

comes to understanding clearly what documentation is needed and by when. Interview participants expressed that having someone dedicated to overseeing and ensuring that all project criteria are met would alleviate the burden from research scientists of having to look for this information, and allow more time for them to focus on their scientific work.

At EMD SRDI, Research budget is allocated per function and the cost tracked is activity based, rather than project based. Each project in pre-ED space is assigned an F code. Once a project enters the ED phase the budget is allocated per project and managed at a project level.

The cost management was not clearly understood in the early-Discovery project teams. According to the interviews, early-Discovery project team members have a limited, if any, role in planning the budget. However, they are expected to keep track of the spend by tracking and reporting it back to their function. All interview participants stated that this type of work is cumbersome and infringes on scientists' time to focus on their research and experiments.

Based on the author's review of project/portfolio financials, it was determined that budget management could not be analyzed due to the lack of budget tracking at the project level in pre-ED phases. Therefore, budget management will not be included in the rest of this study due to the lack of comparability across different stages.

With respect to timelines, based on the author's review of Research Analytics internal documentation, early-Discovery projects performed in-line to, or even better, than the Centre for Medicines Research (CMR) benchmark, seen in Figure 6.

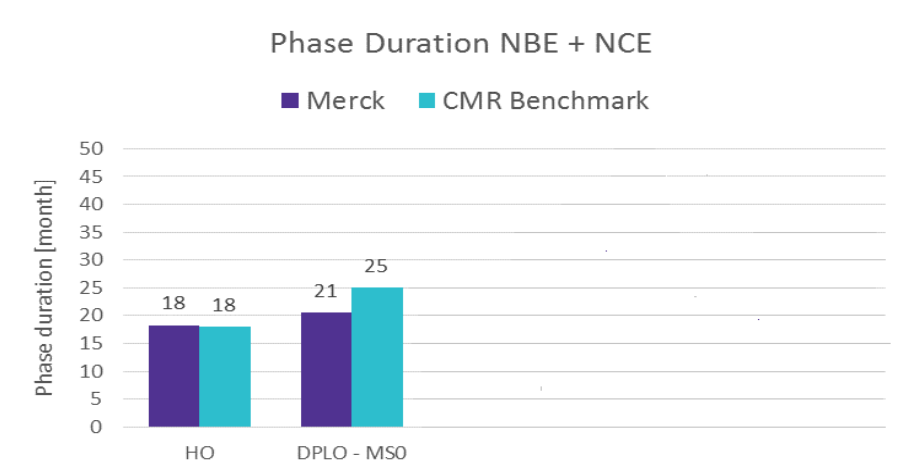


Figure 6. Phase Duration: Merck vs. CMR Benchmark

Although this may be the case, the interview participants expressed that project teams were only sometime given adequate time to reach project goals.

Team Communication

In term of team communication, interview participants expressed that they were mostly satisfied with how their teams shared information and with the team collaboration on a cross-functional level. In recent years, EMD SRDI adopted a lean approach to meeting organization in terms of the level of participation and meeting frequencies. This approach limited the number of participants to only most relevant functions and their representatives. It also decreased the meetings frequencies. In turn, project team meetings benefited by having significantly more productive and efficient meetings; any issues within a team are resolved without further escalations. It should be noted that currently, an average early-Discovery project is composed of 15 members.

The Roles of Project Managers and Stakeholders

Early-Discovery projects (pre-LO/LO) currently do not have an assigned PM. These projects are managed by a lead scientist, also known as DPTL (Discovery Project Team Lead). These individuals are responsible for tracking the progress of projects,

initiating and driving the communication within their teams, adhering to company's guidelines for project acceptance criteria, aligning on project activities and timelines with their teams, communicating projects' status and providing status updates to executive leadership, and scheduling team meetings, to name a few. DPTLs, in most cases, are not formally trained in PMgmt, and based on the interviews tend to manage their projects in a less process-oriented manner. Specific timelines and specific sequence of activities is only sometimes available to functional representatives involved in early-Discovery project teams, and team members do not always adhere to these or tend to lose track on the upcoming deliverables. One of the common themes that was given by the interview participants is that scientists are less process oriented and tend to push back when processes are imposed on them. "Scientists like their freedom to be able to explore and not be held back by processes," one of the interviewees stated.

Based on the interviews, the four most important success factors for PMs managing early-Discovery projects are the skills below, listed in a descending order from the most important to less important:

1. Communication skills
2. Effective leadership
3. Competence
4. Commitment

Survey

An invite to participate in a survey was sent via email to 48 current EMD SRDI employees. The survey was sent out on January 02, 2019 and responses were collected over four weeks. 25 responses were received for a 52% response rate. 16 respondents

were/are involved in LO and earlier projects (64%) and 9 respondents (36%) were involved in post-LO projects only. Figure 7 shows the response level (in percent) for each group.

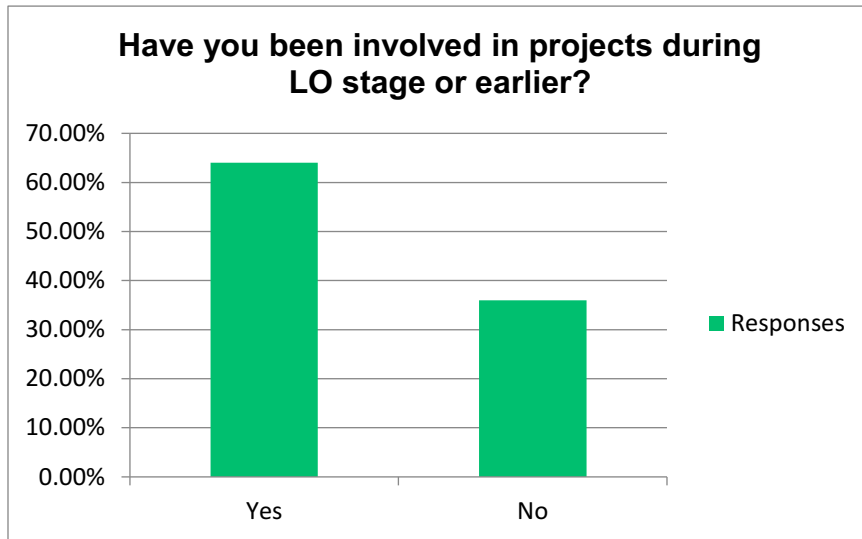


Figure 7. Respondents experience in project stages.

The respondents' job titles ranged from research scientist and lab heads to directors. Their roles on projects were also diverse: line function representatives, Discovery Project Team leads, Global Project Team leads, medical writers, etc. These can be seen in Figure 8.

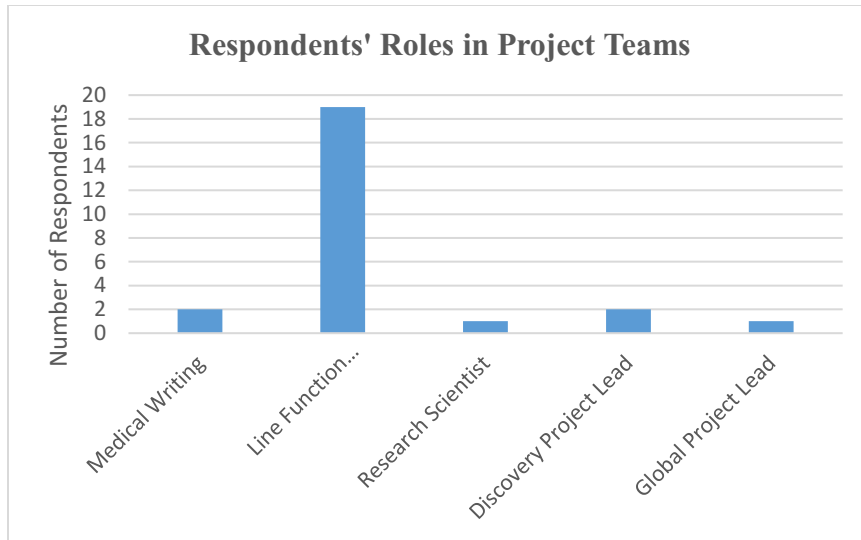


Figure 8. Survey Respondents and Roles.

The response rate to individual questions varied as the author observed that the survey was opened and closed without completing all responses in total of 8 out of 25 (32%) responses.

The survey was comprised of 38 questions in total, with closed and a few open-ended questions. As described in the Chapter III, survey questions were separated into three main categories and an additional open-ended question category: Business Process, Team Communication, the Role of Project Managers and Stakeholders, and In Your Own Words. The questionnaire was split into two sections, one for respondents who were/are involved in LO and earlier projects, and one for respondents who were/are involved in post-LO projects. Based on respondent's answer to whether they had been involved in pre-LO/LO projects, they were automatically taken to questions in appropriate section. The questions in both sections were the same and can be sorted in the following categories:

- Questions 1, 2, and 3 are to confirm the demographics of survey respondents such as their title and role in projects, as well as their experience in early-Discovery projects.
- Questions 4-13 ask participants about the Business Processes in projects they have worked on.
- Questions 14-25 ask participants to rate the level of Team Communication and communication materials used in project teams.
- Questions 26-35 relate to the Role of PM and Stakeholders in project teams and asks the respondents to rate the importance of specific success factors/skills a PM should possess when managing projects. Some of these questions also include open-ended questions, like asking for clarification.
- Questions 36, 37, and 38 are open-ended questions.

Survey Results and Analysis

This section shows the key results from the survey.

Business Processes

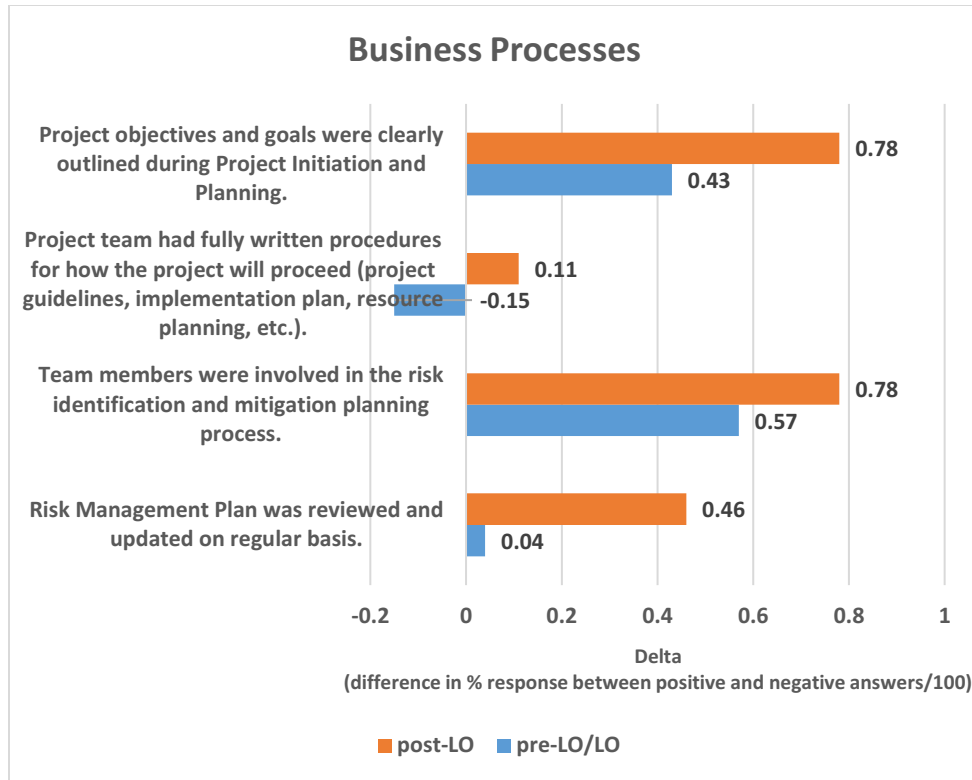


Figure 9. Key results from questions in the Business Processes category.

The total number of responses for both groups was 25. Each question in Figure 9 received 14 out of 25 (56%) responses from the pre-LO/LO group and 9 out of 25 (36%) responses from the post-LO group.

When asked about how often project objectives and goals were clearly outlined during project initiation and planning, 10 out of 14 (71%) pre-LO/LO respondents and 8 out of 9 (89%) post-LO respondents stated that this was usually/always the case. 4 out of 14 pre-LO/LO respondents and 1 out 9 post-LO respondents answered that this is sometimes the case. Delta value in favor of the positive answers was significantly higher for the post-LO group (0.56) than for the pre-LO/LO group (0.38). Although, the survey response rate was somewhat low, it is still safe to say, that based on these answers, project teams in late-Discovery place a higher emphasis on Project Initiation and Planning steps.

When asked if their project teams had fully written procedures (i.e. project guidelines, implementation plan, resource planning, etc.) to follow as the project proceeds, the survey respondents' answers were very diverse. 4 out of 14 (29%) respondents answered that this is always the case, 2 out of 14 (14%) respondents answered that this is usually the case, another 4 (14%) respondents stated that this is sometimes the case, 3 out of 14 (21%) respondents said that this is rarely done, and 1 respondent (7%) answered that they did not know. Similar disbursement of answers was observed in the post-LO group of respondents. 2 out of 9 (22%) respondents said that this was always done, 3 out of 9 (33%) respondents said that this was usually done, 1 out of 9 (11%) respondents answered that this is rarely done, and the remaining 3 respondents (33%) did not know the answer to this question. Using the percent values, calculated delta in favor of positive answers for the post-LO group was 0.11, while for the pre-LO/LO group this value was -0.15. The significant difference in delta values points to the need for improvement in the pre-LO/LO stage in terms of how teams are informed and prepared to move their project forward.

When asked if team members were involved in Risk Identification and Mitigation process, 6 out of 14 (43%) of respondents from the pre-LO/LO group answered that projects they supported always involved their team members in Risk Identification and Mitigation process. 5 out of 14 (36%) respondents said that team members were usually involved in this process, while 2 out 14 (14%) respondents chose sometimes as their answer and 1 respondent chose rarely.

Significant difference in responses was observed in the post-LO group compared to pre-LO/LO group. Although response rate was lower than in the pre-LO/LO group, almost all

respondents (7 out of 9 or 78%) answered that team members are usually involved in the Risk Identification and Mitigation process, with an exception of 2 out 9 (22%) respondents – one choosing “always” as their answer and one respondent not knowing the answer to the question.

Risk Management is one of the core principles that defines the scope of PMgmt and keeping in mind that post-LO projects have dedicated PMs assigned to them, these findings are as expected on one hand, and on the other, interesting. The expected part of these findings is the lack of consistency in how Risk Management is handled in pre-LO/LO projects, which is likely due to differences in management style utilized by scientists who do not have formal PMgmt training leading project teams. The interesting part of these findings is that team members supporting post-LO projects are only usually involved in Risk Identification and Mitigation. With a dedicated PM in these projects, one would expect to see most answers fall into the “always” category, instead.

When asked if the Risk Management plan was reviewed and updated on regular basis, answers from the pre-LO/LO group were spread across-the-board. 3 out of 14 (21%) respondents answered that the Risk Management Plan was always reviewed and updated on regular bases, 5 out of 14 (37%) respondents answered that this was usually true, 2 out of 14 (14%) respondents said that this was sometimes true, while 3 (21%) answered that this is rarely the case, and one respondent did not know the answer to this question. These findings are significant in a way that they once again point to lack of consistency in Risk Management process and support the findings gained from the previous question.

Answers from the post-LO group were very similar to their answers in the previous question. 7 out of 9 (78%) respondents answered that the Risk Management Plan is

usually reviewed and updated on regular basis, while the remaining 22% of responses was divided between one respondent who stated that this is sometimes true, and one respondent who did not know the answer to this question.

Team Communication

The total number of responses for both groups was 24. There were 13 out of 24 (54%) responses from the pre-LO/LO group and 9 out of 24 (38%) responses from the post-LO group.

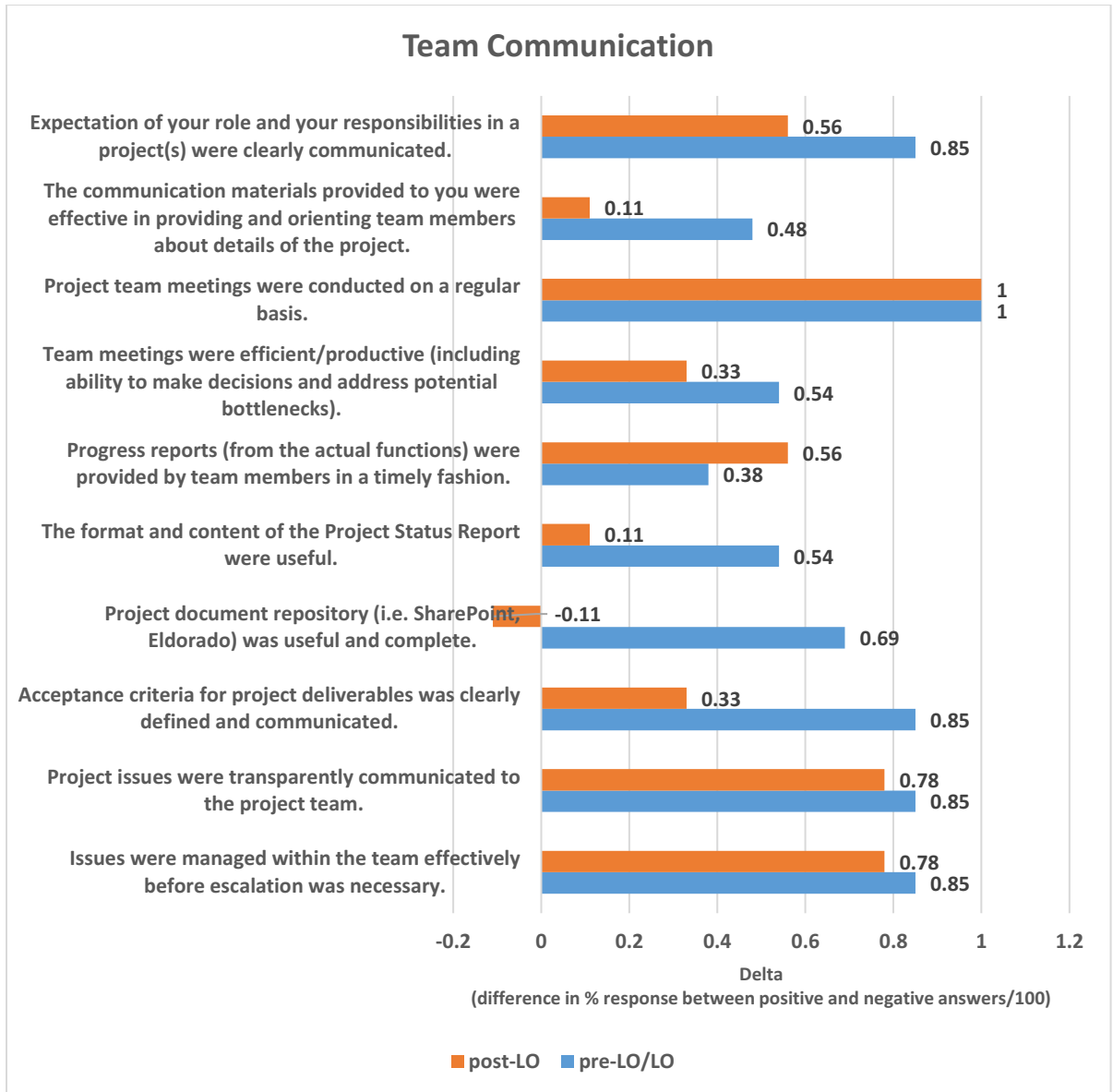


Figure 10. Team Communication.

Results from the Team Communication category of the survey showed that project teams in the pre-LO/LO stage are highly efficient in managing their team communication. As it can be seen in Figure 10, a significant difference in results is obtained from the two groups. Interpreting these results, however, is complicated due to the fact that the post-LO project needs are more complex and distinct from pre-LO/LO projects. Thus, team

structure and communication approach, including the communication tools (i.e. document repository platforms) are not the same.

Role of Project Managers and Stakeholders

Question 31. Based on your experience, please rank the importance of success factors related to the Project Manager role:

When asked to rank Project Manager's key traits/skills needed to successfully manage a project, both groups gave the highest ranking to communication. From the pre-LO/LO perspective, Communication was followed by Effective Leadership and Commitment in order of ranking. From the post-LO perspective, Ability to Coordinate Different Tasks immediately followed the Communication success factor, which was followed by Commitment (as seen in pre-LO/LO responses). Both groups gave the lowest importance ranking to Technical Background and Having Earlier, Similar Work Experience in terms of success factors related to the Project Manager role. See Figures 11 and 12.

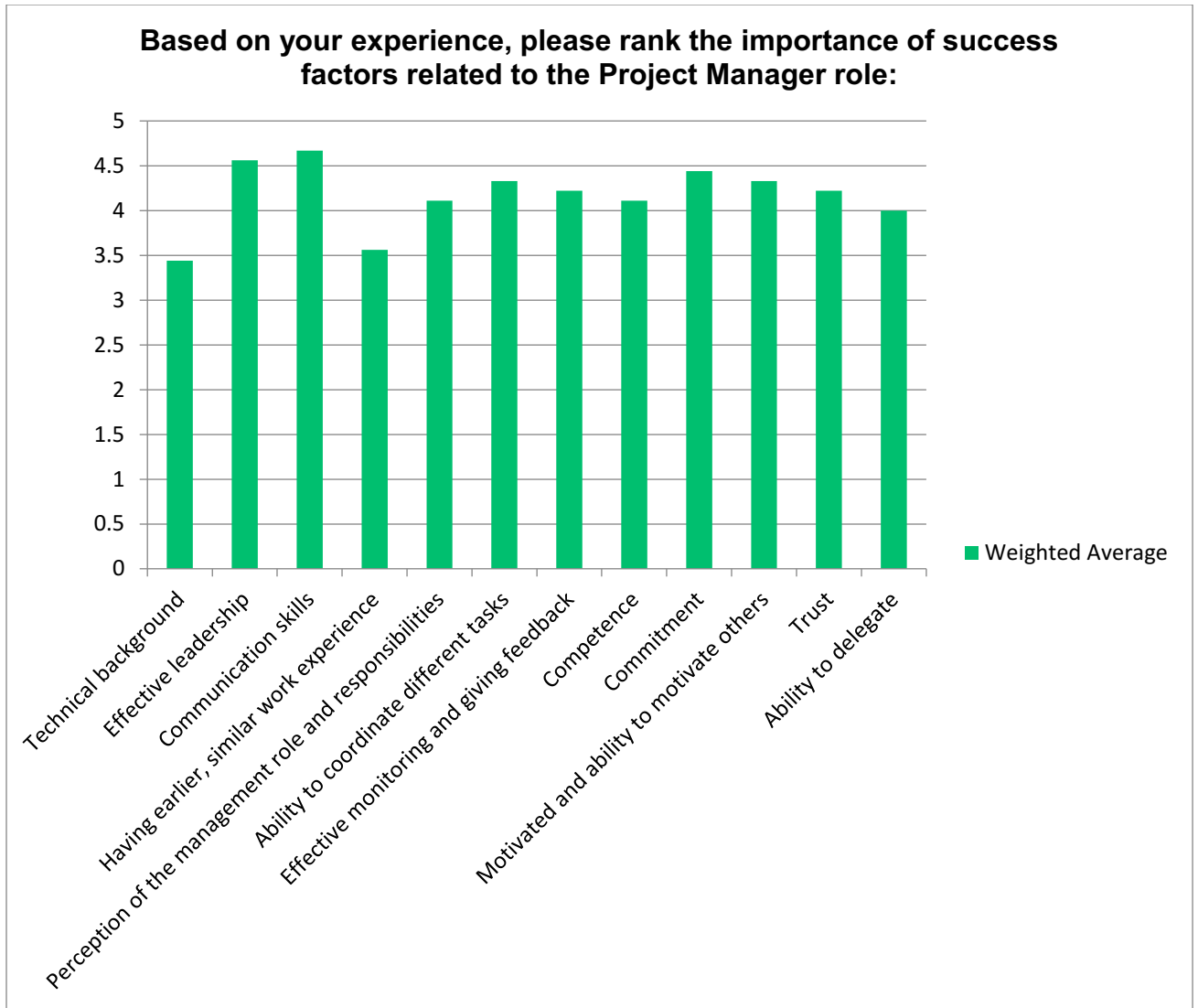


Figure 11. Based on your experience, please rank the importance of success factors related to the Project Manager role.

Answers from respondents that are/were involved in pre-LO/LO projects.

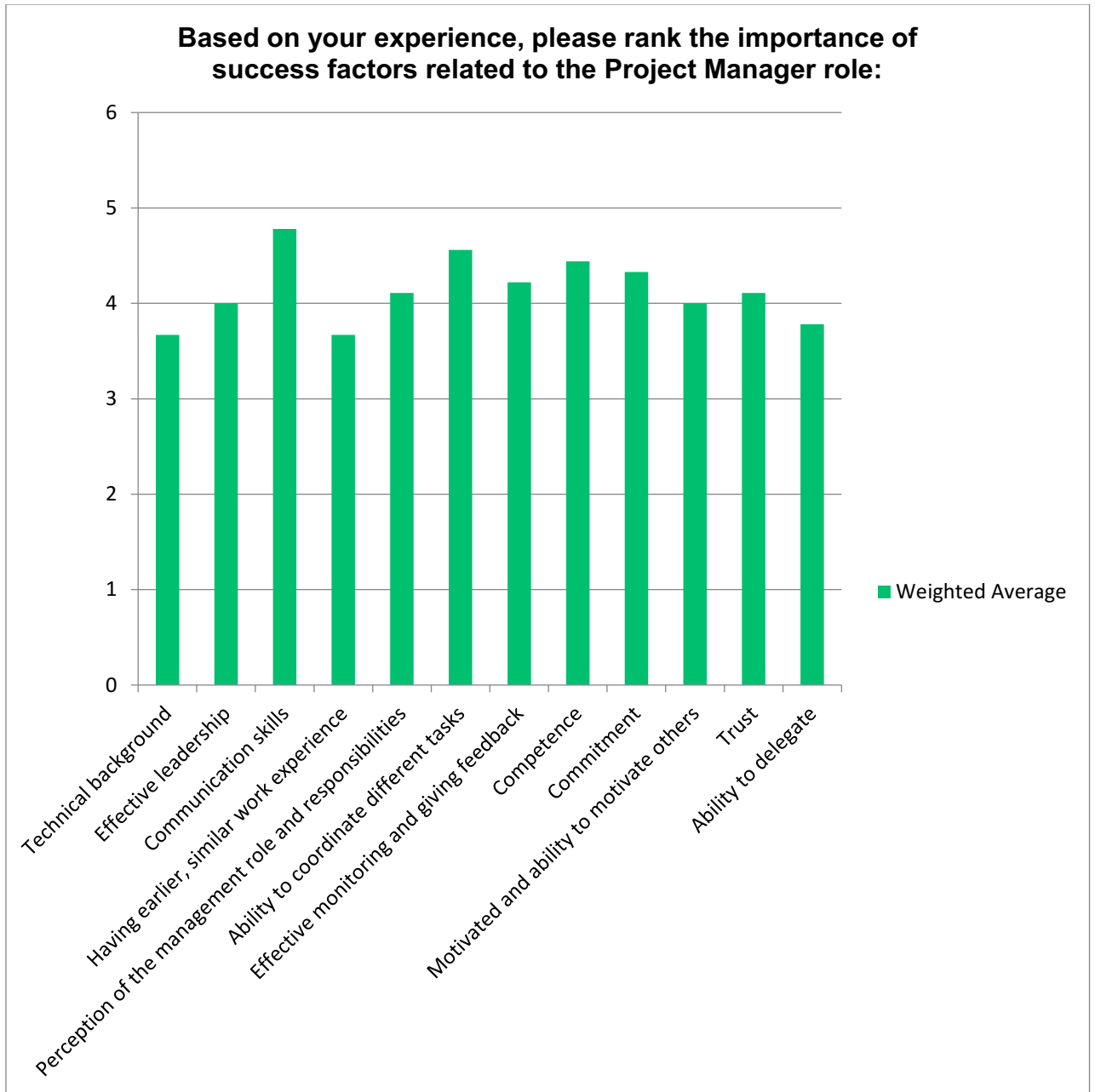


Figure 12. Based on your experience, please rank the importance of success factors related to the Project Manager role.

Answers from respondents that are/were involved in post-LO projects

Question 36. What on this project(s) worked well?

This question received 8 responses from the pre-LO/LO group and 9 responses from the post-LO group.

The author compiled these responses and organized them by their relevance to this study and common theme, and summarized them in Figures 13 and 14 below:

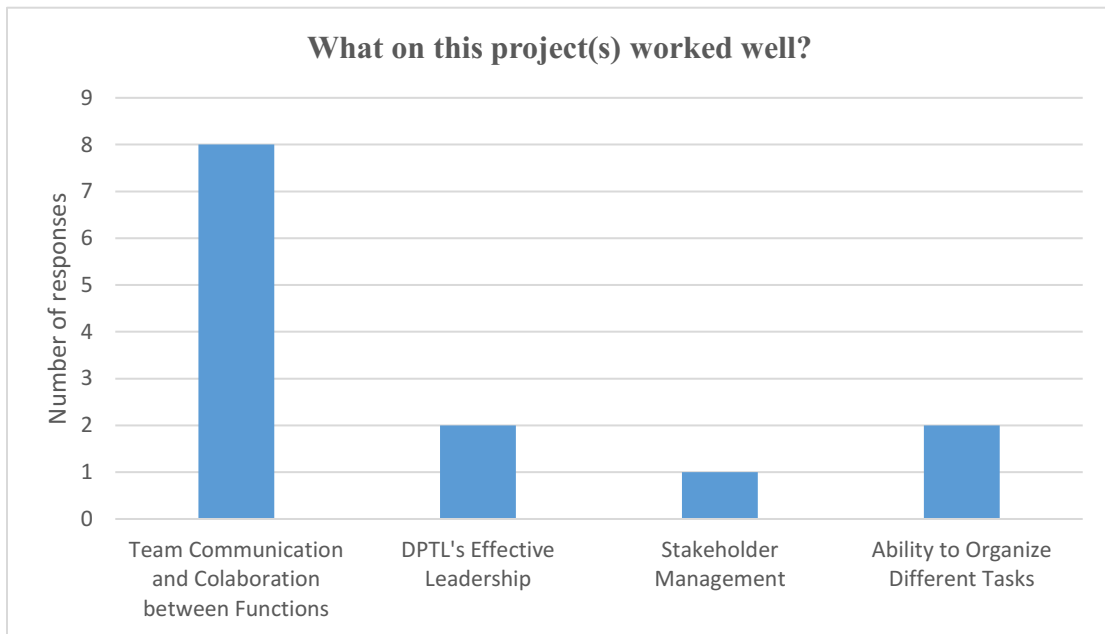


Figure 13. What on this project(s) worked well?

Answers from respondents that are/were involved in pre-LO/LO projects.

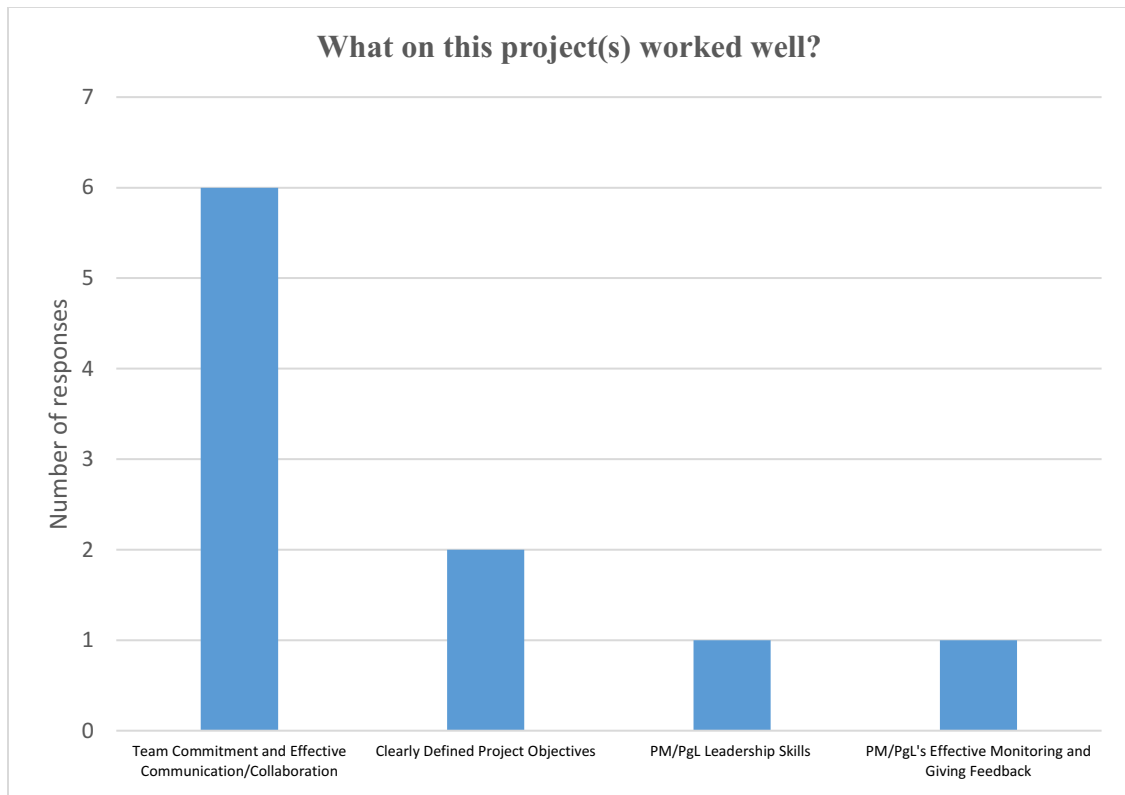


Figure 14. What on this project(s) worked well?

Answers from respondents that are/were involved in post-LO projects.

Since this was one of the questions in the survey that allowed for multiple responses, the total outcome is not 100%.

Question 37. What were the most significant issues on the project(s)?

This question received 8 responses from the pre-LO/LO group and 9 responses from the post-LO group.

The author compiled these responses and organized them by their relevance to this study and common theme, and summarized them in Figures 15 and 16 below. It should be noted that majority of answers received from the pre-LO/LO respondents and some of the

answers from the post-LO respondents were related to project-specific issues and were therefore left out of this research study.

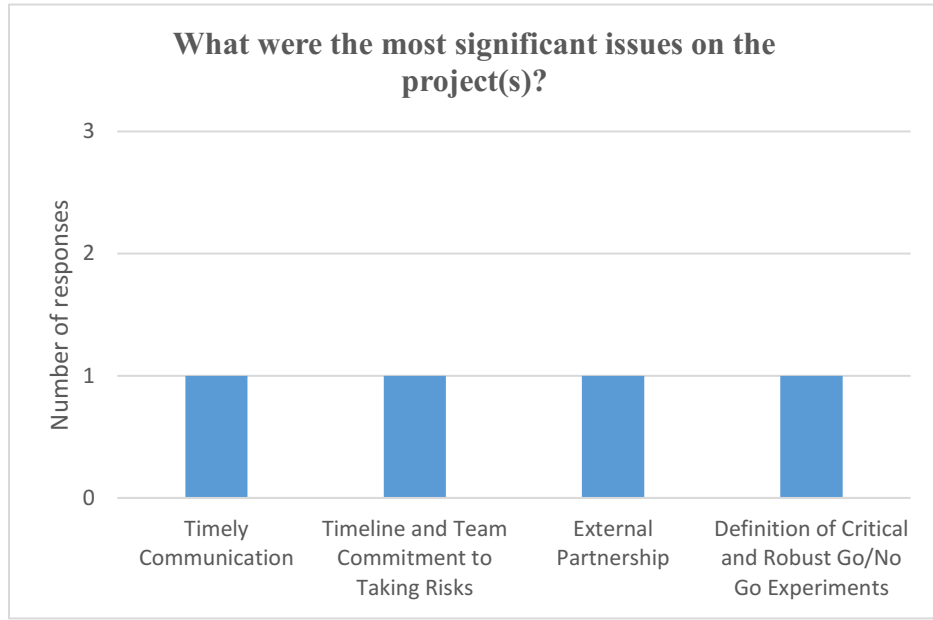


Figure 15. What were the most significant issues on the project(s)?

Answers from respondents that are/were involved in pre-LO/LO projects.

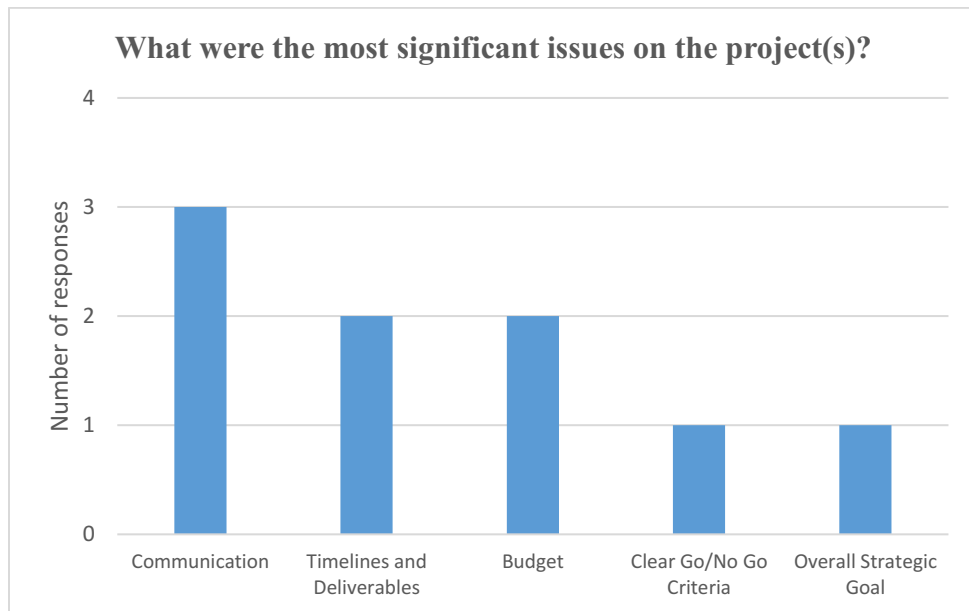


Figure 16. What were the most significant issues on the project(s)?

Answers from respondents that are/were involved in post-LO projects.

As seen in Figure 16, 3 respondents from the post-LO group said that communication was one of the most significant issues on projects they have supported. One of these three respondents stated: “One of the most detrimental things on a team is silo communication. When decisions are taken in small groups behind closed doors, this does not allow for all functions to consider how their deliverables might impact and be impacted by this decision. The PM can play a critical role to bring together relevant functions when they are being left out of important conversations and facilitate different ways to communicate if the usual forums (i.e. team meetings) are no longer effective.” Another one of these three respondents stated: “Ensuring communication of responsibilities for projects involving multiple cross-functional team members posed a challenge.” The remaining respondent stated that in terms of expected deliverables, “unclear directions were given to team by management.”

Question 38. What could have been different if a Project Manager was assigned earlier in the project discovery stage?

Out of 8 responses from the pre-LO/LO group, two individuals stated that not much could be different if a PM was assigned prior to pre-LO stage (i.e. HO), one of the eight respondents stated that assigning a PM at an earlier stage would help but it is not critical.

The other five responses are listed below:

- It may help the project move forward smoothly.

- Better identification of the critical experiments and the models/resources needed to fulfill them.
- Some of the communication issues can be resolved.
- Early to address the issues.
- Better planning of experiments with endpoints clearly defined. This is especially helpful in guiding relatively inexperienced teams or DPTLs.

Out of nine responses from the post-LO group, six respondents answered that either not much would be different, or that they were not sure as they were not familiar with when PMs are assigned to projects. These answers are not surprising since majority of functions involved in post-LO projects come onboard at the DPED or DP0 stage, where a PM is already assigned. The other three responses are listed below:

- I have limited experience in early projects, but the team dynamics would be the same whether a project is early or late, and PMs can play a critical role in facilitating effective team communication.
- Organization of deliverables and effective timelines.
- Better alignment.

The common theme observed in the answers to the open-ended questions (questions 36-38) is Communication and responses in this section correlate to responses seen in the Team Communication category. Based on these results, the author suggests further investigation into communication gaps to determine the source of this finding.

Summary of Findings

Based on results from interviews with experts in the Pharmaceutical R&D Industry, review of project/portfolio records, and the survey aimed at cross-functional team members involved in both pre-LO/LO and post-LO project stages, it is concluded that pre-LO/LO projects can benefit from an early assignment of Project Managers who can add a value to projects at an organizational level, more specifically in terms of improving project planning and risk mitigation. Findings from interviews showed that integration of PMgmt principles in early Drug Discovery can help prevent communication silos, prevent duplication of work, and increase the overall project success. Findings from the survey showed the benefit of early PM assignment in improving project planning and risk management. Since early Drug Discovery projects are very exploratory and based on the findings from the above sources, a full-time PM may not be necessary. In general, early-Discovery project teams can efficiently handle communication and the scientific aspects of their projects, however majority, if not all pre-LO/LO DPTLs are scientists and do not have a project management background. Keeping all project information updated and communicated in a timely manner takes a lot of time and effort on the scientists' part because these individuals have responsibilities for multiple project teams. Thus, as it can be seen from the responses above, quality and consistency of such information may suffer, putting projects' success at risk. Assigning a part-time PM to pre-LO/LO projects to oversee the Business processes (i.e. project planning, including timelines and risk management) and creating clear Go/No Go criteria for project deliverables would be a great benefit to early projects. Additionally, a part-time PM in pre-LO/LO could facilitate DPTLs in team/stakeholder communication,

which would be economically feasible for EMD SRDI because one PM could oversee multiple projects. This type of team structure would allow DPTLs to focus more on managing the scientific aspect of their projects.

Chapter V.

Conclusion

The aim of this study was to evaluate whether, and to what extent early Discovery projects can utilize PMgmt and to understand the cost and benefit of early assignment of PMs. In addition, this thesis also aims to determine the set of skills a PM should possess when managing early Discovery stage projects.

This thesis is based on information collected from one company within the pharmaceutical industry, where EMD SRDI processes are used to draw conclusions that could be relevant to all companies in the industry. Findings from this study support the author's hypothesis that assignment of PMs to early-Discovery projects would bring value to these projects and their teams. The conclusion, which is based on questions that had significant number of responders, is that early-Drug Discovery projects and their teams can benefit from an early PM assignment in the areas of project planning and risk management. Results from this study show that pre-LO/LO teams are very efficient in managing most of their project needs, suggesting that DPTLs can manage their teams as readily as PMs. Evidence gained from interviews and the survey also show that a full-time PM is not necessarily needed for early-Discovery since activities for projects in this stage are still heavily science-based. However, a part-time PM who can manage teams in partnership with a DPTL (i.e. scientific project manager) would be very valuable. Based on the evidence in this study, the author suggests a project management model in which a DPTL manages the scientific aspect of a project and a part-time PM manages the

operational aspect of the project. In this role, a PM would provide an oversight to project demands and activities, and would ensure that a project is moving forward smoothly according to project objectives/expectations and company guidelines/acceptance criteria. The main responsibilities of a part-time PM in early-Discovery projects would be to facilitate communication, plan and follow up on timelines and deliverables, and risk management. This would also reduce the amount of work and time DPTLs and scientists spend in trying to collect, properly document, and communicate project information while having additional various responsibilities for multiple projects at the same time.

In addition to the above, based on responses received from the survey and the interviews, PM's skills/characteristics related to successful management of early-Drug Discovery projects are identified. In general, a PM should be able to identify and eliminate the factors which may have a negative impact on the project execution process early on and address it in a timely manner.

At the beginning of this study, the author identified two key factors that drive the project success and formulated two main questions driving this study. Explanation and conclusion to these questions is exemplified further in the next sections of this chapter.

As a final word to this conclusion, although this study is based on the evidence gained from internal records and a survey of only one company and its employees, its findings can help Pharmaceutical R&D companies interested in evaluating their Drug Discovery PMgmt in serving as a baseline for designing larger, real-time studies that analyze their Drug Discovery PMgmt practices.

Research Question 1: Would applying the PMgmt principles, all or some, strengthen the way of progress for projects from early Discovery stage by bringing more structure and by improving the planning of efforts, time, and risk management?

Based on the evidence in this study, the answer is yes, applying all eight PMgmt principles can help early-Discovery projects and their teams move forward smoothly by bringing more structure through careful and meaningful organization and communication, streamlining processes involved in planning of timelines and specific project-related activities, including risk management.

Research Question 2: What set of skills does a PM need to possess to successfully manage Discovery projects and does it differ from PM skill set needed for Development project management?

Based on the evidence in this study, a PM's skills/characteristics related to successful management of early-Drug Discovery projects were identified. The information gained from the survey responses showed that although pre-LO/LO and post-LO projects differ in their project-related requirements, team dynamics are still the same and thus, PM characteristics and skills needed to manage pre-LO/LO projects are almost the same.

According to the survey findings, a successful PM managing early-Discovery projects should possess (ranked in order of importance):

- Good Communication Skills
- Effective Leadership Skills
- Commitment

- Motivated and Ability to Motivate
- Ability to Coordinate Different Tasks
- Effective Monitoring and Feedback
- Trust

Based on the list above, it is concluded that interactional skills are absolutely in the highest interest for project team members in order to achieve a more effective, efficient, and successful project execution and project control.

Suggestions for Future Studies:

As briefly mentioned above, a longer real-time case study may be valuable in providing a quantitative way to measure and evaluate the cost and benefit of early assignment of PMs. The author suggests a design for a future real-time case study that could further aid the Drug Discovery PMgmt practices in determining what PMgmt models bring the most value to early-Drug Discovery projects and their teams. A high-level study design schema follows next. It should be noted that the design presented below is only a general schema of steps that could be used in planning a case study and can be used as a baseline to build a real-time case study upon.

- Choose a project in early-Drug Discovery (HO/LO).
- Determine the rate-limiting steps and generate a list of success factors (and assign them a rating) that could be used to determine the success of the project and the success of its PM quantitatively. (i.e. improve timelines without adding more full-time equivalents (FTEs))

- Assign a dedicated PM to this project to oversee business operational activities of this project, including, but not limited to generating timelines, resource and budget planning, ensuring deliverables meet the acceptance criteria set by the management.
- Review the progress on a regular basis up to the DPED phase and identify any gaps and rate the success factors based on the rating determined earlier.

Appendix 1.

Interview Questions

Participant information:

1. What kind of projects have you been involved with?
2. What is your role in project teams?

Business processes:

3. What is the level of your involvement in project teams you support?
(What responsibilities do you have in projects?)
4. How satisfied are you with the level of your involvement and responsibilities?
5. How are project activities planned?
6. How are time, cost, and quality managed?
7. What is the most difficult part of supporting early-Discovery Projects?

Team communication:

8. What is an average team size?
9. How satisfied are you with the communication within the team?
10. Are project meetings conducted on regular basis and are they efficient and productive?

The roles of Project Managers and Stakeholders:

11. Who manages the projects you support in early-Discovery?
12. How easy is it to get the access to information you need from the project leader?
13. What do you see as an issue in the way early-Discovery projects are managed that could be improved by having an assigned PM?
14. What do you think are the most important characteristics of a project manager?
15. What characteristics can create inefficiency amongst project managers?

Appendix 2.

Survey Questions

Participant information:

16. Your Job Title:

17. Your role in project teams:

18. Have you been involved in projects during LO or earlier:

Yes No

Business processes:

19. A project plan used as a basis for defining Project Scope and requirements in the Project Proposal?

- Don't know
- Never
- Rarely
- Sometimes
- Often
- Always

20. The list of activities matched with what was defined in the Project objectives.

- Don't know
- Never
- Rarely
- Sometimes
- Often
- Always

21. Project objectives and goals were clearly outlined during the Project Initiation and Planning.

- Don't know
- Never
- Rarely
- Sometimes
- Often
- Always

22. Project team had fully written procedures for how the project will proceed (project guidelines, implementation plans, resource planning, etc.).

- Don't know
- Never

- Rarely
 - Sometimes
 - Often
 - Always
- 23. Time, Cost and Quality were efficiently managed.**
- Don't know
 - Never
 - Rarely
 - Sometimes
 - Often
 - Always
- 24. The initial Project Schedule/Timeline closely compared with the actual schedule/timeline.**
- Don't know
 - Never
 - Rarely
 - Sometimes
 - Often
 - Always
- 25. The estimated Project Budget closely compared with the total actual expenditures.**
- Don't know
 - Never
 - Rarely
 - Sometimes
 - Often
 - Always
- 26. Best Practices and Lessons Learned from prior projects were utilized in this project(s).**
- Don't know
 - Never
 - Rarely
 - Sometimes
 - Often
 - Always
- 27. Team members were involved in the risk identification and mitigation planning process.**
- Don't know
 - Never
 - Rarely
 - Sometimes
 - Often
 - Always

28. Risk Management Plan was reviewed and updated on a regular basis.

- Don't know
- Never
- Rarely
- Sometimes
- Often
- Always

Team communication:

29. Expectation of your role and your responsibilities in a project(s) were clearly communicated.

- Don't know
- Strongly disagree
- Disagree
- Neither agree nor disagree
- Agree
- Strongly Agree

30. The communication materials provided to you were effective in providing and orienting team members about the details of the project.

- Don't know
- Strongly disagree
- Disagree
- Neither agree nor disagree
- Agree
- Strongly Agree

31. Project team meetings were conducted on a regular basis.

- Don't know
- Strongly disagree
- Disagree
- Neither agree nor disagree
- Agree
- Strongly Agree

32. Team meetings were efficient/productive (including ability to make decisions and address potential bottlenecks).

- Don't know
- Never
- Rarely
- Sometimes
- Often
- Always

33. Progress reports (from the actual functions) were provided by team members in a timely fashion.

- Don't know

- Strongly disagree
- Disagree
- Neither agree nor disagree
- Agree
- Strongly Agree

34. The format and content of the Project Status Report were useful.

- Don't know
- Never
- Rarely
- Sometimes
- Often
- Always

35. Project document repository (i.e. SharePoint, Eldorado) was useful and complete.

- Don't know
- Never
- Rarely
- Sometimes
- Often
- Always

36. Acceptance criteria for project deliverables was clearly defined and communicated.

- Don't know
- Never
- Rarely
- Sometimes
- Often
- Always

37. Project issues were transparently communicated to the project team.

- Don't know
- Never
- Rarely
- Sometimes
- Often
- Always

38. Issues were managed within the team effectively before escalation was necessary.

- Don't know
- Never
- Rarely
- Sometimes
- Often
- Always

39. Project team resolved project issues without impacting the Project Schedule or Budget.

- Don't know
- Never
- Rarely
- Sometimes
- Often
- Always

40. Project performance was monitored and clearly communicated to all stakeholders, including the project team, on a regular basis.

- Don't know
- Strongly disagree
- Disagree
- Neither agree nor disagree
- Agree
- Strongly Agree

The roles of Project Managers and Stakeholders:

41. Frequency and content of information that was conveyed to you by the DPTL/Project Manager met your expectations.

- Don't know
- Strongly disagree
- Disagree
- Neither agree nor disagree
- Agree
- Strongly Agree

42. DPTL/Project Manager responded to your questions or comments related to the project in an informative and timely manner.

- Don't know
- Never
- Rarely
- Sometimes
- Often
- Always

43. At the beginning of the project, the DPTL/Project Manager prepared a specific timeline and sequence of activities and used this schedule to manage the overall project to ensure its timely completion.

- Don't know
- Never
- Rarely
- Sometimes
- Often
- Always

44. DPTL/Project Manager clearly and frequently communicated what needs to be done by what deadline and expected people whom they assigned the work to be responsible for breaking down the work packages into smaller and more manageable pieces.

- Don't know
- Strongly disagree
- Disagree
- Neither agree nor disagree
- Agree
- Strongly Agree

45. At the start of the project, the DPTL/Project Manager formally outlined what, why, who, and when so it was clear how the elements of the project fit together.

- Don't know
- Strongly disagree
- Disagree
- Neither agree nor disagree
- Agree
- Strongly Agree

46. Based on your experience, please rank the importance of the success factors related to the Project Manager:

Scale (1-5), where 1 – least important and 5 – most important

- Technical background
- Effective leadership
- Communication skills
- Having earlier, similar work experience
- Perception of the management role and responsibilities
- Ability to coordinate different tasks
- Effective monitoring and giving feedback
- Competence
- Commitment
- Motivated and ability to motivate others
- Trust
- Ability to delegate

47. Stakeholders (i.e. functional management, executive management) were actively and meaningfully involved in the project.

- Don't know
- Never
- Rarely
- Sometimes
- Often
- Always

48. Stakeholder communications were adequate and effective.

- Don't know
- Strongly disagree
- Disagree
- Neither agree nor disagree
- Agree
- Strongly Agree

49. Stakeholders' expectations for the project were clearly defined.

- Don't know
- Never
- Rarely
- Sometimes
- Often
- Always

50. Decisions were clearly communicated by the executive management and understood by the project team.

- Don't know
- Never
- Rarely
- Sometimes
- Often
- Always

In Your Own Words:

51. What on this project(s) worked well?

52. What were the most significant issues on the project(s)?

53. What could have been different if a Project Manager was assigned earlier in the project discovery stage?

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