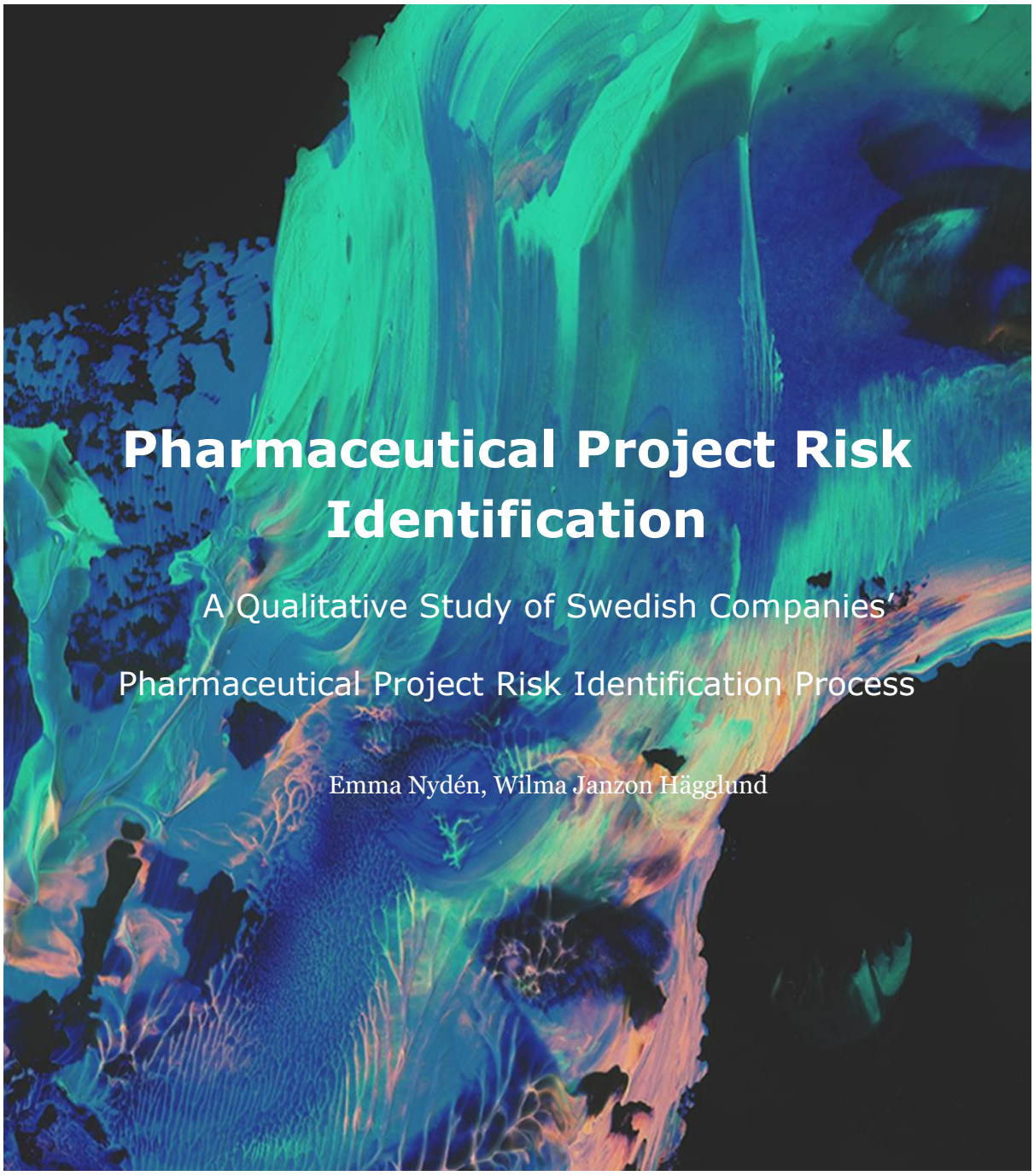

Pharmaceutical Project Risk Identification

A Qualitative Study of Swedish Companies' Pharmaceutical Project Risk Identification Process

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Abstract

The pharmaceutical industry has received increasing attention from society in recent years, mainly due to the development of vaccines to counteract the spread of Covid-19. While other industries have received sympathy for delays, inconveniences, and difficulties the pressure towards the pharmaceutical industry to produce the vaccine against the virus has increased. However, the Covid-19 pandemic has left no one untouched, it has affected the global economy, increased the unemployment rate, reduced incomes, and resulted in disruption for transportation. The Covid-19 pandemic has also left its mark in the pharmaceutical industry. When lockdowns were implemented, it caused restrictions of in country and cross border movements, hampering the transportation and delivery of pharmaceutical suppliers, causing shortages or disruptions. This has resulted in an industry where unpredictability is constant, while still aspiring to provide stability and safe products for the patients through their projects. Even though the industry is known for working on projects, it is still immature in comparison to other industries, regarding project management knowledge, and therefore also knowledge about risk management. Generally, the pharmaceutical industry is hesitant towards risk and being cautious can be beneficial when managing risk. However, the pharmaceutical industry is dependent on innovation and development of new medicines which is often associated with taking risks.

The purpose of this thesis is to provide insights into the beginning stages of risk management for projects within the pharmaceutical industry, during the covid-19 pandemic in Sweden. The Swedish pharmaceutical industry has during 2020 broken new records regarding exports and increased the volume by ten percent whereas the general export in Sweden has decreased. This study explores pharmaceutical projects' risk identification by interviewing eight active project members who have been a part of projects both before and during the Covid-19 pandemic.

A qualitative method was chosen for this study, paired with grounded theory that has provided us with several implications for pharmaceutical projects and their risk identification. We have discovered indications for the structure of the risk identification process. This structure indicates four separate steps of the risk identification process. The first step is *classifying risk,* where cross-functionality plays an important role. Afterwards, the risk identification process enters the complex environment and continues to the second step. This step initiates the *risk search - mixed approach*, consisting of the individual and collective approaches towards risk search. Here, pharmaceutical projects can take guidance from stakeholders such as regulatory authorities. The third step is *reaction* which can be altered by unpredictable disruptions or governed by the stakeholders. In this case, the project re-assesses and returns to the second step *risk search - mixed approach.* However, if the reaction is not to re-assess, the process continues to the fourth step *temporarily completed risk identification*. Then, due to the long project lifespans, the project will ultimately return to the first step and repeat the risk identification process.

Our study contributes to new insights into pharmaceutical risk identification in several theoretical ways. Mainly, we have shown that contrary to previous theories, the pharmaceutical project risk identification entails the classifying of risks before the risk search. Additionally, our findings generate insights for practical purposes for project members and relevant stakeholders.

Keywords: Risk identification, Pharmaceutical industry, Covid-19 pandemic, Project management

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1. Introduction

The degree project will be initiated by an introduction of the problem background within risk identification for Swedish pharmaceutical private firms during Covid-19. Subsequently, a discussion of the arrival of the research problem will occur, followed by the research question. Lastly, the purpose of the degree project will be displayed, accompanied by the focus, delimitations, and limitations that the thesis will hold.

1.1 Problem background

The Covid-19 pandemic created a ripple effect in society and showed to be more than just a healthcare crisis. It affected the global economy, increased the unemployment rate, reduced incomes, and resulted in disruptions for transportation (Pak et al., 2020, p. 241). The pharmaceutical industry took a blow in the initial phase of the Covid-19 pandemic. When lockdowns were implemented, it caused restrictions of in country and cross border movements (Tirivangani et al., 2021, p.1). This hampered the transportation and delivery of pharmaceutical supplies, causing shortages or disruptions in the pharmaceutical supply chain. The idea of a pandemic occurring has been speculated for quite some time (World Health Organisation, 2017). Additionally, with health crises such as the Ebola virus, the H1N1 and SARS pandemics, and more universally, the 1918 Spanish flu, it could be argued that the world should have been more prepared. Adversely, managers have the tendency to not provide the necessary attention towards risk management (Cervone, 2006, p.256), which could be a result of the limited ability organisational research has to explain how organisations do, and should deal with risk (Hardy & Maguire, 2016). Limited research on risk identification, could be a reason why the world was not responding to the risk of a pandemic occurring/happening.

As globalisation has increased over the past centuries and decades, the world has become more interconnected, with supply chains spanning all over the world. This in turn, has made companies more vulnerable to international events which could disturb parts of the supply chain. This has become evident during the pandemic, and a prime example of this has been the supply chain disturbances for pharmaceutical companies during the pandemic (Tirivangani et al., 2021, p.1). Since China is the main exporter in the world, producing 60% of the world's API (Active Pharmaceutical Ingredients), the supply issues started early in the pandemic since the virus had its first outbreak in China (Ozili & Arun, 2020, p.12). As previously alluded to, the supply chain issues started at the beginning of the supply chain, making the issues grave for many industries, including the pharmaceutical industry which could not order key ingredients for their production in the quantities that they ultimately required (Tirivangani et al., 2021, p.1).

A large portion of the research and development side of the pharmaceutical industry works in projects (Hoon Kwak & Dixon, 2008, p.553). This creates a need for extensive risk management and risk assessment. The pharmaceutical industry is somewhat less developed when it comes to project management compared to other industries (Chauhan & Srivastava, 2014, p.57), and because of this, one can assume that pharmaceutical companies faced impactful issues when they were forced to deal with unprecedented risk as a result of the pandemic and its effects. The lack of research on risk assessment and more specifically, risk identification, within the pharmaceutical industry poses a problem when these companies are faced with an unavoidable risk in their environment. This, paired with the fact that project managers often avoid counting in 'scary' or unknown risks, and instead focus on risks that they

have seen before or that are predictable to them and are also easy to handle. Many project managers also avoid risks which they usually do not have to deal with since they are prone to conduct a risk assessment largely because it is a requirement to get their projects approved (Hoon Kwak & Dixon, 2008, p.553). This likely means that the current form of risk management and risk identification which the pharmaceutical industry in Sweden uses today is much less sophisticated or developed than it ought to be. If the risk management within a company is effective and good at prohibiting harmful impacts from risks, this will create value within projects, and ultimately for the company (Willumsen et al., 2019, p.731).

Existing literature tells us that in the world of private firms, risk is continually present (Hardy et al, 2020; Hardy & Maquire, 2016; George, 2020). The phenomenon of risk generally has negative connotations and companies are always working to identify and avoid risks (Hardy et al., 2020, p.3). The inescapable presence of risk is something that companies have been forced to realise, and the society we live in has, due to previous disastrous events, become a 'risk society'. Meaning that, since we cannot fully know what we do not know, we compensate by engaging ourselves in debating, preventing, and managing risks that we, ourselves, have created. Therefore, our society creates a vicious spiral (Beck, 2006, p.329) which can be exemplified by the creation of chlorofluorocarbons (CFC). When CFC was developed, we had no idea that 45 years later that we would realise that CFC caused destruction of the ozone layer. Nobody could predict the unforeseen secondary effects of coolants could endanger mankind through climate changes (Beck, 2006, p.330). The Covid-19 pandemic has been a contributing factor to the 'risk society' that we live in, similarly to how previous disasters such as the Global Financial Crisis have done the same, as described by Hardy and Maguire (2016, p.3).

1.2 Arriving at the research problem

Risk identification is important in today's societal context, and specifically in companies that work in unpredictable environments so that they can avoid risks to the largest extent possible (Picciotto, 2019, p. 474). The existing research on risk identification contains several techniques and tools for this process. Some of these include Risk Breakdown Structure (RBS), Risk Profile, Fault Trees, Risk Event Graph, Brainstorming, and Checklists (Larson & Gray, 2021; Ahmed, Kayis & Amornsawadwatana, 2007; Rodrigues-da-Silva & Crispim, 2014). What this existing research has in common is that it recommends people to work in groups rather than individually when identifying risk. If more people are involved, this comprises the knowledge of the project along with the specific context and environment of the project, making it more possible to identify many of the important risks. Therefore, one should not underestimate the power of the collective mind when it comes to risk identification. Nevertheless, risk identification is the one technique that is mentioned and researched about the least, in comparison to the other risk techniques (Elkington & Smallman, 2002, p.50) and risks are impossible to avoid completely. The Project Management Body of Knowledge produced by PMI suggests that all risks are identifiable. However, one of many human limitations is that it is beyond our capacity to be able to predict all future outcomes due to a lack of comprehension, suggesting that all risks actually are not identifiable, as supported by Pender (2001, pp.81, 83). This may well have been the case with the Covid-19 pandemic. It may have been beyond the scope of knowledge and ability of many project managers throughout the world to predict.

Another limitation to the current praxis within project management is that risk is subjective. A risk may be valued in a certain way according to one person, and it can be valued quite differently according to someone else (Campbell, 2006, p.227). Therefore, identifying risky

projects might not be as easy as it seems. Risk assessment is the process where companies identify and judge the likelihood of events with negative impact occurring, and the subsequent impact that this may entail (Williams, 1996, p.185). Catastrophic consequences can come from the failure to manage risks adequately, and therefore it is crucial to conduct risk identification within risk assessments for companies who are trying to survive in the uncertain world we live in. The risk identification process is the first step in the risk assessment. It is thereby the catalyst for being able to carry out risk management (Elkington & Smallman, 2002, p.50), constituting a crucial tool for organisations. Today, we commit ourselves and try to control risks by always identifying and managing risks in our society (Hardy & Maguire, 2016, p.3). Due to the subjectivity of risk and individual valuations of risk, we deduce that it is difficult to use one mainstream approach to risk assessment, and more specifically risk identification. Therefore, there is a need to create a better way to identify risk to make the risk assessment process more effective and to counteract the consequences of the 'risk society'.

Projects and their teams are constantly needing to identify risks in their environment, both internally and externally (Hardy & Maguire, 2016, p.21). One of the most referenced pieces of literature when it comes to project risk identification is Chapman and Ward (2003). Existing literature emphasises the importance of risk being identified at the earliest stage possible within projects (Chapman & Ward, 2003, p. 105). There is also emphasis on bringing in several people to consult throughout the risk identification process, such as customers or other stakeholders along with the people working within the project and the project manager (Chapman & Ward, 2003, p. 106). Three out of five tasks in the identifying phase of project risk management include summoning people for help with identifying risks. These people are associated with different parts and stages of the project, and so they help with creating a holistic image of project risk (Chapman & Ward, 2003, p. 106). However, project managers might not give risks the attention it needs, some even conduct risk management during the planning phase, in order to meet the requirements of getting the project approved (Hoon Kwak & Dixon, 2008, p.553). According to Cervone, this does not consequently imply that project managers do not consider the issues attached to risks (2006, p. 256). Instead, project managers conduct a comprehensive survey of the project and its risks to know how much "margin of risk" they should add on (Cervone, 2006, p.256). Hence, project managers do not completely ignore risk, but they only carry out very superficial practices to prevent the risks from taking place and therefore, spotting real risky projects can be hampered due to the generalisation from project managers. As a result of lack of awareness and over-optimism about one's project, leading to project managers not accepting the part of reality which states that projects are risky undertakings (Raz et al., 2002, p. 107).

Instead of exploring and mapping out possible unknown risks, project managers tend to focus only on the most common risks they have observed in the past (Hoon Kwak & Dixon, 2008, p.553). Today, having a good project plan with an evolved monitor- and control system is not enough. Many projects experience delays, overruns, and defeat even though risk management tools and techniques have been developed to counteract these outcomes. However, not many project managers use the tools and techniques to gain project success (Raz et al., 2002, p.101). Project risk management practice has shown to be correlated with the success of meeting the project's time and budget goals (Raz et al., 2002, p.105). Additionally, a clear indication for the need of continuous research on project management to provide practitioners with instructions and tactics for their project management approach is the rapid increase in memberships with the Project Management's Institute (PMI) (Larson & Gray, 2021, p.5). Therefore, by developing a set of indicators or identifiable conditions so that risks with a project can be detected and addressed before the project has failed will be favourable for projects and

companies that carry them out (Pinto & Mantel, 1990, p. 268). Project risk management should be implemented into the culture of project management activity as a routine and recurring event.

There is a clear bias in project management when it comes to which projects get more attention paid towards risk management. Project risk management practices are added to a higher extent towards projects that have greater uncertainties to prevent the risks, because of the preconceived notion that exists, that high-risk projects are often less successful than low-risk projects (Raz et al., 2002, p.105). Often, even managers who have more experience are also appointed to more complex projects while less experienced get simpler types of projects (Raz et al., 2002, p.102). In fact, high-risk projects are no less successful than low-risk projects (Raz et al., 2002, p.105). Managers do not put as much focus into preventing risks or using risk management techniques or tools in low-risk projects. While in high-risk projects, more techniques are resorted to, and the projects are managed more carefully and therefore the two types of projects have the same level of success. Something that is missing and needs to be made visible is that projects with low uncertainty can also face delays and do not have success as a guarantee. Although high-risk projects have greater uncertainties and may require greater resources, low-risk projects should also use risk management practises to minimise the risk of failure and increase the success rate. However, in the same way that there are different types of projects, different types of risk management practices are also needed, which can be used in different ways and for different purposes. Nevertheless, the message remains, high-risk projects should not be the only projects to engage in project risk management. Projects with lower risk, and therefore projects in general, would benefit from enforcing project risk management (Raz et al., 2002 p.107).

As mentioned, pharmaceutical companies tend to work in projects and projects contain risks. Through previous studies, it has been shown that pharmaceutical project management is less mature than in other industries such as financial services, telecoms, and engineering construction (Chauhan & Srivastava, 2014, p.57; Cooke-Davies & Arzymanow, 2003, pp.475, 477). Even when compared to other high-tech industries such as IT, Aerospace and manufacturing, the pharmaceutical industry is still a bit behind (Chauhan & Srivastava, 2014). The reason why this is so may be many, but for pharmaceutical companies, implementing an effective risk management in projects is both challenging and demanding (Hoon Kwak & Dixon, 2008, p.552). Additionally, from a broader and more in-depth perspective, more research has been done in the field of IT than pharmaceutical (Hoon Kwak & Dixon, 2008, p.554), which can further explain their lack of risk management in projects. Having said that, the lack of implementation causes a higher chance of risk appearing which has proven to implicate in exceeding budget and postpone schedule. Therefore, providing a way to implement an effective risk management for pharmaceutical companies can contribute projects to encounter cost, schedule, and specification (Hoon Kwak & Dixon, 2008, p.553), and additionally, prevent excessive firefighting.

The Swedish pharmaceutical industry broke new records in exports, increasing the volume by ten percent, while Sweden's exports in general decreased with six percent during 2020 (lif, 2022). We consider Sweden to be highly engaged within the pharmaceutical industry, since one of the leading pharmaceutical companies in the world, AstraZeneca originates from Sweden, along with other companies such as AkzoNobel, Vitrum and Nouryon.

1.3 Research question

In reference to previously mentioned research gaps and the background to the topic, the research question we aim to answer with this degree project is:

- *How do companies conduct risk identification within pharmaceutical projects during the covid-19 pandemic in Sweden?*

1.4 Purpose

The purpose of this thesis is to provide insights into the beginning stages of risk management for projects during Covid-19 in Sweden, within the pharmaceutical industry, which is of crucial importance to our society. Therefore, the goal is to establish an insight and gain a deeper understanding around pharmaceutical companies approach when identifying risk in their projects, during the covid-19 pandemic in Sweden. Although previous literature concerning risk management and the role it has within a project is well-documented, we strive to broaden the knowledge through our degree project by including practitioners using interviews. In addition, we aim to elaborate how pharmaceutical companies have managed identifying risks during the pandemic, where uncertainty is consistent. By exploring which strategies and practices are successfully useful for pharmaceutical companies, we desire to bring value for future research and practitioners when identifying risk and proceeding with projects. In addition, in our judgement, the study could introduce techniques and generate knowledge for future disasters, potentially resulting in rapidly and more efficient prevention and protection towards disasters. However, on the one hand, disasters are highly unpredictable in both effect and occurrence. Therefore, it can be complicated to predict what is to come for the future. One the other hand, we argue that our study can still provide an understanding and insight into how companies can make themselves more prepared for uncertainties. Which is useful and beneficial for companies involved in projects but also for more general companies in uncertain environments. It could potentially guide and support them in elections and decisions regarding similar environments.

1.5 Focus, delimitation, and limitation

The focus of our degree project will be on analysing pharmaceutical companies exclusively. The selection was made based on the desire to capture an industry that evolves, to a high degree, around projects and as previous studies have shown (Chauhan & Srivastava, 2014, p.57) is less mature in project management. We are aware that, deciding on the pharmaceutical projects' perception and their evolution regarding risk, we turn our backs on many industries and perspectives that manage risk e.g., financial services and engineering construction. Nevertheless, these fields could be an enchanting area to study for future research. Even though we will not focus on these fields, it is possible that the contributions our degree project will generate could be applicable to other industries as well, that stands in front of similar uncertainties and unpredictable environments. However, as mentioned, the study will solely focus on the pharmaceutical industry, as we sought to concentrate on the detected research gap within pharmaceutical project management.

We have also delimited our thesis to analyse a specific part of risk assessment, risk identification. This is because we want to gain a detailed understanding about how pharmaceutical companies approach risk, and how they work to identify these risks in their

environment. If we were to analyse risk assessment, we believe that this would be too broad, and that this could leave our results quite scattered, losing the potential to answer a specific and detailed research question. That is the reason for our specificity within risk management and risk assessment. We have also chosen risk identification since we believe that there is a gap in the current research, specifically when it comes to risk identification within specific industries such as the pharmaceutical industry. There are many articles and authors which investigate the risk assessment process and where risk identification is mentioned as a step along the way (Williams, 2017; Project Management Institute, 2021), but there is often no in-depth analysis into the specific identification process. We hope to contribute to filling this gap, and to provide some answers which hopefully can be extrapolated into other industries outside of our chosen industry.

Additionally, we will limit this study to pharmaceutical projects in a certain geographical area, which we have chosen to be Sweden. This enables us to have as many common factors between the participants as possible to be able to analyse their answers based on their common background. Furthermore, something that reinforces our choice of limitation was the covid-19 pandemic. Regulations, restrictions, and precautions that have been implemented by different governments within their countries due to the pandemic have caused companies to experience different environments even though they exist on the same market. Since the preventive measures have been severely different between countries, focusing on one country enhances the possibility to compare the participants in an unbiased way. Therefore, the ongoing covid-19 pandemic has played a part in the geographical limitation.

2. Scientific methodology

For this chapter, we start to discuss the choice of subject and pre-understandings. Thereafter, we have mentioned research philosophy and addressed our philosophical assumptions. Subsequently, the research approach and research design are discussed to give more insight into why our degree projects are shaped as it is. Lastly, literature search and source criticism are presented.

2.1 Choice of subject

The choice of research subject originates from a project management course within *Civilekonomprogrammet* at Umeå University. During the course, our interest in risk management within projects emerged which eventually forged this research subject. Subsequently, we began to search for research gaps and niches within project management. Our first direction was to explore companies' entire risk management process which, due to lack of time and resources, was adjusted. With the support from our supervisor, we narrowed the area down to project risk identification. Secondly, we thought about looking into the construction industry, since they frequently conduct projects. However, we identified that the pharmaceutical industry was not as researched or covered as the construction industry, and thereby we could justify the need for further research to be conducted. The pharmaceutical industry became more suitable since it also became apparent that the industry had been highly affected by the ongoing covid-19 pandemic. In addition, the covid-19 pandemic has displayed new challenges for companies from the perspective of business research. Altogether, we have found risk identification for pharmaceutical companies, affected by the covid-19 pandemic to be a suitable object for this study.

2.2 Pre-understandings

Preunderstanding is previously retrieved knowledge, insights and experience which becomes useful when comprehending "new" research and contexts (Ryan, 2011, p.220). Additionally, pre-understanding can enhance the quality of a research, since it can increase both visibility and transparency, as well as proximity to the phenomenon (Stenbacka, 2001, p.554). Our preunderstandings related to our topic mainly lie within project management and risk management. As mentioned above, we have taken courses related to project management before, and we also have seven semesters of experience in university courses within business administration. However, our preunderstandings about the topics related to this thesis are mostly second-hand preunderstandings. This means that they are based on literature rather than first-hand experiences (Stenbacka, 2001, p.554). This means that proximity to the phenomenon may be more of a challenge in our case compared to if we were to have first-hand preunderstandings. We will remain aware of them throughout our research process and make every attempt to ensure access through proximity and understanding of the phenomenon we are researching (Stenbacka, 2001, p.553).

Furthermore, our knowledge about the pharmaceutical industry is limited. This is especially true about the industry before the covid-19 pandemic. This can display itself as a barrier (Stenbacka, 2001, p. 553) since we will not have any first-hand pre-understandings concerning the pharmaceutical industry. First-hand pre-understanding is acquired through personal experience, whereas second-hand is based on literature (Stenbacka, 2001, p.553; Ryan 2011, p.220). However, through previous knowledge within management, specifically regarding risk- and project management, we will attempt to conquer the barrier, combined with an objective

literature research. An objective literature research is conducted to prevent possible partiality, and to move towards a holistic view on the phenomenon (Stenbacka, 2001, p.553). Previous experiences laying the base for biases and partiality should be mitigated by the process of an objective literature search.

2.3 Research philosophy

Research philosophy is derived from the research paradigm. There are two main paradigms, positivism and interpretivism (Collis & Hussey, 2014, p.43-44). Research philosophy presents the fundamental assumption during the research, since it is the nature of knowledge, reality, and existence (Collis & Hussey, 2014, p.43). Therefore, it is essential for researchers within management to contemplate this since the different philosophical choices can determine and impact the study extensively. Interpretivism is the paradigm most often used when conducting research within the social and humanitarian sciences. This is because interpretivism allows for the subjectivity of reality, along with the existence of multiple individually experienced realities (Collis & Hussey, 2014, p.46). Interpretivism is often used for research within humanist areas as it pairs well with the qualitative method (Collis & Hussey, 2014, p.46). The qualitative method and the interpretivist view allow for research to gain a deeper understanding about a phenomenon or subject, also being our goal with this thesis. This can be done through interviews where the respondent reflects on their own experiences and their subjective reality along with their personal relationship to and experiences with the phenomenon (Bell et al, 2019, p.32). We want to gain a deeper understanding about the risk identification process within Swedish pharmaceutical projects before and during the Covid-19 pandemic. On the contrary, positivism takes an objectivist approach, where reality exists separately from social actors while also being objective and observable, and often 'measured' by testing hypotheses (Bell, Bryman, and Harley, 2019). The positivist approach works towards generalising a result for the relevant population along with extrapolating the results into predictions (Collis & Hussey, 2014, p.46-47), while this is not seen as the purpose when the interpretivist approach is used.

There are three main assumptions in the research philosophy; ontology, epistemology, and axiology (Collis & Hussey, 2014, p.47-48; Saunders, 2019, p.133), which will be presented below. Initially, we will clarify the choice within philosophical assumptions made for our study. Then, we will also explain what the choices will mean for the study and finish with presenting the arguments to justify why these choices were made and why other philosophies were not applicable in our context.

2.3.1. Ontology

We have chosen subjectivism as our ontological view for this thesis. This is because it aligns with our research area which belongs in the social sciences. Ontology is the philosophical assumption regarding the nature of reality, and we have chosen to approach ontology from the interpretivist end of the continuum of paradigms, resulting in subjectivism (Collis & Hussey, 2014, p.49). This end of the paradigm operates from the assumption that reality is a social construct produced as a result of human interaction and imagination, and there are multiple realities (Collis & Hussey, 2014, p.49). Therefore, we deem this appropriate for our thesis, since we will be interacting with our respondents to gain an understanding about their subjective realities and contexts (Helmi Alharahsheh & Pius, 2020, p.41-42). The most prevalent constructs relating to our thesis are risk identification and project management, which both are built on human interaction and can be argued to be social constructs, further strengthening the argument for the subjectivist approach.

Objectivism is on the other end of the continuum of paradigms. This assumption falls under positivism, which views reality as something external to the researcher that can be observed and then measured (Collis & Hussey, 2014, p.49). Because of this, it is often used in the natural sciences, where knowledge is more absolute and quantifiable (Saunders et al, 2019, p.133). Objectivism is not suitable for our study since we want to gain a deeper understanding about our respondents' own realities and experiences, implying that we need to acknowledge the existence of several realities (Helmi Alharahsheh & Pius, 2020, p.42). Subjective reality is not something which can be 'observed' in the sense that objectivism suggests, but we as researchers need to be a part of the study to be able to interpret the respondents' experiences, something which can only be done by the use of subjectivism. Other than the nature of reality, the view on knowledge and its validity also needs to be considered for this thesis. Epistemology is the philosophical assumption concerned with knowledge, and what we deem to be valid knowledge (Saunders et al, 2019, p.135).

2.3.2. Epistemology

Epistemology pertains to what we see as acceptable and valid knowledge. This differs greatly between interpretivism and positivism (Saunders et al, 2009, p.119). Epistemology also concerns how a researcher goes about revealing and uncovering knowledge (Helmi Alharahsheh & Pius, 2020, p.40). Under interpretivism, complex and individual views on reality and the prevalence of different contexts constitutes acceptable knowledge. It is even preferred, as the researcher wants to gain a deeper level of understanding about the topic of relevance (Saunders et al, 2009, p.116). The most appropriate approach to this study will be the interpretivist view. We argue that this is the case because we want to find out about our respondents' feelings and experiences to gain an understanding about their experience with risk identification in pharmaceutical projects before, and during the pandemic. This means that we constitute our respondents' individual and contextual experiences and realities as valid knowledge in this study.

Positivists see tangible and objective facts as the most accepted knowledge, and often conduct research in the social sciences through the use of a deductive method and surveys, similar to research in the natural sciences (Bell et al, 2019, p.30). This is done in an attempt to 'measure' the phenomenon they are researching. Interpretivists argue that social interactions and the knowledge collected from an interpretivist approach are not quantifiable, but instead should be analysed more in-depth within its context to gain a deeper understanding with the use of an inductive approach (Bell et al, 2019, p.31). One important criticism towards interpretivism is how the subjective values and biases of the researcher(s) affects the research being conducted (Collis & Hussey, 2014, p.48)

2.3.3. Axiological

The axiological assumption pertains to how one's values affect the research being conducted, and how this should be addressed appropriately according to the chosen philosophical assumption (Collis & Hussey, 2014, p.47). Positivists often criticise the interpretivist view because they argue that research should be conducted free of values on behalf of the researcher (Saunders et al, 2009, p.114). This approach is not appropriate for our study because we argue that to answer our research question in a satisfactory manner, we must allow our values to influence our research. This decision is supported by the interpretivist assumption that humans and their knowledge are inseparable (Helmi Alharahsheh & Pius, 2020, p.42). This is likely to present itself in the theories we chose to include, the questions we ask in the interviews, and the analysis we perform on the collected data. We are aware that our values will influence the

study, but we also argue that it is necessary to fulfil the purpose of the study and for us to gain an understanding about risk identification in pharmaceutical projects.

Another reason for why the positivist assumption is inappropriate for this study is that we cannot guarantee that the research will be free from bias and values. Even if we are aware of some of the ways in which our values affect our study, we are surely not aware of all the ways our values and biases affect our research. Furthermore, to make sure that our choices are compatible and work together, choosing philosophical assumptions on the same side of the continuum of paradigms is important for a coherent scientific method. This means that we should make choices which reflect the situation we are in with our study and make choices which allow us to approach the research from a subjective point of view.

2. 4 Research approach

The thesis aims to answer the research question through an inductive process. This begins with empirical observation, and thereafter we will attempt to detect a pattern within the relevant area of research. This approach aligns with our purpose of the thesis, aiming to make generalisations to a broader area. In sociology, there are two primary methods to conduct a study, deductive and inductive (Collis & Hussey, 2014, p.7). These two approaches are complete opposites of each other, describing the most extreme parts of the spectrum, beginning their reasoning logic from each end of the spectrum. However, it has become more acknowledged that a combined approach is used, both deductive and inductive processes during the study, an abductive approach.

The inductive approach was developed when deductive became deficient, which is when deduction cannot describe or clarify human interaction in a social perspective (Saunders et al., 2019, p. 155). The lack of capturing social science with the deductive approach has created a demand for the inductive approach. Since interviews will demand social interaction, our judgement is that the inductive approach is more suitable for our thesis. The inductive approach is a method where the reasoning starts by observing empirical reality, subsequently followed by a generalisation. Therefore, the inductive approach can be described as moving from the specific to the general (Collis & Hussey, 2014 p. 7). As mentioned, the inductive approach is more appropriate for our study, since the purpose of this thesis is to provide insights into the beginning stages of risk management for projects during Covid-19 in Sweden, within the pharmaceutical industry, which is of crucial importance to our society. Thus, hopefully be able to generalise the findings, going from experience to theory, and applying the theory to other industries or areas. Since the deductive approach is contradictory to the inductive, the deductive becomes inapplicable.

The deductive approach has a theory as the basis of empirical study and is the way natural science normally conducts their studies, since it captures the data in a better way (Saunders et al., 2019 p. 153-154). With deduction, the theoretical frameworks that have been developed are tested against the empirical findings (Collis & Hussey, 2014 p. 7). Initially stating hypotheses which creates the foundation for the study and then either reject or accept the hypotheses, depending on the empirical findings. With our study, we detect some difficulties in quantifying the data in the deductive approach, risking leaving out important parts of the research due to the lack of knowledge discrimination in social science. Hypothesis testing is not preferable in our study and consequently neither is deductive or abductive approach. Additionally, according to Collis and Hussey (2014, p.47) the inductive is the most suitable

approach when conducting a study with the previously mentioned interpretivism assumptions we have.

2.5 Research design

Since we aim to deepen the understanding around pharmaceutical companies' ability to identify risk in their projects the chosen research classification for this thesis will be analytical research. The chosen research design relates to the purpose of the study and then indirectly connects to the research question we aim to answer (Saunders et al. 2019, p. 173). Our study aspires to answer the question of 'how' the analytical research, also known as the explanatory research, connects the parts properly. This research goes further than describing characteristics, to analysing and explaining the phenomena that are being studied (Collis & Hussey, 2014, p.5). This aligns well with our chosen research question, since we want to find out how Swedish pharmaceutical companies conduct risk identification in project management during the Covid-19 pandemic.

Exploratory, descriptive, and predictive research are other methods that could be used. An exploratory research method is well suited for a phenomenon that has only a few or no earlier studies (Collis & Hussey, 2014, p.4), to generate a basic idea of the phenomenon. Since the field we aim to study has an established foundation and a great amount of existing literature, we consider this method not as suitable as analytical research. Furthermore, the descriptive approach could have been appropriate if we had another take on our topic. The descriptive approach aims to describe the phenomena as they exist (Collis & Hussey, 2014, p.4), which in our context, will not provide as much depth as the analytical research will, as this omits the 'how', which is crucial to our research. Lastly, predictive research, which goes even further than every earlier mentioned research. Predictive research goes even further than the analytical by developing and explaining future prediction, based on hypothesised and general relationships (Collis & Hussey, 2014, p.5). This could be useful in the future. However, the Covid-19 pandemic has caused a unique environment, making it difficult to generalise it to a prediction, which is supposed to be applicable elsewhere in the future. Conclusively, exploring the additional methods further demonstrate that the most suitable design to select for our study is the analytical design.

2.6 Literature search

The process of the literature search for a thesis project is crucial to the success of the project. This is because literature search and reviews allow the researcher to identify and understand the existing body of knowledge of the topic under investigation, which in turn reveals the relevant research gaps (Xiao & Watson, 2017, p.93). It is important to search for literature with the relevant context in mind (Bell et al. 2019, p.95). Presenting the literature search and review is also a conscious effort on behalf of the authors to provide high methodological transparency, as suggested by Aguinis et al (2018, p.86).

Within our literature search process, we have used a 'funnel' approach, as suggested by Xiao and Watson (2017, p.103). This has meant that initially, we searched for keywords relating to our research question and risk identification. These keywords, along with the number of search results in Google scholar can be seen in Appendix 1. Early on we discovered that risk identification was connected to comparable keywords and included in larger contexts such as 'Riskification', 'Risk Assessment' and 'Risk management'. Subsequently, we used the additional keywords in the literature search to retrieve greater knowledge of the subject. The

search highlighted the pharmaceutical industry as lacking in literature of risk identification and general risk management. This resulted in narrowing the search to address risk identification specifically for the pharmaceutical industry and pharmaceutical projects. Thereafter we read articles and books about our chosen topic to gain an understanding about the current body of knowledge and decided if the research gaps are significant enough to justify our research. When looking for existing research, one needs to have a screening technique for what literature should be referred to within the thesis. We firstly inserted our key words into the search function used, which mainly was Google Scholar. Then we looked at the *titles* of articles, books, and book chapters to see if it related to our area of research. After this, we made sure that the *abstract* was relevant, and that it contained the information we were looking for. Finally, we made sure that the *full text* also pertained to our chosen area and that the information included was relevant (Xiao and Watson, 2017, p.103). In our case, there were some articles we found which could be eliminated due to their irrelevance to our topic. These articles were for example, related to later stages in risk management.

Other than the information provided in the literature under review, researchers also need to ensure the credibility and quality of the literature. There are many different opinions on how the inclusion and exclusion criteria should look like when it comes to quality of literature. However, ultimately, it is up to the authors to agree on how they want to design the inclusion and exclusion criteria. One way to rank and judge the quality of studies and other literature is with checklists (Xiao and Watson, 2017, p.106). We have decided to include literature which fall under the following list of criteria: (1) articles should be peer reviewed and available in full-text, (2) published by an academic journal and (3) Books should either be recommended by lecturers as course literature or frequently referred to in peer-reviewed literary works. In addition, to evaluate the quality of our literature used in our theoretical framework we used the Academic Journal Guide 2021 (It was earlier ABS 2021) Ranking list (Kumar Jena, 2021). According to the ranking list, a significant amount of our literature claimed a 4-ranking and 3-ranking which indicates that the retrieved articles originate from Journals of higher quality. The databases mainly used during the literature process of this thesis were Google Scholar and the Umeå University library database. According to Bell et al. (2019, p.98), online databases are the most valuable sources of academic journal references. Furthermore, as mentioned previously, course literature from past courses were also used.

2.7 Source criticism

When gathering information from existing literature, it is important to critically review the sources. As mentioned, we have mainly used Google Scholar and the Umeå University library database as our sources when gathering information from previous research. Despite these two sources having a large amount of information and existing literature, it is important to remain critical towards sources before deciding to use them. There are four different criteria which lay the foundation for source criticism according to Thurén and Werner (2019, p.12)., which are authenticity, time context, interdependence, and the freedom of tendency.

Authenticity concerns the legitimacy of the source when it comes to distinguishing between real and fake information. A source is authentic if it lives up to what it claims to be and is not falsified in any way (Thurén & Werner, 2019, p.27). One way of analysing authenticity during this thesis has been to cross-check with other sources to see if they portray a similar sentiment. If two sources make opposing claims regarding the same topic, then further analysis will be needed to make sure that correct information is included in the thesis. Controlling a source for

authenticity is especially important when it comes to using the internet (Thurén & Strachal, 2011, p.13).

Time context is the second criteria. This criterion addresses the relation between the time of the event and the story of it. If longer time has passed since the story was written, you have more reasons to doubt the story (Thurén & Werner, 2019, p.12). The more in time an article is written, the more reliable the source is (Thurén & Strachal, 2011, p.14). During our study, the used sources have a breadth regarding the years they are published. This may cause them to be less reliable than recently published articles. However, we have aimed to always use the latest published articles to apply as updated knowledge as possible. Older articles have been applied in combination with other additional and more current articles, to ensure that the older articles are still relevant. The reason why we have used older articles is mainly because risks within projects began to receive attention at the same time as project management started to grow, during World War II, with the Manhattan-project (Larson & Gray, 2021, p.20). This created the foundation and definition of risk. However, it has stayed undeveloped until recently when project managers have realised the impact of bad risk management (Larson & Gray, 2021, p. 213). Therefore, older articles have contributed to the foundation while more up-to-date articles have increased the knowledge and made it more applicable to modern days.

The third criteria are concerning *interdependence.* Interdependency implies to ensure that the source is not just a transcript or summary of previously published sources (Thurén & Werner, 2019, p.12). Throughout our degree project, we have constantly used primary sources to create our foundation used in literature research. When discovering an intriguing theory or model we aspired to seek the primary source, instead of using any secondary references. This is also a factor to why we have used older published sources, as previously mentioned. Lastly, the criteria *freedom of tendency,* intend to ensure that authors of sources have not had any ulterior motives and therefore provided an incorrect image of reality (Thurén & Werner, 2019, p.12). To take this criterion into consideration we have used peer-reviewed sources or books in combination with peer-reviewed sources to strengthen the impartiality and quality of our degree project. However, there is a challenge in ensuring that the authors of the used sources are completely impartial, which is a consideration to take into account.

2.8 Overview for chosen scientific methodology

Table 1. Overview for chosen scientific methodology

Philosophical assumptions 1. Ontology 2. Epistemology 3. Axiological	1. Subjectivism 2. Interpretivist 3. Interpretivist
Research approach	Inductive approach
Research design	Analytical
Literature research	Funnel approach

3.0 Theoretical framework

Our theoretical framework establishes a comprehensive synthesis of relevant literature integrating studies on (1) risk identification (2) pharmaceutical project management, and (3) contextualised for the Covid-19 pandemic and Sweden as the geographical location. We critically examine the existing literature by unpacking the central key concepts and highlight the relevant gaps related to the three above mentioned topical areas. The chapter is structured in a way so that different topical areas have been integrated, forming a theoretical framework which is appropriate for the purpose of our thesis. We have connected risk identification with pharmaceutical project management to give a better understanding of how they work together and explore what the relevant knowledge gaps in the existing literature are, along with their importance. Furthermore, we have looked at how risk identification within pharmaceutical projects may be affected by the geographical location and the Covid-19 pandemic in order to pay attention to the context of the thesis and its purpose, and to give more depth to our theoretical frame of reference.

3.1 Risk identification in pharmaceutical project management

The following section will cover the subject matter regarding risk identification and pharmaceutical project management in a combined way. The section is structured to (1) give the reader an understanding of risk identification as a concept before (2) incorporating pharmaceutical project management, to finally (3) demonstrate how risk identification should be searched for and classified based on existing literature in pharmaceutical projects.

3.1.1 Risk identification concept

When a company, project or temporary organisation implements risk management there are several steps to complete, including risk identification. For companies, risk management's main obligation is to estimate the risk for the company and then communicate it to top management (Sultz, 2008, p. 40). According to George "whether major or minor, all risks should be isolated and treated accordingly" (2020, p.975). The top management's responsibility is to determine, based on their risk appetite or tolerance, how to manage the risk. Whereas for projects, risk management's main responsibility is to work as a preventive process to reduce surprises and negative consequences caused by unwanted events (Larson & Gray, 2021, p.215). Risk management can therefore be defined differently depending on its purpose. To ensure that the pharmaceutical project meets its objective, it is therefore important that the risk management is processed correctly and aims to avoid and minimise uncertainty (Brown & Grundy, 2016, p. 123).

Risk identification consists of two tasks: (1) *searching for risks* and (2) *classifying the risks* (Chapman & Ward, 2003, p.105). Since risk identification is the first step in the risk management process, it is the initiative component that paves the way for the rest of the risk management process. In agreement with Brown & Grundy (2016, p.128) only a foolish project manager would manage a project, believing that no risks will emerge. As described, an ignored risk at the beginning, can appear later on during the project, impacting the project at a much higher cost than if the risk would have been managed earlier. Emphasising the importance of a well conducted identification of risks and the benefit of a proactive approach. Having said that, the difficulty with risks is that it has a way of repeatedly appearing during the project life cycle. When previous risks have been addressed, new ones come up (George, 2020, p.975). A common mistake done during the risk identification is to only focus on objectives and not the

event that could cause consequences (Larson & Gray, 2021, p. 217). For example, seeing the objective risk of failing to meet the budget, while actually the event causing it might be excessive spending, poor negotiating towards suppliers, or poor estimates. By also searching for the event causing the risk, one could find the solution to prevent the risk completely (Larson & Gray, 2021, p.217).

Risk can be defined very differently on a case-by-case basis (Chapman & Ward, 2003, p. 7). According to the US Project Management Institute (PMI) risk is "an uncertain event or condition that, if it occurs, has a positive or negative effect on a project objective" (2000, p. 127). If the uncertain events appear, it will affect the project objectives, meaning the cost, schedule, and quality (Larson & Gray, 2021, p. 213). The UK Association for Project Management (APM) has a similar definition, saying that risk is "an uncertain event or set of circumstances that, should it occur, will have an effect on the achievement of the project's objectives" (1997, p. 16). What the definitions have in common is that they both emphasise the two components of risk; *likelihood to occur* and *impact***.** Risk comes natural in projects, no degree of planning could conquer risk (Larson & Gray, 2021, p.213), therefore in the environment's projects provide, risk is an uncertain event. Risk has a cause and, if it materialises, an effect (Larson & Gray, 2021, p.213). When conflicts about risk arise between the public and the experts, it can often be traced back to the unestablished disagreements about the topic, including what is meant by "risk" (Fischhoff et al., 1984, p. 124). Additionally, when the concept of risk is not defined, decision-makers rely on their own assumptions about the meaning of risks (Yildiz, Dikmen and Birgonul, 2014, p.522). Without a clarification of risk, miscommunication and confusion are more likely to appear.

The theories generated from research with decision-makers involved does not always accurately represent what reality looks like. In the research being conducted on decision-making within risk management, the decision-maker is often given well-defined problems and the probability distribution connected to the situations, on which they can base their decisions (Maytorena et al., 2007, p.317). However, to actually make the right decision, the decision-makers need to actively search for information which they might not initially have (Maytorena et al., 2007, p.317).

Risk is present in all types of work, and risk management is very prevalent in project management literature. The risk management process is key to the survival of projects, and often occurs in the beginning of the project life cycle, as this is the point in time when risks have the lowest cost to the project (Larson & Gray, 2021, p.214). However, both the project lifecycle and the risk management process differ between industries, and the pharmaceutical industry and projects are no exception.

3.1.2 Projects in the pharmaceutical industry

A project is defined by Cleland and Kerzner as "human and non-human resources pulled together into a temporary organisation to achieve a specified purpose" (1985, cited in Turner & Müller, 2003, p.3). This definition will be used for this thesis as it draws attention to the human interaction and the values and beliefs within the project and shows that a project is to an extent defined by the people who belong to it. This is important to consider in connection to risk identification as it is affected by values and beliefs (Maytorena et al., 2007, p.315). Projects are also vessels for organisational goals, such as goals of change, resource utilisation, uncertainty management, and of course the production function (Turner & Müller, 2003, pp2-6). There are five major characteristics of projects as stated by Larson and Gray (2021, p.7). The project must have (1) an *established objective* along with (2) a *defined beginning and end*

when it comes to the lifespan of the project. There are often (3) *several different professionals and departments* involved in the project as it aims to (4) *do something which has never been done before*. There are also (5) *special requirements* involved in projects when it comes to *time, cost, and performance*.

To address the needs for adequate quality, compliance, and specific regulatory needs, the pharmaceutical industry needs project management for projects to succeed (Chauhan & Srivastava, 2014, p.56). Brown and Grundy (2016, p.16) argue that contemporary project management is ideally suited for the pharmaceutical industry. Furthermore, to cater to the implementation difficulty and the need for redefining the project once it has started, along with the unique regulatory specifications, pharmaceutical projects should contain five key stages. These five stages of what can be classified as the pharmaceutical project lifecycle, are defined by Brown and Grundy (2016, p.17-20). They consist of (1) *defining the project*, (2) *project strategy*, (3) *detailed project planning*, (4) *control and implementation*, and (5) *learning and review*. Even though these stages show us the process of a pharmaceutical project from start to finish, the pharmaceutical industry still has a long way to go when it comes to developing their use of project management. The specification of project management for the pharmaceutical industry is important due to the way that different environments and conditions it experiences affects how project management influences pharmaceutical projects. This is important to know, since the internal and external environment is where the temporary organisation scours for potential risks and problems. The special requirements when it comes to, for example, regulatory requirements mean that stages such as stage 3: *detailed project planning*, is needed, which is not acknowledged as a part of 'general' project management. Specifications such as stage 3 can also show us where the common risks unique to pharmaceutical projects may lie, which is important as it is part of the purpose for this study.

As mentioned previously, we use the definition "human and non-human resources pulled together into a temporary organisation to achieve a specified purpose" (1985, cited in Turner & Müller, 2003, p.3) for a project. This is because this definition highlights the human aspect of projects. The project is dependent on the people involved, especially the project manager. Still, the project lifecycle does not just happen on its own. It needs to be conducted and monitored by the project manager who plays an essential role when it comes to the success of the project. This is also true for the pharmaceutical project manager, who's role will be described in the next sub-section.

3.1.3 Pharmaceutical project management

Project managers within pharmaceutical projects contribute with crucial knowledge for the projects' survival. According to project managers in the pharmaceutical industry in India, quality, time, and cost are factors which they deem most important for a project's success (Chauhan & Srivastava, 2014, p.58). However, these project managers identified risk management as much less important, identifying risk management to contribute with only 16% to project success, compared to 76.36%, 89.94%, and 83.35% for the three previously mentioned factors (Chauhan & Srivastava, 2014, p.58). However, as we have identified in 1.2 'Arriving at the research problem', along with what will be described regarding risk as a concept, risk and risk management is crucial to the survival of project success. This is something which Chauhan and Srivastava agree with, and they support our research purpose by stating that risk management needs more attention in the pharmaceutical industry (2014, p.58).

Since projects are different from the everyday operations of most organisations, they require their own manager, called the 'project manager'. The project manager's job is in some ways similar to other manager jobs, especially in the sense that it is the project manager's responsibility to make sure that the objectives and goals of the project are met (Project Management Institute, 2021, p.4). However, the project manager's role differs in the sense that they need to work with a fixed lifespan, and they need to be able to manage and familiarise themselves with the non-repetitive activities of the project (Larson & Gray, 2021, p.11). There are pressures on project managers which may be more apparent and obvious compared to regular managers because every decision that they make has a meaningful impact on the project as the lifespan often is so limited. When projects are seen as temporary organisations, the project manager also becomes the chief executive (Turner & Müller, 2003, p.5). This means that they become responsible for setting goals and objectives along with delegating responsibilities and motivating the project group members. Along with motivating their subordinates, the project manager should also make sure that their authority is clear and respected among the group members (Turner & Müller, 2003, p.5). Project managers in the pharmaceutical industry need to be able to focus on the project at hand without being overwhelmed by work outside of the project and are preferably people who have relevant and long-lasting experience of project management and the pharmaceutical industry (Brown & Grundy, 2016, p.60). This experience may be extra important compared to other industries as, for example, the regulatory constraints are complicated and have massive effects on the project if they are not handled properly. An important aspect of the pharmaceutical project manager role beyond objectives and budgetary concerns, is to monitor the attitude and energy within the project team. This needs to be considered to keep up morale for the good of the project (Brown & Grundy, 2016, p.192).

Chauhan and Srivastava found that in their survey, 12% of their project manager respondents had the view that project management has a low or moderate impact on project success, despite the known importance of project management on project success (2014, p.57). This attitude is also reflected in Cooke-Davies and Arzymanow, where both leadership and project management capability of pharmaceutical projects score much lower compared to other industries (2003, p.477). This indicates that not only does the practice of pharmaceutical project management need to be researched and developed more, but project managers in the pharmaceutical industry need to believe in the importance of project management for this to materialise into project success.

There are many important properties of a pharmaceutical project manager. Experience is one that is especially important as mentioned by Brown & Grundy, (2016, p.192). This is because of industry-specific conditions such as regulatory rules and regulations. However, there is a gap in the literature when it comes to pharmaceutical project managers and the impact that their experience has on their risk identification performance.

3.1.4 Experience and risk identification

Experience is a factor which is quite prevalent when looking into the phenomenon of risk identification, especially in pharmaceutical project management as mentioned above. However, the causal relationship between experience and risk identification performance is debated amongst researchers. Furthermore, there are other indicative factors of a project manager which affect the success of a risk identification process.

Chapman (1990) and Al-Tabtabai and Diekmann (1992), both argue that experience of a project manager does have an impact on the identification of risks (cited in Maytorena et al. 2007, p.316). They argue that professional training, knowledge, and most importantly, experience of the project sector over time all influence a project manager's ability to identify risk. Despite that, Maytorena et al. (2007, p.322) demonstrate that there is no significant association between risk identification performance and previous project management experience which is defined by a project manager "age, years in management, years in job title" (Maytorena et al., 2007, p.322). The style of information search used in risk identification within project and risk management is very important as this plays a large part in the success of the risk identification. Also, there are factors outside of managerial experience which affect the style of information search. These factors are risk management training and the graduate level of the project managers which both have positively correlated relationships with risk identification success (Maytorena et al., 2007, p.323).

Project managers that are graduates tend to alternate between both feedback style and information search style in order to identify risks, while non-graduates are not as keen to use any of the styles (Maytorena et al., 2007, p.321 & 323). Compared to graduates, non-graduates identify risks that are based on any type of information search to a larger extent, wherein the risks are identified grounded in their past personal experience (Maytorena et al., 2007, p.321). This argument is supported by Hoon Kwak and Dixon, (2008, p.553) who also argue that risk identification is often based on past experiences when it comes to risk, resulting in novel risks not being identified to the necessary extent. This is important since it is impossible to say, without an adequate risk assessment, whether these 'new' risks can jeopardise the project objectives (Raz et al., 2002, p.101). What is unquestionable though is risk and uncertainties presence within the project, it would be absurd for a project manager to believe that no risks will emerge when managing a project (Brown & Grundy, 2016, p.128). Despite that, it is reasonable for project managers to find some difficulty with addressing how risks and uncertainties evolve during the project life cycle, since they are not always constant. The following part will bring depth to risk and uncertainties within the project and how they tend to progress during a project.

3.1.5 Risk and uncertainties within projects

Risks are present and need to be managed in every organisation. As stated, projects have increased among organisations. Especially since companies strive to improve their market share and increase profit by improving processes and their product towards the customer (Mohammad Sabbaghi & Allahyari, 2020, p.111), and projects are a useful tool of the customised demand society has developed. However, since projects differ from routine, they often contain more risks. Even more so, considering projects have time-bound objectives and requirements to accomplish which results in time-bound choices and pressed decisions. Generally, the time-objective in projects could be defined as the 'critical path'. The critical path is the activities that take the longest and, if delayed, will likely affect the timeframe for the entire project (Brown & Grundy, 2016, p.118). Pharmaceutical projects are typically complex at a technical level and instead of addressing the critical path before a project starts, pharmaceutical projects have the tendency to straighten out the most crucial part of the project along the way (Brown & Grundy, 2016, p.118). Dealing with the risk along the way means jeopardising the project, even more so since pharmaceutical projects are complex - risks are more present.

When starting a project, the people involved should be aware of how risks behave during a project, in order to optimise the project and the work. Risk and uncertainties have a way of aligning with the project life cycle. They are present throughout the project, but particularly apparent in the earliest stages, the defining and planning stage (Chapman & Ward, 2003, p.7). The possibility of a risk appearing is at its highest during the early stages. (Larson & Gray, 2021, p. 214). As the project proceeds, the risk declines since uncertainties gradually disappear and solutions about critical issues are determined. The major disparity between risk and uncertainty is that risk, unlike uncertainty, can be associated with probability. Risk, however, can be defined very differently on a case-by-case basis (Chapman & Ward, 2003, p. 7) since risk consists of both unpredictability of the future and inexperience of impact. Opposite to risk, which decreases during a project, the cost impact of a risk event increases over the life of the project (Larson & Gray, 2021, p.214). These two concepts make up the Risk Event Graph, see figure 1. A mismanaged risk control in the beginning of a project could therefore be largely detrimental for a project if it occurs at the end of the project. Emphasising that risk management should be a proactive system, rather than reactive. A successful management of project risk not only reduces negative consequences of undesirable events, but also helps the project manager to prepare them to act when an advantage is possible and control the future in a better way, to enhance the chance of meeting the project objectives (Larson & Gray, 2021, p. 215). Brown & Grundy, stating that by managing a risk of a project, you actually manage the entire project (2016, p.123).

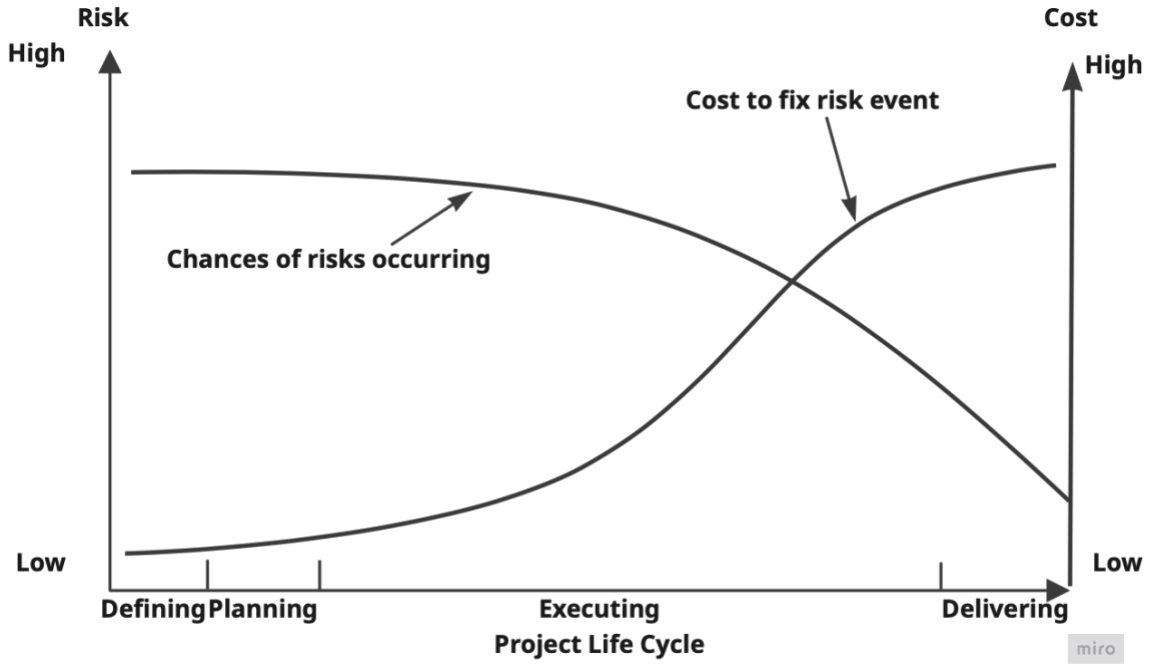

Figure 1. Risk Event Graph (Larson & Gray, 2021, p. 215)

Projects have the capability to streamline risk management, which could be a contributing factor for its emerging popularity. However, to do the streamline as successfully as possible, one must separate the different types of risk.

3.1.6 Classifying pharmaceutical risks

To enable the efficiency of risk management for companies, it is necessary to classify the different types of risk (George, 2020, p.975. The pharmaceutical industry consists to a large degree of creation and production of drugs, which revolves around projects. One must therefore classify the risk in order to manage it correctly. According to Mohammad Sabbaghi and Allahyari (2020, p.112) there are several risks involved in production project management. However, they have labelled the risks into five categories: supply risk, process risks, demand risk, control risk, and environmental risks (2020, p.112). *The supply risk* is the most important risk to mitigate in production since it can affect the whole project. The risk of raw materials not being supplied as expected can be a result of other risks (Mohammad Sabbaghi & Allahyari, 2020, p.112). *The process risk* is when the product has not been produced to meet the expectations on time or quality. Continuously, *demand risk* is more of an external risk, meaning the risk from lack or shortage of demand for a special product. Thereafter, *the control risk* is the result of insufficient quality control. Lastly, *environmental risk* which is the risk of environmental effects that can result from physical, social, political, legal, operational, and economic environment. These five risks establish the challenges a project can face during the executing stages of a project. However, Mohammad Sabbaghi and Allahyari (2020, p.112) has developed additional types of risk involved in production projects management. Presenting the common risks that are managed in pharmaceutical production projects, while also covering, to a certain extent, more areas that a project consists of, see table 2. For example, the covid-19 pandemic could be categorised as an environmental risk that emerged. As mentioned, the pandemic caused supply-difficulties in the pharmaceutical industry, generating delays for many projects and companies, which could indicate a 'transit time'-risk according to table 2. Even though table 2, combined with previous five categories of risk, covers many different types of risk, one should be aware that the sources of project risks are unlimited. Especially since risk is subjective, a certain risk may be categorised differently depending on the person performing the evaluation to one person (Campbell, 2006, p.227). Thus, one type of risk can also be categorised to another type. Since companies nowadays have the tendency to only perform superficial risk assessments, there is a chance that they respond to a risk that is wrongfully viewed. According to Stulz (2008, p.41) wrongfully viewed risk could result in important risks being ignored and as shown, ignored risk could be harmful for a project, both financially and timewise.

Table 2. Risks involved in production projects management (Mohammad Sabbaghi and Allahyari, 2020, p.112)

Risk	**Definition**
Financial	Change in exchange rate
Transit time	Change in the transit time including the transportation and clearance
Forecast	Errors in needs estimation that resulted in over- or underestimate inventory
Quality	Damaged, unfinished, and different products, part, or material in different areas
Safety	The products that endanger safety
Disruption in business	Inability to produce or selling the product to customers
Survival	Factory bankruptcy
Tools and inventory ownership	Disagreement about the inventory ownership, overuse of vehicle owned by others
Culture	Insufficient information about people, culture, and language
Opportunism	The supplier's opportunistic behaviour with customers
Oil price	Change in oil price

Hopefully the risk is viewed correctly, which would enable the right risk assessment. Nonetheless, before viewing or deciding on the category of the risk, one must find the risk. The searching of risk is a part of the risk identification (Hoon Kwak & Dixon, 2008, p.553).

3.1.7 Risk identification techniques in pharmaceutical projects

Research concerning the risk management process argues for its importance, while simultaneously being underdeveloped. According to Brown & Grundy (2016, p. 123), risk management for pharmaceutical projects is "the systematic application of policies, procedures, methods and practices to the tasks of identifying, analysing, evaluating, handling and monitoring risk", also known as the risk management process. The risk management process simplified is the process of identifying risk, making the assessment of risks impact and likelihood, how the response to risk should and lastly creating a response control system (Larson & Gray, 2021, p.216). We have, as mentioned, chosen to focus on the identification of risks, due to the lack of research there is within the subject in comparison to the other parts of the risk management process. According to Maytorena et al. (2007, p.315) numerous best practice standards, guides, tools, and techniques have been developed to make the project risk management process more effective. However, they display that most of the instruments created only address the analysis phases of the risk management process and not the identification phase. Even though the analysis phase is completely dependent on that the identification of risk has been accurately conducted in the first instance (Maytorena et al., 2007, p.315).

Searching for risk, which is one of the two tasks of identifying risks, can be supported by several techniques and tools. The most common and suitable for pharmaceutical projects consist of (1) *consulting*, (2) *risk profile* (3) *critical path method* and, (4) *historical data* (Brown & Grundy, 2016, p.123; Maytorena et al., 2007, p.351; Charoo and Ali, 2012, p.948). The overall atmosphere and mindset when working in a pharmaceutical project with identifying risk is to work according to Murphy's Law, meaning that 'anything that can go wrong, will go wrong'. Therefore, possible assumptions will be tested and considerations about the project environment and future scenarios will be made (Brown & Grundy, 2016, p.124). Even though an optimistic attitude is preferable at the implementation and execution of the project, critical thinking is more suitable when identifying risk since the purpose is to find potential problems before they happen (Larson & Gray, 2021, p.219).

Consulting

Asking people in the team is one way of the different searching approaches (Brown & Grundy, 2016, p.123). Research has been found that demonstrates that groups are more superior in finding risk than the individual. Teams make more accurate appraisals than individuals and use techniques such as brainstorming with an open mind to identify as many potential risks as possible (Larson & Gray, 2021, p.216; George, 2020, p.975; Maytorena et al., 2007, p.316). Which also indicates that the identification process is not duty-bound to just the core team. However, the drawback of brainstorming is the chance of developing groupthink (Maytorena et al., 2007, p. 316; Larson & Gray, 2021, p. 420) Searching for risks would benefit by input from stakeholders and is therefore something the core team should desire (Larson & Gray, 2021, p.212). Senior management, the project team and other stakeholders should be deeply involved with identifying risk to ensure that all perspectives have been explored and considered (George, 2020, p.977). Involving stakeholders, for example through interviews, makes them more committed to the project success while also acquiring their perspectives. According to Rezakhani (2021) and George (2020, p.975), expert interviews are one of the main sources of risk detection which indicates how important consulting and getting other people input on the project is for reaching the project objectives (Maytorena et al., 2007, p.316). Stakeholders have the tendency of being partial, affected by their feelings. Therefore, by including expert interviews, one combined several perspectives on the project and minimise the chance of collecting biased opinions. Additionally, experts usually have an academic foundation to stand on when they make statements, making their opinions more trustworthy.

Risk Profile

Another advantageous technique to detecting risk within pharmaceutical projects is a risk profile (Brown & Grundy, 2016, p. 124). The risk profile is a list of questions that consider several traditional areas of uncertainty on a project (Larson & Gray, 2021, p. 217). This can also function as a checklist, which is classified as one of the most used risk identification techniques used over the past two decades (Maytorena et al., 2007, p.316). The questions included in the risk profile, are usually based on previous similar projects that have been executed (Larson & Gray, 2021, p. 217). An effective risk profile is a profile that has developed and refined questions that will disclose strengths and weaknesses for the projects that are presently managed. The benefit of having a well-established risk profile is that it can consider several departments for the projects, making the project team contemplate various perspectives that will provide new identified risks (Larson & Gray, 2021, p. 217). Risk profiles are beneficial because they can be tailored to account for the specific industry's important aspects (Brown & Grundy, 2016, p.124). Even though the risk profile is based on previous similar projects, which can be profitable, it can also be a drawback. To be useful, the risk profiles must be updated and

refined, which normally is conducted by the personnel from the project office (Larson & Gray, 2021, p.218). If they are not up to date, using the risk profile has the potential to be irrelevant for the project at hand. One condition which needs to be met for a project to be called a project is that it is novel in some way (Larson & Gray, 2021, p.7). This means that risk profiles, which are based on previous events and experiences, cannot be used alone if one wants to conduct a thorough risk identification.

Since the risk profile will not be enough to cover the identification of all risks, it can be combined with other techniques and tools. Looking into the activities included in the critical path, one can identify additional risks (Brown & Grundy, 2016, p.123).

Critical Path Method (CPM)

The Critical Path helps create and visualise the project network (Larson & Gray, 2021, p.171). The Critical Path consists of determining the *total duration of a project* and which *activities that are dependent on each other*. To find the critical path one must define the least amount of time necessary to complete each task with the least amount of slack in the project, commonly referred to as the critical path method (CPM) (Larson & Gray, 2021, p.172; Sara, 2012, p.6). Meaning that, if one activity is delayed, the whole project is delayed with the same amount of time (Larson & Gray, 2021, p.172). All activities in the project combined creates a schedule of the project, which then visualises which activities are more sensitive regarding time and thus carries a greater risk of sabotaging the project. What CPM also enables is improved resource management (Brown & Grundy, 2016, p.129). In some projects, activities are planned parallel while not considering that the resources may not be enough. This can result in a delayed project due to the fact that one must have waited for resources to be available. Therefore, by conducting the CPM, one might notice a resource gap which, if not filled, could lead to a significant delay, but is then giving the opportunity to plan more properly (Brown & Grundy, 2016, p.130).

Brown & Grundy (2016, p.130) have found that pharmaceutical projects often have the perception that everything will happen on time. Implying that preparation and planning is not always possible. CPM primarily creates estimation of the future (Sara, 2012, p.7), therefore the CPM can additionally be used as a schedule where certain checkpoints need to be made, to double-check and ensure that resources and the schedule is proceeding as planned (Brown & Grundy, 2016, p. 130). However, since CPM mainly highlights the time objective for a project, supplementary techniques, and tools to find possible risks are required to a project.

Historical Data

Historical Data is one of the main sources of detecting risk (Rezakhani, 2021; George, 2020, p.975). Historical Data is based on *risk registers*, *databases* and *archives* conducted by previous similar projects in the past (Larson & Gray, 2021, p. 219). When formal risk profiles are not available, historical data can be used as a compliment. Project teams can then explore what went or could go wrong on similar projects as a way of detecting potential risks (Larson & Gray, 2021, p. 219). Risk register is a part of historical data and a tool to document risk and address suitable methods to respond to the risk (George, 2020, p.975). Risk registers consist of four categories; *risk, risk identified, risk causes* and *risk responses* (George, 2021, p.975). The use of historical data is many, but the main ones are that it plays a strategic role in making project decisions, gives direction to the project team in the management of risks throughout the project and enables project stakeholders to better understand the impact of project risks identified (George, 2020, p. 975). Even though the usages of historical data are advantageous, it should be emphasised as mentioned previously, that historical data should merely be used as

a complement. Either a complement when formal risk profiles are not obtainable, or when additional perspectives of the project are needed. Historical data cannot alone be the technique or tool used, since it relies on past conditions, therefore not always fully applicable to new environments and projects.

3.1.8 Concluding remarks

What previous sections have shown is that the importance of being thorough when it comes to risk identification can never be overstated within pharmaceutical project management, due to its direct effect on project success. Risk identification can be influenced by different factors, such as context and the relevant industry. From this theoretical chapter, we can deduce that the risk identification process is affected by the fact that it exists in a certain industry, i.e.. the pharmaceutical industry. Due to the industry-specific conditions, pharmaceutical risk identification needs continuous attention. Thereby, managing risk should be something proactive, not reactive in order to help a project as much as possible to reach the project objective of time, cost, and scope. Therefore, identifying risk at the earliest stage possible, can help projects to survive. Previously in this theoretical chapter, we have discussed risk identification and pharmaceutical project management. However, we have not explored these phenomena in the context of our thesis. In 3.2 we will discuss how risk identification in pharmaceutical projects may be influenced by the relevant contexts, which are the Covid-19 pandemic and Sweden as the geographical location.

3.2 Contextual influences on pharmaceutical project risk identification (PPRI)

As Zahra (2007, p. 443) states, understanding the nature, dynamics, uniqueness, and limitations of a situation can enrich future studies. Thereby, to enrich our study and give it more depth, we explore the topics of pharmaceutical project risk identification in the relevant contexts of time and place, being the Covid-19 pandemic and Sweden as a geographical location. Exploring the phenomena which are being studied without connecting these to relevant contexts means that a dimension of the research is lost, especially for the reader (Zahra, 2007, p.445). Exploring contextual influences also means that one avoids attributing a result to a phenomenon such as pharmaceutical project management, when in actuality it is produced as a result of contextual factors. Therefore, this study will highlight the contextual influences on our chosen topic, in hopes to enrich our research contribution.

3.2.1 PPRI and the Covid-19 pandemic

The Covid-19 pandemic has had meaningful impacts on the pharmaceutical industry. Some short-term impacts include changes in demand, supply shortages, changes in regulations, panic-buying of medical supplies, and changes in the research and development process (Ayati et al., 2020, p.800). There have also been predictions regarding the long-term impacts of the pandemic on the pharmaceutical industry. These include delays of approval, the slow-down of the pharmaceutical industry growth, and changes in consumption (Ayati et al., 2020, p.802). The impacts mentioned above all pose risks which the pharmaceutical industry must deal with at one time or another. However, in complex projects such as pharmaceutical projects, risks tend to be interconnected, and can thereby create positive feedback loops, which make the risk identification process more challenging (Williams, 2017, p.56). Thereby, the risk identification process in the pharmaceutical industry must consider and predict the possibility of interconnectedness between individual risks that are identified.

Within projects, decision-makers often operate under individual cognitive frames, which are their means for making sense of their environment when the current information is of an ambiguous nature (Kaplan, 2008, p.729). These cognitive frames can be determinants of how decision-makers perceive their environments and how they make decisions during times of uncertainty (Kaplan, 2008, p.729). Similarly, Campbell (2006, p.225) also discusses the partial subjectivity of risk, which mirrors the argument of cognitive framing. Subjective views on risk and cognitive frames can therefore be argued to have impacts on what decision-makers such as pharmaceutical projects managers see as risks, and how these are identified. The risk identification process is an important component of risk management which must be done well for the project to succeed (Picciotto, 2019, p. 474). This means that the success of these projects during the Covid-19 pandemic has very much depended on who the project manager and other project members are and what their capabilities and characteristics are when it comes to risk identification.

Since risk is given a numerical value based on the likelihood and impact of the risk occurring (Williams, 1996, p.185), the partial subjectivity of risk and cognitive frames can be argued to have a direct impact on how risks are handled in individual cases. This claim is also supported by some of the risk identification techniques that are used in pharmaceutical project management, since these often are grounded in historical data and experience (Charoo & Ali, 2012, p.948). This indicates that the information which has been/is available during the Covid-19 pandemic may not be as helpful as one might think. Since many pharmaceutical project managers have needed to deal with unprecedented risks regarding the pharmaceutical industry during the course of a pandemic due to its novelty, one may argue that experience has become less useful compared to other qualities. Furthermore, the classification/categorization stage of risk identification is partly based on predictability (Maytorena et al., 2007, p.316), which subsequently indicates that risk identification during the Covid-19 pandemic has become significantly more difficult.

An exception from the increasingly difficult risk identification within pharmaceutical projects has been projects concerned with the process of developing vaccines against the Sars-cov-2 virus. These projects were ultimately risk-free, since governments all over the world purchased vaccines in advance along with providing funding for these projects (Winch et al., 2021, p.3-4). These specific projects had different project life cycles due to the ability to omit threats from the external environment, which meant that the amount of time between the beginning and end of these projects could be significantly reduced (Winch et al., 2021, p.4). The pharmaceutical industry is generally seen as an industry that is unwilling to take risks. This can also impact the speed of the decision-making in the industry (Dorabjee et al., 1998, p.209). Fast decisions are needed in a situation such as the Covid-19 pandemic, and this has likely meant that risk identification has been conducted at several different stages of pharmaceutical projects as an effect of the pandemic's changing environment. However, the lack of risk involved in the Covid-19 vaccine projects may therefore have been behind the unprecedented speed of the vaccine development and rapid decision making.

It is important to contextualise Pharmaceutical Project Risk Identification when it comes to the Covid-19 pandemic as the combination of the two may have unique implications for pharmaceutical projects. It is also important to contextualise PPRI in terms of the geographical location, being Sweden in this case. This will be explored further below.

3.2.2 PPRI Sweden as a research context

We chose Sweden as the context for our study for several reasons. First and foremost, the Swedish risk management decisions are highly influenced by the government, aligning with Sweden's risk legislation, which is among the strictest in Europe (Lofstedt et al., 2000, p.159). The unique constellation of experiences each and every project represents originates from the structural characteristics of the projects but also from the social and political environment the project is within (Picciotto, 2019, p. 477). Resulting Swedish pharmaceutical project to be within an intriguing political environment.

Secondly, Sweden is a part of a quite complex system for the authority involved within the pharmaceutical industry. As for Sweden, a member of the European union, the European Federation of Pharmaceutical Industry and Associations (EFPIA) implements directives, regulations, and recommendations which the Swedish government and subsequently the Swedish Medical Products Agency (MPA) has a responsibility to enforce (Zetterqvist & Mulinari, 2013, p.2). The European Commission has developed national codes, rather than having one large body of regulations (Brown et al., 2009, p. 549). The European Commission's approach is “comply or explain”, meaning that member states have the authority to not fully obey EFPIA directives however an explanation, to why they will not obey, is then needed (Brown et al., 2009, p. 549). As a result, in addition to being aligned with Swedish and European Union marketing and pharmaceutical regulations, the Swedish pharmaceutical industry is also in compliance with the international industry codes of practice (Zetterqvist & Mulinari, 2013, p.2). In fact, the MPA, has delegated their responsibility on enforcing the regulations to the Swedish Association of the Pharmaceutical Industry (LIF) (Zetterqvist & Mulinari, 2013, p.2). Resulting in an industry which is highly governed by authorities. The World Health Organisation (WHO) has estimated that 25 % of the medicines consumed in developing countries is counterfeit (Gautam et al., 2009, p.251). Counterfeit medicines include drugs which have been rejected by regulators or manufacturers. Fortunately, counterfeit medicines do not originate from Sweden, approximately 75 % originates from India (Gautam et al., 2009, p.250), thereby displaying the success of the Swedish pharmaceutical industry system.

Third, the pharmaceutical export industry is growing in Sweden. During 2020, the Swedish pharmaceutical industry broke new records in exports while the general export for Sweden decreased (lif, 2022). Demonstrating what Lofstedt et al. (2000, p.159-160) stated, that the globalisation combined with Swedish high standards results in an increase in exports while also hampering imports, as regulations might increase costs. Therefore, the government's involvement in the industry, setting high standards to meet, results in raised prices. When the pharmaceutical expenditure grew significantly in Sweden, it could be traced to new expensive drugs being launched on the market (Wettermark et al., 2008, p.538). However, high regulations not only increase the final price for consumers, but also raises the caution when pursuing a project since there are more financial resources involved. The pharmaceutical industry is generally an industry that is hesitant towards risks (Dorabjee et al., 1998, p. 209). Cautiousness contributes to a thorough risk management (including risk identification), or at least to the desire to make a more thorough one, as studies have shown that risk management is often mainly carried out to get the project approved (Hoon Kwak & Dixon, 2008, p.553). Being more cautious can be beneficial when managing risk, however the pharmaceutical industry is depending on innovation and the development of new medicines (Cardinal & Hatfield, 2000, p.248-249), which creates a dilemma. Innovation is often associated with taking risks (Borgelt & Falk, 2007, p.123), while the pharmaceutical industry is cautious and hesitant

towards risk. Hesitation towards risk results in longer processing time when making decisions. To make the decisions more efficient, risk management could act as a guide for pharmaceutical projects, similar to risk management within companies (Sultz, 2008, p. 40).

Lastly, not only does globalisation affect Swedish exports but it also increases vulnerability to risks since an organisation becomes more open to the whole world (Norrman & Jansson, 2004, p.435). Companies, organisations, and projects should no longer only focus on their own risks, but also the risks other actors have if they are included in one's supply chain (Norrman & Jansson, 2004, p.435), since their risks can indirectly become our risk. Well-defined problem objectives facilitate both using appropriate risk management tools and identification of risks (Charoo and Ali, 2012, p.948). Emphasising the importance of a well-established base when conducting risk management. The basis for risk management is highly founded on the initial part, risk identification, which is the component that can make or break a project's success (Picciotto, 2019, p. 474). Since the world is nowadays more "open" due to globalisation, the demand for established risk management has been enhanced considering that projects are more vulnerable and can be affected to a higher extent by external factors. Therefore, organisations, both temporary and permanent, should prioritise managing risks since it can prevent project failure.

3.2.3 Concluding remarks

Addressing Sweden as the geographical area during the Covid-19 pandemic will contribute to an intriguing study due to its complex environment. The projects to develop vaccines against the Sars-cov-2 were ultimately risk-free projects due to governments all over the world providing funding and therefore protecting projects from failure. However, the covid-19 pandemic has affected additional parts of the society and is considered to cause long-term impacts on the pharmaceutical industry, i.e., delays of approval and slow-down of the pharmaceutical industry growth. Delays of approval due to the pandemic can be combined with Sweden as a geographical area since Swedish risk management decisions are highly influenced by the government and during 2020 Sweden saw a growth in the industry. Therefore, the two contexts, separated and combined, have the capability to influence our topic and by highlighting them we hope to enrich our research contribution.

4.0 Practical methodology

In this chapter, practical methodological choices will be presented. Initially, we will present our general methods for data collection and the reason for choosing the method. Thereafter, the selection of our participants is presented along with how the interviews were conducted. Lastly, a step-by-step of our data analysis is provided, followed by the research ethics we have aspired to obtain.

4.1 Data collection methods

To ensure that the research question is answered, and the purpose fulfilled, researchers need to recognise that the chosen data collection method is a fit with the philosophical assumptions (Howard-Grenville et al., 2021, p.1315). We have approached the data collection method in a way that continuously acknowledges and goes in line with our philosophical assumption, interpretivism. This is done to ensure that we use data collection methods that are the most suitable for our specific study. We argue that existing data is inadequate to answer our research question concerning risk identification in Swedish pharmaceutical projects in connection with the Covid-19 pandemic. Additionally, we intend to gain a deeper understanding concerning pharmaceutical companies' ability to identify risk in their projects, and how that has changed because of the covid-19 pandemic. Therefore, primary data has been acquired, giving us the greatest chance of answering the research question. Secondary data, such as data sets from previous studies or pre-existing databases (Collis & Hussey, 2014, p. 196-197), can be useful as a complement to the primary data in the study. Since qualitative data requires context to be understood (Collis & Hussey, 2014, p.130), background information needs to be collected first. Therefore, secondary data will be used as a basis for contextualising the primary qualitative data in our study.

The primary data being collected for this study was through interviews. More specifically, we carried out semi-structured interviews. This is suitable when considering our interpretivist approach to the research we conducted, as we aim to gain a deeper knowledge surrounding the subjective realities of our respondents when it comes to project risk identification in their industry. When approaching the research in an interpretivist manner, the type of data to be collected is qualitative. Semi-structured interviews are the most common and appropriate way to gain a deeper understanding about the topic of investigation, and semi-structured interviews give the interviewer some freedoms (Collis & Hussey, 2014, p.133). For example, the order of the questions can be altered to better fit the natural flow of the conversation while still giving it some direction, and the questions used in semi-structured interviews are often open ended. This means that the answers which are prompted go beyond a simple ‘yes’ or ‘no’, and are often more in-depth and personal, providing the researchers with extensive knowledge about the topic based on the respondent’s experiences (Collis & Hussey, 2014, p.133). Semi-structured interviews also give us the opportunity to use probing questions if we want the respondent to develop an answer further, including questions which ask why, how, and if the respondent can provide examples (Collis and Hussey, 2014, p.136). Additionally, a semi-structured method is also preferable since there is no follow-up interview. The interviewer can then confirm or clarify continuously throughout the interview without jeopardising the interview guide (Saunders et al., 2019, p. 434).

Two of the most common other options when it comes to conducting interviews are the structured and unstructured interview. We argue that these types of interviews do not fit our study. This is because in the structured interview, the interviewers ask the same questions in

the same order, and there is a possibility of missing important information if one does not allow the interview to stray in the slightest from what is planned. The structured interview is also more associated with the positivist paradigm, which we are not using (Collis and Hussey, 2014, p.134). The reason why we will not be using the unstructured interview is because in this type of interview, the interviewer does not prepare questions in advance, and must develop them during the course of the interview. This makes it very difficult to take notes and to fully absorb the information which the respondent is providing. This type of interview also means that it is likely to miss crucial information that the respondent may have but does not share unless asked the right questions (Collis and Hussey, 2014, p.133).

The collected primary data is non-numerical for two main reasons. Firstly, non-numerical data goes in line with the interpretivist paradigm, and secondly, we argue that the decision to use non-numerical data gave us the opportunity to collect all kinds of information regardless of if it is measurable or not. The reason behind not collecting numerical data is because the subjective realities of the respondents cannot be measured, and they are far too complex and intricate to distil into a numerical value, which is the essence of numerical data (Collis & Hussey, 2014, p. 130). This is also one reason which explains why we did not opt for the positivist paradigm. Considering all the participants have different experiences and views on risk identification within pharmaceutical projects, interviews were more appropriate since it aligned with the subjective approach.

4.1.1 Sampling technique

Since we conducted an analytical qualitative study, our aim was to obtain further knowledge concerning a specific topic, which requires participants with experience and knowledge. Therefore, it would be impractical for us to study the whole population, highlighting the need for a separate part of the population; a sample (Bell et al., 2019, p.409). In our degree project we first and foremost chose to conduct a purposeful sampling, as a method to ensure that our sample was relevant for the research we were carrying out. Meaning that we used our judgement when choosing participants, we believe were able to answer our research question. Purposeful sampling is the most common sampling method for qualitative research (Bell et al., 2019, 391). With purposeful sampling we had the opportunity to actively include appropriate participants which we believed were able to answer our research question (Bell et al., 2019, p. 408). Our selection of participants was based on three criteria that need to be upheld.

Firstly, the companies we included were companies that operate within Sweden. As explained, the covid-19 pandemic has implied different regulations and restrictions depending on the country. Therefore, with the intention to assemble comparable data, we required that all companies had been active on the same market. Secondly, our respondents needed to be active in the pharmaceutical industry. By active, we mean that the organisations/individuals participating in the interviews must have been a part of projects which have taken place both before and during the Covid-19 pandemic. Additionally, since we aspired to investigate the activities, pharmaceutical projects performed when identifying risks, it is of relevance that the respondents also are active within pharmaceuticals. Previous studies, as mentioned, have shown how several parts of the pharmaceutical industry have failed to achieve knowledge about project risk management. Therefore, we decided to not make any limitations within the industry i.e., only focusing on researching pharmaceutical companies, to enable a holistic view of the industry. This criterion was implemented with the purpose of getting in contact with an environment that is highly engaged with risk. The participants we conducted interviews with, all originated from pharmaceutical companies and were either a manager or a member of

pharmaceutical projects. This provided us with the holistic view of how a pharmaceutical project operates and enabled us to establish the theory we present in future chapters.

When the research, concerning appropriate participants, was initiated through the trade association for the pharmaceutical companies in Sweden, Lif, we developed knowledge about organisations and whether they fulfilled the earlier stated criterion. Subsequently, we contacted suitable companies through email, and other suitable individuals via LinkedIn. We asked them if they were willing to participate and informed them about our degree project and the criteria's they need to fulfil through an information form. Through the contact we could therefore confirm and distinguish if they have the possibility to participate in an interview. Eventually, if not addressing the appropriate manager, we requested the manager to forward our request to people they thought had knowledge and experiences regarding risk identification within pharmaceutical projects. The individuals that then accepted to participate in our study, contacted us to determine time and place to conduct the interview and signed a consent form, agreeing on the terms of participating in our research. Both the information form and the consent form used towards our participants can be found among the appendices, specifically appendix two and four.

Our choice of purposeful sampling relates to a non-random sampling. When a sampling frame is difficult to identify in advance, random sampling becomes impossible and therefore a non-random sampling is applicable (Collis & Hussey, 2014, p.198). There are several reasons why non-random sampling was beneficial for our research. Firstly, since we did not intend to generalise from the whole population it was more suitable for us to directly contact the participants who might provide appropriate data. On the contrary, in positivist studies, it is more appropriate to use a random sampling method since the goal is to generalise from the population (Collis & Hussey, 2014, p. 194). Secondly, with non-random sampling techniques we had the possibility to find participants that satisfied our criteria. Lastly, the non-random sampling is a relevant method relating to the interpretive paradigm since the focus was concerning the experience and the knowledge the participants had on the phenomenon (Bell et al., 2019, p. 34; Collis & Hussey, 2014, p. 197). Thus, this sample technique was most suitable to the purpose of providing insights into the beginning stages of risk management for projects during Covid-19 in Sweden, within the pharmaceutical industry.

Besides purposeful sampling, snowball sampling has been used as a complement to purposeful sampling, due to the essentiality of including people with experience of our phenomenon (Collis & Hussey, 2014, p. 132). Snowball sampling consists of asking the participants in the study if they are aware of anyone who has similar experience or knowledge and if they can assist in linking us together (Collis & Hussey, 2009, pp. 199). We considered snowballing to be an appropriate method due to the large networks project managers usually have (Larson & Gray, 2021, p.11). Meaning that project managers tend to establish a network where all stakeholders are included, therefore the manager we created contact with could, with high probability, establish a contact with further managers or people with experience of projects. Additionally, to the first two non-random sampling, snowball and purposeful sampling, there is natural sampling (Collis & Hussey, 2014, p. 132). Natural sampling technique refers to when researchers have negligible influence on the composition of the sample (Collis & Hussey, 2014, p. 132). Our participants are required to have certain experience with the phenomenon concerning risk identification in pharmaceutical projects. Therefore, we judged natural sampling to not be adequate for the purpose in the study.

Conversely, random sampling is an additional method where the entire population has an equal chance to be asked to participate (Collis & Hussey, 2014, p.51). Random sampling relates highly to positivism since the goal is most commonly to generalise the population (Collis & Hussey, 2014, p.197). However, random sampling requires a defined suitable sampling frame (Collis & Hussey 2014, p. 197) and is appropriate when a specific category of people is not sampled in the research question (Bell et al., 2019, p. 389). Thus, for our degree projects we deemed random sampling to be inappropriate.

Lastly, the sample size of the study is important to acknowledge and decide upon. A sample size in qualitative research can depend on different factors. In some studies, a sample size is determined in advance based on the desire to secure saturation in the research. Saturation is achieved when new interviews will add minimal or no new information (Aldiabat and Le Navenec, 2018, p.247). Bell et al. (2019, p.398) claims that when striving for research saturation, a sample size is unnecessary to specify, considering that saturation cannot be given in advance. Saturation can be achieved early in the research or sometimes not even if a large sample size is obtained, therefore it is difficult to know beforehand. On the other hand, saturation might not always be needed in a study. Saunders et al (2019, p. 315) deems that not achieving saturation can be seen as an indicator that the phenomenon has more research opportunities. Our degree project did not strive to reach the saturation point, as there were time constraints which prevented this. Furthermore, the population of people who work in projects within the pharmaceutical industry in Sweden massively exceeded the time and resources we possessed, rendering the saturation point unrealistic in our case. However, we aimed towards gaining a deeper understanding of the topic by conducting eight interviews which are realistic for our time constraints. Additionally, Hagaman and Wutich (2016, p. 205) assures through their study that six to sixteen interviews are reasonable.

4.1.2 Conducting the interviews

The most suitable way of carrying out interviews in a qualitative study such as this one, is face to face. This is because it allows the participants to see each other and makes it easier to form a trusting relationship, while also resulting in more potential participants becoming actual participants (Bell et al., 2019, p.621). Since the participants for our study were scattered around Sweden we conducted the interviews through videoconference devices, such as Zoom to avoid time consuming travelling (Collis & Hussey, 2014, p. 134). Even though face-to-face interviews are advantageous, remote meetings have its benefits and, in our case, it has enabled higher participation from other geographical areas (Solarino & Aguinis, 2021, p. 663). When conducting interviews remotely one can choose between videoconference devices or phone calls. All our eight interviews were carried out as a videoconference call. According to Solarino & Aguinis (2021, p.663), videoconference is the preferable option since it allows us to absorb the non-verbal expressions. The meaning of their statements may therefore be easier to analyse (Bell et al., 2019, p.471). Nevertheless, phone calls can reduce biases due to the lack of visual contact which can be a relief for participants. All things considered, we judged that our thesis benefitted the most from the video conference option.

In respect of the participants' time and energy, we had a predetermined time frame for the interviews. Additionally, effective planning and good time management are essential components throughout our thesis since we had a limited timeframe for the degree project. The interviews were therefore limited to 45 minutes. Unstructured interviews are the type of interview that is very-time consuming, while structured interviews with closed questions are the most time effective option (Collis & Hussey, 2014, p.133), and semi-structured is therefore

somewhere in the middle. It is common to underestimate the time needed for an interview (Saunders et al., 2019, p. 465). However, we considered 45 minutes to be suitable both for the interviews and for the time needed to transcribe and analyse the data that is aligned with our timeframe for the thesis. The interviews we conducted were all near the predetermined time frame, however some interviews were short-lived and some exceeded.

To adhere to the semi-structure of our interviews, we based them on an interview guide, where we had questions and themes prepared before the interview began (Collis and Hussey, 2014, p.133). All interviews had the same structure. Our questions were forwarded to the participants in advance for them to process the questions, making them more prepared, which hopefully contributed to more thoughtful and developed answers. Our open-end question enabled the participants to produce full answers, since they required a longer, developed answer (Collis & Hussey, 2014, p. 133). However, the interviewer is responsible for being involved and encouraging during the interview and by observant participation from the interviewer one can become more integrated with the respondent (Bell et al., 2019, p.475; Collis & Hussey, 2014, p. 133). Asking questions in return mad the participants elaborate their answer and was crucial to gain insights (Collis & Hussey, 2014, p.135). Still there was a chance of interrupting the participants when doing so, therefore the interviewer needs to manage the situation gently (Saunders et al., 2019, p. 466) which we took into consideration. The importance lies within having a balance between the questions, the themes and at the same time receiving advanced questions that contributed to an insightful data analysis (Saunders et al., 2019, p. 466).

The interviews began by informing the respondents about our research ethics, including how we will handle their information and that their identity remains confidential throughout and after the study. We also asked our respondents if they consented to the interview being recorded, in order to ease the transcription of the interviews later. Additionally, each participant had received and signed a consent form going in detail regarding the research ethics. Still, the participants had the right to withdraw and/or decline to answer a particular question (Saunders et al., 2019, p.268). The interview guide helped us stay on the relevant topics of the interview and ensured that the predetermined duration of the interview was maintained to a reasonable extent. In the end, all the participants were asked whether they had anything they wanted to add, since according to Solarino & Aguinis (2021, p.663) this can lead to additional relevant information and deepen the insights.

4.1.3 Interview guide

The semi-structured interviews that have been carried out were based on our interview guide. The interview guide consists of different themes, in total seven main themes and three sub-themes, all related to our research question, see table 3. As soon as the themes were accomplished, we continued with constructing the questions to each theme with the research question, the theoretical framework, and the purpose in consideration. The balance to keep in mind for the researcher is to formulate simple and short questions that are not leading but still provide enough data to answer the research question (Bell et al., 2019, p.440 & 441).

Table 3: Themes in the interview guide

Introduction
Background/ Personal Experience
Pharmaceutical industry
Pharmaceutical project management
During covid-19 Risk identification Risk identification techniques Classification of risks
Experience
Contextualising

The interview guide comes in two different versions which can be seen in appendix six and seven, one in English and one in Swedish, to be able to conduct the interviews in the best possible way, in a language both parties master the most. This will prevent the chance of translation problems or similar issues when facing a language barrier (Bell et al., 2019, p.70). Since both researchers and the respondents had Swedish as a mother tongue, the interviews were conducted in Swedish, which enabled us to collect more insightful and richer data. Nevertheless, if any of the participants prefer English when conducting the interviews, the researchers were flexible to change. This is done because the researcher tried to use the language that is comprehensible and relevant for the participants (Bell et al., 2019, p.440).

Considering that each participant was encountered with the same questions, each interview had the same structure and began with an introduction addressing the purpose with the study, introducing the researchers and the rights each participant has. The intention with the introduction is to prepare the respondent for the interview and create a pleasant atmosphere, in order to gain trust. The first few minutes can have a great impact on the rest of the interview; therefore, it is the researcher's responsibility to shape the start in the best way possible (Saunders et al., 2019, p.456). By mentioning the respondents' rights before the interview and assuring their confidentiality they should become more relaxed and open about the data they can provide for us (Saunders et al., 2019, p.456). Following the introduction were questions connected to the different themes. First and foremost, the interview contained background questions to be able to contextualise the respondents following provided data. Thereafter all questions included in our interview guide were asked. Altogether, the questions were asked openly and neutrally to avoid bias or any confusion (Saunders et al., 2019, p.457). A non-bias approach to asking questions will allow the respondents to formulate answers that are based on their reality of the phenomenon and describe environments or processes as they wish, which is an essential component in order to conduct successful semi-structured interviews (Saunders et al., 2019, p. 458-459). Throughout each interview, the respondents were continuously asked

short follow-up questions to evolve their answers and deepen the data. At the latter part of the interview, probing and specific questions were asked. The intention was to encourage more exploration in specific areas (Saunders et al., 2019, p.459). At the end of the interview, participants were first asked a summarising question, followed by a question regarding if they had anything additional data they would like to provide. Giving the interviewee a moment to reflect on the interview and an opportunity to give their opinion about risk identification in the pharmaceutical industry.

4.1.4 Recording and transcription

We decided to record the interviews, which was done by recording the audio of the interview. Recording the audio makes interviewers more attentive of what is being said during the interview, giving us the possibility to follow-up on any uncertainties or interesting observations. Recording also minimises the chance of the interviewers being distracted with taking notes (Bell et al., 2019, p.478). The recordings were only done once the respondents had been informed about our research ethics, how we will handle their information and once they consented to us recording the interviews.

However, if the respondents did not consent to the recording of audio, we would be prepared to take notes and gather information as much as we could. We also took some notes during the interviews even if we recorded them, in order to ask appropriate probing questions and to note if we wanted to proceed into a different question after the current one. The audio recordings were done on our mobile phones as well as on zoom, and two devices were used throughout all the interviews to avoid technical difficulties resulting in losing audio recordings.

To make the respondents more comfortable with the recording once they had consented, we reminded them that they will remain anonymous along with their company name, meaning that the interviewers are the only ones who will know that they are the source behind this specific information. Anonymity has been highlighted throughout our contact with the respondents so that we know for certain that they have been aware of and comfortable with the structure and conditions of the interview. However, this does not fully eliminate the hesitation some respondents might feel (Bell et al., 2019, p.445), but we believe that the steps we have taken to mitigate this have been successful

Once the interviews were recorded, we chose to transcribe the audio into text. This was done by first using a transcription tool, which transcript the audio recording. This was done to save time. Then, we went through the recordings and the text to make any necessary amendments to make sure that the audio and the text were identical. The transcriptions were ultimately done to be able to use grounded theory to analyse the data we have collected. They were used to conduct our data analysis, which is the foundation of our ability to be able to potentially answer our research question.

4.2 Data analysis

Analysing qualitative data can be problematic but the key is to have a method (Saunders et al., 2019, p.637). If we are not reflexive and explicit about how our analytical process has proceeded which eventually generates theoretical insights, transparency in how we analyse data cannot be provided (Grodal et al., 2020, p.591).

Since the aim of our project degree is to formulate theories based on what has been observed in reality instead of testing theories in reality, the chosen method for analysing the data when collected is grounded theory. The grounded theory assumes that one should break down the collected data one has, to identify the key components (Collis & Hussey, 2014, p. 577). The process involves analytically applying specific types of codes to the data, which is done through a series of coding cycles that in the end leads to a theory. Therefore, the theory that is developed is "grounded" or highly rooted in the original data (Saldaña, 2013, p.51).

For the content analysis, there are two alternative approaches, inductive and deductive (Elo & Kyngäs, 2008, p. 109). The inductive approach is more suitable to our purpose than the deductive, since we aspire to generate new theoretical insights and gain a deeper understanding on how pharmaceutical projects have managed to identify risk during the Covid-19 pandemic. Therefore, the inductive approach is adopted to our content analysis, where we will go from the particular to the general.

Since researchers rarely get the coding right the first time (Saldaña, 2013, p. 10), the coding process has been implemented several times. Additionally, the coding-process has been conducted separately between the researchers, to gain perspectives on the data collected. This, combined with a repetitive coding process, we aspire to increase our reliability in the data. As we have coded and recoded, we have strived for our codes and categories to become more refined and more conceptual and abstract, therefore creating a more solid foundation for the theory building (Saldaña, 2013, p. 11). Additionally, the coding-process has been conducted separately between the researchers, to gain perspectives on the data collected. Afterwards the researcher compared their coding and discussed any discrepancies to comprehend each other's interpretations of the data. This, combined with a repetitive coding process, we aspire to increase our reliability in the data. Furthermore, the data analysis format has been inspired by Evansluong (2016), which includes the four different steps presented in the following section.

Step 1. Developing initial codes

Our first step in developing concepts and eventually a theory, is to create initial codes by analysing the transcribed interviews. The initial codes are "first-impressions" (Saldaña, 2013, p.5) for the researchers. Asking questions has been a valuable tool when analysing the data (Grodal et al., 2020, 593), enabling us to search for answers in the transcribed interviews. The objective is to get a general overview of the data by reading through and understanding it (Saunders, 2019, p. 205). This step generated a total of 430 initial codes across the eight different interviews, which can be seen in table 4, below.

Table 4: Overview of initial codes

Case	Role of respondent	Duration of interview	Pages transcribed	Number of initial codes	Percentage of total codes
Interview 1	Project manager phase 1	38 min	9 pages	50 codes	11,62 %
Interview 2	Project manager phase 2	39 min	10 pages	52 codes	12,09 %
Interview 3	Project manager phase 2	43 min	9 pages	48 codes	11,16 %
Interview 4	Project manager phase 2	27 min	11 pages	47 codes	10,93 %
Interview 5	Medical director	39 min	9 pages	45 codes	10,46 %
Interview 6	Scientific officer	56 min	13 pages	70 codes	16,27 %
Interview 7	Regulatory affairs director	52 min	12 pages	62 codes	14,41 %
Interview 8	Project manager phase 2	47 min	11 pages	56 codes	13,02 %
Total			**85 pages**	**430**	**100 %**

Step 2. Developing first-order codes

Secondly, aligned with Bell et al. (2019, p. 528) key concepts, we conducted a first-order analysis to generate first-order codes. The process included an analysis of the initial codes across all interviews, to distinguish similar topics that the researcher found interesting concerning risk identification in the pharmaceutical industry. The core of the process of qualitative analysis is to generate categories that can form the foundation for new theoretical insights (Grodal, 2020, p.594). Through coding we can organise our data into categories because they share similar characteristics (Saldaña, 2013, p. 9). Similar components, elements or quotes were therefore assembled into a first-order code, creating categories. To avoid misrepresentation, and to stay true to the real-life context of the data collected from the interviews, the data extracted from the interviews was always used in the appropriate context and quoted as it was spoken by the respondents. Developing first-order codes is the first step of going from the specific to more general findings (Grodal, 2020, p.594). As a result, the first-

order codes were created. In total we identified twelve first-order codes which are displayed in table 5, below.

Table 5: Overview of first-order codes

First-order codes
1.a.1. Placing disruption by creating expertise-based allocation process
2.a.1. Developing a collection of common disruptions through previous mistakes
2.a.2. Adapting experienced techniques in unreliable surroundings based on previous projects
2.a.3 Obtaining a holistic and critical view of the project
2.b.1. Considering numerous characteristics by gathering diversified groups
2.b.2. Using brainstorming as a technique to gather several inputs
3.a.1. Approaching uncertainties continuously in a rapidly changing context
3.a.2. Making temporary decisions in an uncertain environment
3.b.1 Implementing virtual technologies to carry out routine procedures
4.a.1. Protecting the patient's safety by resource allocation
4.b.1. Handling disruptions by maintaining an open dialogue
4.b.2. Reporting continuously the project's progress

Step 3. Developing second-order codes

Thirdly, we included existing literature in the procedure and compared it to the first order codes. According to Eisenhardt (1989, p.544), comparing emerging concepts, theories or hypotheses with present literature is an essential feature when building theories. We used literature from the theoretical framework to interpret the data that had been collected. A combination of the first-order codes and representative literature created the second-order codes which can be found in table 6, displayed below.

Table 6: Overview of development of second-order codes

First order codes	Representative literature	Second-order codes
1.a.1. Placing disruption by creating expertise-based allocation process,	Risk identification consists of two tasks: (1) searching for risks and (2) classifying the risks (Chapman & Ward, 2003, p.105). The risk identification process is an important component of risk management which must be done well and organised in order for the project to succeed (Picciotto, 2019, p. 474). Risk identification is crucial for the subsequent risk management process (Elkington & Smallman, 2002, p.50). Chapman (1990) and Al-Tabtabai and Diekmann (1992), both argue that experience of a project manager does have an impact on the identification of risks (cited in Maytorena et al. 2007, p.316).	1A. Positioning uncertainties through structuring the project

2.a.1. Developing a collection of common disruptions through previous mistakes	(Larson & Gray, 2021, p.216; George, 2020, p.975; Maytorena et al., 2007, p.316). The use of brainstorming and historical data to identify risks in projects. Instead of exploring and mapping out possible unknown risks, project managers tend to focus only on the most common risks they have observed in the past (Hoon Kwak & Dixon, 2008, p.553).	2A. Exploring previous outcomes individually to collect possible uncertainties
2.a.2. Adapting experienced techniques in unreliable surroundings based on previous projects	Project risk management practice has shown to be correlated with the success of meeting the project's time and budget goals (Raz et al., 2002, p.105).	
2.a.3 Obtaining a holistic and critical view of the project	People with different knowledge about different parts and stages of the project are important, and so they help with creating a holistic image of project risk (Chapman & Ward, 2003, p. 106)	
2.b.1. Considering numerous characteristics by gathering diversified groups	Different views on risks are necessary (Campbell, 2006, p.227).	2B. Obtaining a collective idea by studying several perspectives
2.b.2. Using brainstorming as a technique to gather several inputs	(Larson & Gray, 2021, p.216; George, 2020, p.975; Maytorena et al., 2007, p.316). The use of brainstorming and historical data to identify risks in projects.	
3.a.1. Approaching uncertainties continuously in a rapidly changing context	Risk identification is crucial for the subsequent risk management process (Elkington & Smallman, 2002, p.50). It is also important to do this early on in the project (Chapman & Ward, 2003, p. 105)	3A. Developing an agile approach to tackle uncertainties
3.a.2. Making temporary decisions in an uncertain environment	Detecting risks would benefit by input from stakeholders and is therefore something the core team should desire (Larson & Gray, 2021, p.212) Risk event graph (Larson & Gray, 2021, p.214)	
3.b.1 Implementing virtual technologies to carry out routine procedures	The Covid-19 pandemic has impacted the industry in several ways. According to Ayati et al., (2020, p.802), delays of approval, changes in consumptions and slowdowns. Predictability has decreased, making risk identification more difficult (Maytorena et al., 2007, p.316). Project risk management practice has shown to be correlated with the success of meeting the project's time and budget goals (Raz et al., 2002, p.105).	3B. Responding to change by alternating between different approaches

4.a.1. Protecting the patients' safety by resource allocation	Even though Sweden is a member of the European Union and therefore takes directives from EFPIA (Zetterqvist & Mulinari, 2013, p.2), the Swedish risk legislations is among the strictest in Europe (Lofstedts et al., 2000, p.159).	4A. Prioritising security measures by producing effective products
4.b.1. Handling disruptions by maintaining an open dialogue	Detecting risks would benefit by input from stakeholders and is therefore something the core team should desire (Larson & Gray, 2021, p.212)	4B. Receiving approval from authorities in disastrous conditions by following guidelines
4.b.2. Reporting continuously the project's progress		

Step 4. Developing aggregate dimensions

Finally, we also analysed the second-order codes with representative literature, emphasising what has already been mentioned, the importance of comparing emerging theories with present literature (Eisenhardt, 1989, p.544). When conducting this step, the research questions were in consideration. This, since we want to ensure that the emerging concepts and theories will be able to answer the research question. Thereafter, we arranged and structured the concepts and theories, combined with the literature, into a more summarised and abstracted level, creating the aggregate dimension. Accordingly, 4 aggregated dimensions were generated which can be seen in table 7, displayed below.

Table 7: Overview over development of aggregate dimensions

Second-order codes	Representative literature	Aggregate dimension
1A. Positioning uncertainties through structuring the project	Risk identification consists of two tasks: (1) searching for risks and (2) classifying the risks (Chapman & Ward, 2003, p.105). The risk identification process is an important component of risk management which must be done well and organised in order for the project to succeed (Picciotto, 2019, p. 474). Risk identification is crucial for the subsequent risk management process (Elkington & Smallman, 2002, p.50). Chapman (1990) and Al-Tabtabai and Diekmann (1992), both argue that experience of a project manager does have an impact on the identification of risks (cited in Maytorena et al. 2007, p.316).	1.Classifying risks through cross-functionality
2A. Exploring previous outcomes individually to collect possible uncertainties	Risk identification consists of two tasks: (1) searching for risks and (2) classifying the risks (Chapman & Ward, 2003, p.105). Detecting risks would benefit by input from stakeholders and is therefore something the core team should desire (Larson & Gray, 2021, p.212)	2. Risk search - mixed approach
2B. Obtaining a collective idea by studying several perspectives	Different views on risks are necessary (Campbell, 2006, p.227). People with different knowledge about different parts and stages of the project are important (Chapman & Ward, 2003, p. 106) (Larson & Gray, 2021, p.216; George, 2020, p.975; Maytorena et al., 2007, p.316). The use of brainstorming and historical data to identify risks in projects. Project risk management practice has shown to be correlated with the success of meeting the project's time and budget goals (Raz et al., 2002, p.105). Instead of exploring and mapping out possible unknown risks, project managers tend to focus only on the most common risks they have observed in the past (Hoon Kwak & Dixon, 2008, p.553).	

3A. Developing an agile approach to tackle uncertainties	Risk identification is crucial for the subsequent risk management process (Elkington & Smallman, 2002, p.50) It is also important to do this early on in the project (Chapman & Ward, 2003, p. 105). Detecting risks would benefit by input from stakeholders and is therefore something the core team should desire (Larson & Gray, 2021, p.212) Risk event graph (Larson & Gray, 2021, p.214)	3. Reacting to disruptions and complexity
3B. Responding to change by alternating between different approaches	Project risk management practice has shown to be correlated with the success of meeting the project's time and budget goals (Raz et al., 2002, p.105). The Covid-19 pandemic has impacted the industry in several ways. According to Ayati et al., (2020, p.802), delays of approval, changes in consumptions and slowdowns. Predictability has decreased, making risk identification more difficult (Maytorena et al., 2007, p.316)	
4A. Prioritising security measures by producing effective products	Even though Sweden is a member of the European Union and therefore takes directives from EFPIA (Zetterqvist & Mulinari, 2013, p.2), the Swedish risk legislations is among the strictest in Europe (Lofstedts et al., 2000, p.159).	4.Considering external stakeholders to accommodate demands
4B. Receiving approval from authorities in disastrous conditions by following guidelines	Detecting risks would benefit by input from stakeholders and is therefore something the core team should desire (Larson & Gray, 2021, p.212)	

4.3 Research ethics

Ethical principles are an important part of the research process and ensure that all participants are treated fairly and in accordance with the vastly accepted ethical standards adhered to within the research community (Bryman & Bell, 2017; Saunders et al, 2019; Collis & Hussey, 2014).

We have made a conscious effort throughout the research process to make sure that we adhere to academic ethics in our research and the processing of our gathered information from the respondents. To show how we have treated our respondents and their participation in an ethical manner, we have used Bryman and Bell's (2007, p.71) suggestions for ethical research principles, shown in table 8, located below.

Table 8: Ethical research principles

Ethical principles (Bryman & Bell, 2007, p.71)	**The researchers' ethical approach to research during this study:**
Harm to participants The psychological and physical well-being of both the researchers and the participants need to be preserved and ensured in order to not inflict harm onto any of the participants	We approached the interviews with open mindsets to appear welcoming to our participants. The participants could also sit either in the comfort of their own homes, or at their place of work, somewhere they are acquainted with and comfortable at.
Dignity There needs to be respect for both the respondents' and researchers' dignity, which will avoid causing discomfort or anxiety for any of the participants	We showed our respondents respect throughout the interviews, and we continuously affirmed their statements to assure them that we were listening and that their information was valuable and interesting.
Privacy The researchers need to protect the privacy of the respondents	We did not ask any personal questions which the respondents may deem uncomfortable. We also made sure that the questions were strictly related to their professional roles.
Informed consent The researchers need to ensure that the respondents' consent depends on a full understanding of the ethical research principles which are adhered to throughout the study	An information form along with a consent form were provided to the respondents so that they were fully informed about the circumstances of the interview. This was also done to show our respondents what was expected of them and of us as researchers.
Anonymity The researchers make it clear to the respondents that their identity will not be disclosed or identifiable through the participation of the study	Through the use of the consent form, the information form, our other emails, and making a statement at the interview before the recording started, the respondents were informed repeatedly that their anonymity was guaranteed throughout the course of the study.
Confidentiality The researchers ensure the confidentiality of research data for the respondents and the organisations they represent	This was also ensured by providing them with an information form and a consent form which they had to sign. These forms ensured them of the confidentiality which was promised by us.
Deception, Honesty, and transparency There is a chance of disruption for the research process due to respondents lying or being misleading, as well as the misrepresentation of data on behalf of the researchers**.** All participants involved in the research process must exhibit honesty, trust, and openness	We believe that the respondents had all the possibilities and incentives to be honest during the interviews. However, if someone was deceiving it is difficult for us to discover that. We trust that the information provided to us by our respondents is their actual perceived realities which they have recounted to the best of their knowledge and memory.

Affiliation If the research is funded or sponsored, alternatively if there are other professional affiliations, this needs to be disclosed by the researchers	Our research has not been sponsored. However, we have made it clear to our respondents about which university we attend, along with our personal information and the contact details to our supervisor.
Reciprocity Mutual benefits for both researchers and respondents need to be ensured throughout the research process, and active participation and collaboration is needed from all participants	We have had active participants throughout our interview process, and all of them were happy to answer our questions. The only time they did not answer a question, was if they did not know the answer, or if they felt like they did not have a good answer. We also told all our respondents that, if they wished, we could send them the thesis once it was finished.
Misrepresentation The researchers need to avoid reporting the research findings in ways that are misleading, misrepresenting, and that may cause misunderstandings	One way of ensuring that the data is represented correctly and appropriately was transcribing the audio from the interviews. We also conducted the coding of the data separately several times to ensure that the most appropriate coding took place. By doing this, we also minimised the risk of representing certain data outside of their relevant context, since both authors had to compare their coding.

4.4 Overview over practical methodology

Table 9: Overview over practical methodology

Data Collection methods	Primary data through interviews Secondary data through literature search
Sampling technique	Purposeful and snowballing
Conducting the interviews	Semi-structured interviews Via video or phone calls
Research ethics	Table 8. Ethical research principles
Analysis method	Inductive Grounded theory

5.0 Empirical findings

Within this chapter our findings from the data collection will be presented. Initially we will present an overview of the findings. Subsequently we will present the aggregated dimensions separately and in depth, to decompose the first order and second-order codes that the aggregated dimensions consist of.

5.1 Findings and data structure

Our degree project objective is to provide a greater knowledge regarding how risk identification has been conducted in pharmaceutical projects during the Covid-19 pandemic within Sweden. The data analysis process was carried out through a grounded-theory approach, which has been addressed in earlier chapters. Additionally, the data analysis, which was built upon three levels, aggregate dimensions, cross-case second-order codes, and cross-case first-order codes, will be presented further. The data structure of the analysis can be seen in figure 2, which is an overview of how the four aggregated dimensions were produced. Therefore, we have used our data analysis to produce a data structure that reveals the findings we will present to answer our research question. As a result, we intend to present our result with both completeness, clarity, and credibility, which are all important considerations when presenting the results (Zhang and Shaw, 2012, pp.10-12).

The aggregate dimension (1) **Classifying risks through cross-functionality,** consists of one component: (1A) Positioning uncertainties through structuring the project

Secondly, the aggregate dimension (2) **Risk search - mixed approach** is composed of two elements: (2A) Exploring previous outcomes individually to collect possible uncertainties and (2B) Obtaining a collective idea by studying several perspectives

Thirdly, the aggregate dimension **(3) Reacting to disruptions and complexity** consists of two themes: (3A) Developing an agile approach to tackle uncertainties and (3B) Responding to change by alternating between different approaches

Lastly, aggregate dimension **(4) Considering external stakeholders to accommodate the demands** is based on two components: (4A) Prioritising security measures by producing effective products and (4B) Receiving approval from authorities in disastrous conditions by following guidelines

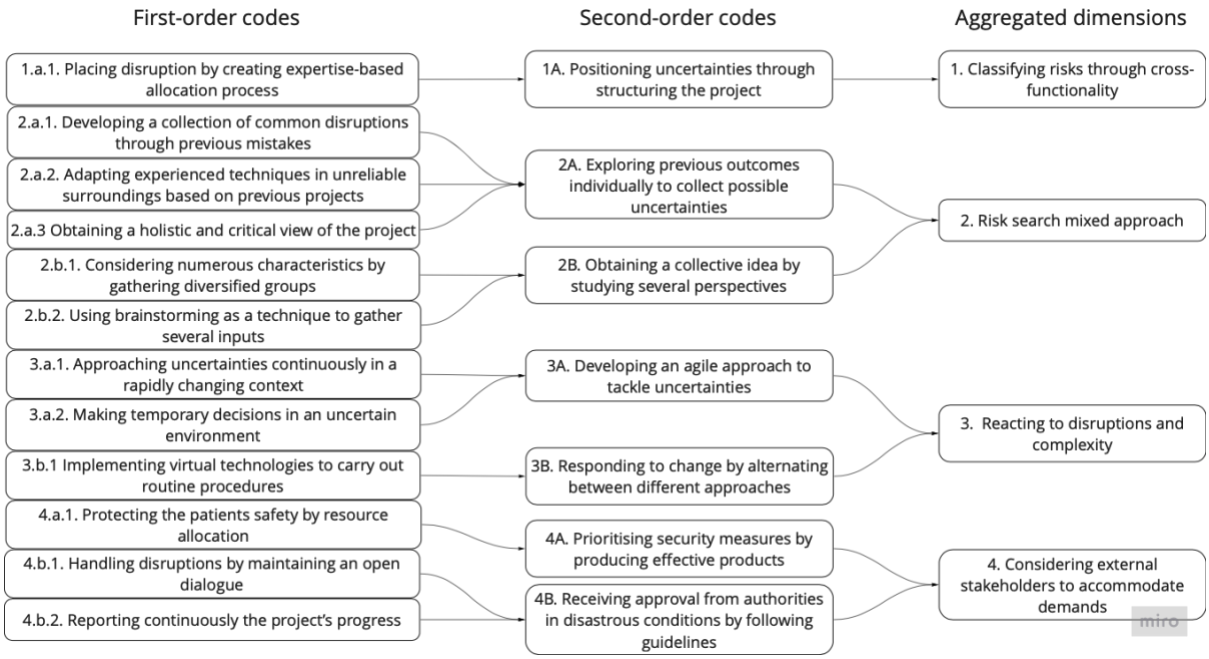

Figure 2: Overview of the data structure

5.2 Aggregate dimension 1: Classifying risks through cross-functionality

When pharmaceutical projects conduct risk identification, the findings implied that classifying risks by using cross-functionality was the initial action. In order for companies to even talk about risks, they need to have a certain structure within their organisation and know who is responsible for which area. Therefore, they also need to collaborate between functions needed to successfully complete the project and create cross-functionality. It then became apparent that organising uncertainties is made through the structure of the project (1A).

1A Organising uncertainties through structuring the project

When organising uncertainties (1A), several different groups, departments, and functions merge to orchestrate each possible disruption and its area of responsibility (1.a.1). This proved that the structure of a project when organising uncertainties facilitates the risk identification process, since it addresses who needs to take care of possible disruptions.

"The specialist functions get to provide their input [..] come in with their risks and then you look at it together and you see how it affects: if there are any internal crushing functional dependencies and things like that [..] then a person in the project team is assigned and will be primarily responsible for monitoring the area of risk" - Respondent 1

"It is often the case that those who are under the area of responsibility find their risks themselves and are experts in how to handle them, document it and mitigate it and also tell others that those risks exist so that the projects know about it. [...] if it is not obvious where they fall under the right area of responsibility, we discuss it in cross-functional meetings; how do we do this? Or one escalates upwards in the organisation" - Respondent 7

"There are, so to speak, dependencies between the different functions and if my risks affect others or if I have seen others' risks affect me, I am responsible for having that discussion together with the other function representatives in our project teams." - Respondent 2

5.3 Aggregate dimension 2: Searching for risks through varied approaches

When project groups search for risks within pharmaceutical projects, there is a need for individual efforts as well as collective ones. The mixture of both individual and collective approaches allows the project's risk search to be more comprehensive. Thereby, exploring previous projects' outcome when assembling imaginable uncertainties as an individual (2A), constitutes one half of the searching process. Furthermore, studying several perspectives during disastrous conditions by declaring a collective idea of possible uncertainties constitutes the other half (2B).

2A. Individually, exploring previous outcomes to collect possible uncertainties
The findings from our interviews indicated that the outcome of previous projects influence how individuals approach uncertainties. Developing a collection of commonly occurring disruptions through reviewing previous mistakes lays the basis for lessons learned (2.a.1.). Adapting experienced techniques into unreliable surroundings by considering previously performed projects to discover possible options (2.a.2.) also contributes to how individuals approach uncertainties, especially during the Covid-19 pandemic. To be able to approach uncertainties as an individual, project members need to obtain a holistic view of the outside world as well as within the project by being critical to uncover weaknesses of the project (2.a.3). This shows that within the risk identification process, tried and tested approaches are being used in uncertain times, and there are demands on the group members when it comes to their perspective of the project and its surroundings.

"What we do is that if it is the first time something happens, one is not aware of it. But then we try to learn from the whole thing, and the next time we are doing the same thing, this becomes a risk that we include in the planning stage. We then make a judgment about if it is worth taking the risk or not." - Respondent 2

"It's experience. That you should have worked in many different projects and maybe different work environments. To have experiences from different countries and cultures" - Respondent 4

"Yes, but today it is not nearly as spontaneous or detailed in the meetings. Experiences from previous projects are very important during the pandemic. Because if someone new comes in during the pandemic and must solve these things, it has to be very difficult" - Respondent 8

Our respondents indicated that the tools and techniques used are based on what was used before the Covid-19 pandemic (2.a.2). Although respondent 4 indicates that there was digitalization, the same tools were used for searching for risk.

"The normal proceedings would be to sit together with post-it notes. Everyone writes, you put it up on the board and prioritise doing it together. It is difficult when everyone is sitting at home, but there are tools within Teams which can be used in approximately the same way… But otherwise, the process has been the same." - Respondent 4

When asked about if the pandemic has affected the way risks are found and identified, Respondent 1 indicated that the same techniques are used during the pandemic and its subsequent unreliable surroundings as before it happened:

"No, not how we find them, but more that new risks have appeared that we did not see before as a result of the pandemic… But then we have not changed our behaviour in identifying risks, but it's more that there are new risks." - Respondent 1

Our respondents also indicated that it is important to obtain a holistic and critical view of the project, both internally and externally (2.a.3).

"I think that it is important to have a holistic view on the whole thing so that you can see your risks from a larger perspective… and then judge the risks with regard to at what point in time the risks are considered" - Respondent 2

"To see it in its entirety, be proactive, you have to think ahead. What do we need, what are we missing, what needs to be completed, so that we have everything we need." - Respondent 7

"It is often the larger perspective that you need to take in. A project member is often dependant on another project member, so it is the entirety." - Respondent 3

"Yes, I think that to put a lot of focus into analysing the project, the surroundings, and all kinds of things to identify possible risks early on…You look at strengths and weaknesses which becomes the internal perspective. Then there are opportunities and threats out there" - Respondent 1

2B. Obtaining a collective idea by studying several perspectives

2B is concerned with studying several perspectives during disastrous conditions by declare a collective idea of possible uncertainties. How this has manifested itself under the contextual circumstances has been described by our respondents.

Collectively, there are many factors which aid the project group in their risk search. For example, considering numerous factors such as experience, personalities, and characteristics by gathering diversified groups (2.b.1.) collects the group's most preferable qualities for dealing with uncertainties. Our data indicates that there is one type of technique which is widely used among project teams. Using brainstorming as a technique in order to gather several inputs on possible disruptions that could jeopardise the project (2.b.2) does this well in the pharmaceutical industry.

"You shouldn't have a group that sits and only thinks in the same ways. It's important to have people with different competences and preferably also… that there are different types of people who are there, not just different competences. Luckily, there is often a good mix of personality types in project groups, and it is a must to have that." - Respondent 6

"To have a pretty diverse team is a good possible starting point, and we do since everyone comes from different functions. So that's one thing. Experience, absolutely…" - Respondent 8

"You want to try to have a pretty blended group so that you get different points of view. So that everyone doesn't think in the same way, and so that you come up with some different risks and not only the ones you would think of yourself. You need a group where people work in some different departments so that you get different points of view" - respondent 5

"Well, particularly when it comes to this with identifying risks, it is this with having a blended group of people with different views to find the risks that do not often come up… But then with these other risks that are a little more difficult to come up with you need the group to find them. To think more outside of the box." - respondent 5

Our respondents indicated that brainstorming was the main technique used in their risk identification process when it comes to searching for risk. This also makes it possible to gather diverse inputs from the team (2.b.2).

"We usually look at brainstorming first. Everyone just lists everything, and then we try to sort them and group them together. Some may be quite similar…" - Respondent 4

"First we think about which risks may exist. We go around and find out, we have brainstorming sessions." - Respondent 5

"The brainstorming technique is something we absolutely use" - respondent 1

"Then we have brainstorming sessions where we spend time on this, so everything is allowed and then we eventually reduce and see what the things we really can identify as the big risks" - Respondent 8

5.4 Aggregate dimension 3: Reacting to disruptions and complexity

The findings revealed how pharmaceutical projects have a reaction towards disruptions and the complexity of the industry which leads to changing their approach towards risk identification. When identifying risk pharmaceutical projects have the tendency to adapt or develop an agile approach towards uncertainties (3A) due to the unpredictable environment they are within during the covid-19 pandemic and in general. Additionally, the findings also indicated that pharmaceutical projects have during the covid-19 pandemic been responding to changes as a consequence of needing to alternate between approaches (3B) and therefore identified new risks.

3A Developing an agile approach to tackle uncertainties
Pharmaceutical projects are within an unpredictable industry; therefore, projects evolve an agile approach to uncertainties as a way of detecting new factors or possible disruptions (3.a.1). Furthermore, since pharmaceutical projects involve several participants and need to counter all their demands, decisions made often need to change or be adjusted during the long lifetime a project has (3.a.2).

In the process where pharmaceutical projects try to identify risks, most respondents addressed how they continually, during a project, approach uncertainties (3.a.1) to detect new considerations to take into account since the industry has been changing rapidly during the covid-19 pandemic. Project members have experienced several times where something in the initial parts of the projects appears sustainable and doable, but suddenly the industry changed and the project where no longer could progress. This results in pharmaceutical projects having the tendency to re-evaluate previously detected possible disruptions or allegations to make remarks of any adjustments that need to be made or if they can continue without changes.

"*Something looks to be good and all of a sudden it shows that we cannot deliver, due to a factory closed again or whatever it can be, which can have horrific consequences [...] so for*

each risk, an assessment is made that we need to follow this up within a certain time interval or at a certain time" - Respondent 2

"*You cannot do it in any simple way, to ensure all regulatory requirements and patient safety requirements, therefore it somehow becomes more complex [...] We usually check what the risks are before the project, then we usually have several risk assessments within the project when, for example, we make a new product*" - Respondent 5

"*We have, in the beginning, a crisis plan and then we follow it up continuously during the project [...] Sometimes you have to throw the project and re-do it if it does not go well or if a by-product that does not exist suddenly enters the market*" - Respondent 7

The last building block for 3A is how pharmaceutical projects confront several demands due to their complex environment and therefore decisions are seldom permanent (3.a.2). Pharmaceutical projects consist of several processes with even more involved participants, both external and internal, and they all possess request pharmaceutical projects try to satisfy. Therefore, when taking all the requests into consideration and confronting those demands one decision is often modified.

"It is so incredibly complex in the pharmaceutical industry, at least in this large company there are so many different units and different departments that must be involved and contribute their share…" - Respondent 7

"There were far fewer choices for us (during the Covid-19 pandemic), and this applied globally, so it was not only our company's choices that were limited, but everyone's choices that were limited all of a sudden. Therefore, the competition was higher, the prices went up and you might have to contract with a higher risk without having so many facts. [...] So then we have a risk document that keeps changing continuously." - Respondent 2

"There are so many stakeholders involved, who give their point of view. [...] We have constant meetings during the process where you regularly discuss what happens to the various parts, linked to risk. [...] I think the case is that you set, like, the frame itself, in the beginning, then you work with the various sub-risks, quite continuously during the project." - Respondent 1

3B Responding to change by alternating between different approaches

Despite the previously mentioned procedures of developing an agile approach towards uncertainties, pharmaceutical projects have also, during covid-19 pandemic, respond to changes in order to alternate between different approaches (3B). Mainly these responses have consisted of replacing physical presence to social distancing and therefore creating innovative methods for the projects routing procedures (3.b.1).

Due to the covid-19 pandemic many project members experienced how innovative they had to be to be able to proceed their work. The simplest task was no longer feasible since many did not have the right equipment at home or social distance got in the way to ensure patient safety. Therefore, during the covid-19 pandemic pharmaceutical project had to identify risks through alternative ways and also found new risks within that.

"Everyone started working from home, we met a lot like this, digitally. Not only internally but also towards our customers, or our doctors with whom we have contact. So, we needed to

change the educations we do quite quickly, instead of having them physically, have them digitally. [...] We also got to be a little innovative in how we can ensure that patients receive study-drugs and get their check-ups. So, we always had to be very innovative in finding new ways to solve the situation we had" - Respondent 2

"Before the pandemic, we sat in Webex meetings, you hardly knew who was in the meetings, you heard someone talking in the background. Now you have a massive control, you can watch and talk at the same time. It feels like digital development has taken 20 years forward within 2 years. [...] Of course there is a risk of missing something, that communication will suffer. Before, you sat in a room and could meet and talk, talk a little at the Coffee Machine, where you solve a lot of problems. It's not so spontaneous anymore, so I think covid and this working from home have made it a little more "blockish" in some way, it does not flow as well." - Respondent 1

5.5 Aggregate dimension 4: Considering external stakeholders to accommodate demands

The importance of external stakeholders and their relationship with pharmaceutical projects has been clearly indicated by our data collected from the interviews. Prioritising security measures through distributing effective pharmaceuticals (4A) has been highlighted by many of our respondents. Also, receiving approval from regulatory authorities by following stated guidelines during disastrous conditions (4B) is something which has been highlighted during the Covid-19 pandemic.

4A. Prioritising security measures by producing effective pharmaceuticals

The safety of the patients is something which is of paramount importance to pharmaceutical projects and their members. Therefore, protecting the patients' safety by allocating resources to sustain the project's objectives (4.a.1) is an important part within all pharmaceutical projects.

Our respondents have recounted the patient focus as an overarching objective for the pharmaceutical industry and projects.

"We continually focus on the patients. What we do has a purpose to serve the patients. And our purpose with the company is really to ensure that the right patient receives the right pharmaceutical product or medicine at the right time" - Respondent 3

When referring to the development of the vaccine development during the pandemic, Respondent 3 exemplified how patient safety is something which cannot be tampered with in the pharmaceutical industry:

"One can think that it went too quickly, and that the safety aspect was compromised but that was not the case at all. It happened exactly according to how we develop all other pharmaceuticals." - Respondent 3

4B. Receiving approval from authorities in disastrous conditions by following guidelines

To receive approval from regulatory authorities by following stated guidelines during disastrous conditions, pharmaceutical projects need to live up to the standards and requirements of the pharmaceutical authorities and maintain a good relationship with them. This is done through handling possible disturbances appropriately by maintaining an open dialogue (4.b.1.)

and by continuously reporting on how the project is progressing (4.b.2.).

The respondents of this study have reflected on their communications with regulatory authorities. They have indicated that maintaining an open dialogue is an appropriate and effective way of handling disturbances (4.b.1).

"We must adhere to them. That is the way we organise our programs. And then we have interactions with authorities. We had an interaction with Läkemedelsverket in Sweden at the end of March where we asked some questions just to, yeah just to really ensure that we are not missing anything for the next step. In this case we had changed the process for the molecule that we use and then we have to ensure that it is okay to use." - Respondent 4

"Well, we mainly communicate with FDA and EMA, and they are both high quality authorities who come with a lot of good input. Also, luckily, it is possible to have discussions with them about their opinions and ideas. But they are also good when it comes to input from their point of view, with many good comments which makes us furrow our brows and really consider what we need to think about in different ways. They provide us with valuable input, but they also provide input which is open for discussion" - Respondent 6

Furthermore, our respondents have also recounted how they continuously must report the progress of the project (4.b.2) to the regulatory authorities as a part of following the conditions of the guidelines and regulations that they operate under.

"*Then we also have to submit to the authorities everything we have found. Eventual side-effects and things like that… So, if something comes up, we see it and then we have to report it to the authorities so that they know everything that we know. So, there are very well-established processes for how we go about things, and there are very strict demands from the authorities that everything is reported on time."* - Respondent 7

"When you send in an application to be able to sell a product, you have a risk management plan which is included in the application. Within that you have gone through everything…In our case it has to be sent to the authority and be approved, and for every thing that is added, it must be updated and sent to the authority again. So even if you have a big application which goes in, it is possible that you have to send only that (risk management plan) with what has been added." - Respondent 7

6.0 Discussion and Theory Elaboration

In this chapter we have attempted a more thorough analysis of findings presented previously. The chapter consists of separate discussions of each aggregate dimension and compares them to the existing literature, which shows both similarities and differences. Furthermore, the discussions combined will then contribute to a theory elaboration. With the theory elaboration we will present a proposed model to answer the research questions of this thesis, of how companies conduct risk identification within pharmaceutical projects during the covid-19 pandemic in Sweden.

6.1 Classifying risks through cross-functionality

In contrast to existing literature, our results indicated that risk classification is the first step for drug projects when risk is identified. According to Chapman & Ward (2003, p.105), risk identification consists of two tasks: (1) searching for risks and (2) classifying the risks. Our findings instead indicate that risk identification first classifies the risk and who is responsible for the area that the risk belongs to. Thereafter the search for risks begins. e.g., a project member is responsible for searching for the risk in their area. For example, toxicological risks.

Nevertheless, the findings also agree with existing literature that highlights the importance of risk identification (Picciotto, 2019, p. 474; Elkington & Smallman, 2002, p.50). Even if the findings change the rotation scheme between classifying and searching, the significance is still the same, according to our findings. According to Picciotto (2019, p.474) risk identification is a component that holds a project's success in its hands. It must be done well and organised for the project to succeed. Our findings rather suggest that the classification of risk is something solely relying on the structure of the organisation and project. Within the structure, each member of the project is given great personal responsibility. If the structure is distinct, the classification of risk will be obvious.

Why the member is given the large responsibility within their function in the project mainly allocates to their large amount of expertise and knowledge. Our interview uncovered how each member often holds a high education and a lifetime of experience within the pharmaceutical industry. Therefore, the organisation is often comfortable giving project members the task and responsibility to identify risks themselves. Due to this, the allocation process for how to classify the risk is self-acting and hard for project members to pinpoint. Therefore, our findings agree with Chapman (1990) and Al-Tabtabai and Diekmann (1992), who both argue that experience has an impact on the identification of risks (cited in Maytorena et al. 2007, p.316). However, it should not be interpreted as meaning that the classification is not sufficient. Pharmaceutical projects instead have such well-organised structure that facilitates the search for risk.

6.2. Searching for risks through varied approaches

Based on our findings, searching for risks within pharmaceutical projects in the risk management process consists of two approaches which are complements to each other. These are the individual and the collective approaches. Initially approaching the process of risk searching is mostly done on an individual level. This is where project members' previous experiences and projects allow for a personal collection of common disruptions can be created, as supported by (Hoon Kwak & Dixon, 2008, p.553). This collection then lays the basis for a comprehensive and well-rounded risk search on an individual level within the member's

specific area of expertise. Expertise comes from both the group members' educations, as well as their relevant practical experiences.

Within the literature related to risk identification and experience, there is a lack of consensus as to whether experience has an influence on the quality of the risk identification process. However, our findings indicate that experience does significantly influence the ability to find possible and probable risks according to practising project members, which is consistent with the arguments of Brown & Grundy (2016, p.192), as well as Chapman (1990) and Al-Tabtabai and Diekmann (1992) (cited in Maytorena et al. 2007, p.316). Our respondents have indicated that previous experiences lay the foundation for how one approaches new projects, and that risks often are transferable from old projects to new projects within the same area. This is also aided by the previously mentioned classifying of risks, as project members often approach risk searching on an individual level almost solely within the area connected to their function within the project.

As stated, transferability becomes possible if the project members and project managers have previous experience. However, our respondents have also indicated that even in unreliable surroundings such as the Covid-19 pandemic, experience is also a virtue when it comes to being able to identify risks for the project they are currently working on. An interesting finding from our data is that project members and project managers often find it difficult to specifically and explicitly explain how they go about finding risks. For them, it often 'just happens'. This is, to us, a further indication of the importance of experience for successful and comprehensive risk searches.

Something which has been discovered through our interviews, is that having a holistic view of the project is something which project members deem as a beneficial perspective. This can be related to Kaplan (2008, p.729), and the presence of cognitive frames during ambiguous situations. Seeing both the project and the external environment in their entirety means that project members are more likely to include a larger range of possible disturbances, uncertainties, or risks.

This holistic view needs to be complemented with a critical view, which our respondents have indicated to give project members a better opportunity to become aware of weaknesses or risks. Having a critical view can almost be considered synonymous with a realistic view in the case of pharmaceutical projects. Our respondents have indicated that somewhere around 90% of pharmaceutical projects fail before they are able to sell a product. This is because of the countless obstacles pharmaceutical projects face during their lifespan. This means that experienced project members likely are aware of and almost expect the project to be unsuccessful. Existing literature mentions the existence and influence which a critical view can have on handling risks. Larson & Gray (2021, p.219) argue that it can be difficult and paradoxical to be optimistic about the prospects of the project, while simultaneously having a critical view on the project to be able to find risks.

Once risk search has been conducted on an individual level, the project team gathers and collectively conducts a risk search. Gathering the project team means that people with different experiences, personalities, and characteristics come together to utilise numerous perspectives on the possible risks that may come up during the life span of the project. Almost all our respondents mentioned brainstorming as the technique they use in their risk search. If a respondent did not use the specific phrase 'brainstorming', they most often indicated in other words that this is the technique used by the team. Using brainstorming within a diverse group

facilitates the creation of a collective idea of the relevant risks for the project. This argument is also made by Larson & Gray (2021, p.216) and George (2020, p.975).

6.3 Reacting to disruptions and complexity

Our third aggregated dimension, established from our interview, demonstrated that the companies in charge of the pharmaceutical projects had during the covid-19 pandemic been forced to change their approach when conducting routine procedures. Mainly because of the restrictions. Further, the covid-19 pandemic impacted the industry with delays and slow-downs which is coherent with current literature that also highlights the consequences of the pandemic (Maytorena et al., 2007, p.316). The unpredictability of the pandemic has caused the urge to obtain innovative solutions that can alternate between conditions. So, when restrictions are tightened, pharmaceutical projects can proceed without change since they have techniques and tools that are hybrid.

When an unpredictable disruption appears, our findings show that it causes a reaction to either (1) decide to continue and therefore establish a temporary completed risk identification or (2) re-consider the identification of risk and investigate if the unpredictable disruption has changed the previous perception of which risks the project has. Depending on the disruption, it could either not change the fact that the project must proceed as planned or the disruptions caused things to change, i.e., delivery-delays which then made them miss the deadline which had greater consequences. Therefore, each disruption during the pandemic must be handled separately due to its complex environment. No two disruptions are alike. Pharmaceutical projects have therefore developed an agile approach which could accommodate for the danger of a risk occurring late in the project and causing threatening consequences to the project, according to the risk event graph (Larson & Gray, 2021, p.214).

The second option results in a pharmaceutical project conducting a re-assessment of the risks. Our respondents showed that they are familiar with developing innovative solutions that can function as a hybrid and alternate between conditions. However, the pandemic has highlighted the necessity of an agile approach towards risk. Since the predictability has decreased, which makes risk identification more difficult (Maytorena et al., 2007, p.316), project members have seen the agile approach as the solution. Our findings indicated that the frame and the foundation of risk identification is made in early stages, which is favourable according to Chapman & Ward (2003, p. 105). Thereafter if a disruption appears, a re-assessment can be made, if not a temporary completed risk identification is established. Additionally, what our findings discovered is that no risk identification can ever be permanently established due to the complex environment. Not only do pharmaceutical projects have several participants involved within the project, which has shown to benefit risk identification when stakeholder get involved, similar to Larson & Gray (2021, p.212). Moreover, the project usually proceeds over a longer period. Some of our respondents had experienced projects that lasted over fifteen years. This results in that decisions can rarely be permanent. Thus, decisions about what risks exist cannot be everlasting either. Therefore, projects have the tendency to re-evaluate the risk identification within a certain time interval or at a certain time, creating an agile approach to risk identification.

6.4 Considering external stakeholders to accommodate demands

Our fourth and final aggregate dimension distilled from our data relates to how the project and its members maintain the relationship with their external stakeholders. Primarily, the purpose of the pharmaceutical industry is to provide patients with pharmaceutical products to improve their health, and this is also mentioned as the project objective by many of our respondents. They all mention patient safety as a crucial factor within their industry. This can be related to two of the major characteristics of a project, having an *established objective*, and there being *special requirements* pertaining to *time, cost, and* ***performance*** (Larson & Gray, 2021, p.7). The performance is especially important when relating pharmaceutical projects to the external stakeholders, both in the sense of effectiveness of the product for the patients' sake, and also living up to the regulatory standards set by authorities.

Our respondents have indicated that the importance of their relationship with regulatory authorities cannot be overstated. They rely on authorities constantly throughout the risk management process, and the authorities give pharmaceutical projects a framework to adhere to. This makes it easier for project members and project managers to know how to approach uncertainties and risk. Larson & Gray (2021, p.212) argue that input from stakeholders is beneficial and can be seen as a tool in the risk identification process, and this is also confirmed to be true in practice by our respondents.

As Lofstedts et al (2000, p.159) mention, within Europe, the Swedish risk legislations is one of the strictest. This strict legislation paired with the need for input from stakeholders which previous literature suggests, further indicates the importance of the relationship with regulatory authorities. Furthermore, along with the very complex environment that exists within the pharmaceutical industry, our respondents have indicated that a continuous dialogue with stakeholders, and especially with regulatory authorities is crucial to the survival or success of the project. Being able to have an open and continuous discussion with authorities about specifics within pharmaceutical projects means that hurdles and challenges can be overcome faster and with greater ease. This continuous dialogue is also something which is encouraged, and at times, demanded by the authorities. For example, if a new risk is identified, this *must* be reported to the authorities as they always demand all the information available about the project.

6.5 Process model for risk identification during the covid-19 pandemic in pharmaceutical projects

These discussion points can be combined and facilitate an elaboration of a model. A common criticism towards the inductive approach is that the theorising, or the mode elaboration has not started close enough to the phenomenon (Shepherd & Sutcliffe, 2011, p. 363). Since our model, of how pharmaceutical projects perform their risk identification during covid-19, contained a thoughtful data analysis with grounded theory approach we therefore argue that we have created a model and theory as close to the data as possible. Additionally, when developing our model, see figure 3 of how pharmaceutical projects conduct risk identification we have considered four essential elements: What, How, Why and Description and explanation (Whetten, 1989, p.490-491). 'What' represents which factors are included in the model. According to Whetten, (1989, p.490), the challenge here is to find the right balance by including relevant factors and excluding factors that add little value to understand the model. 'How' portrays the relationship between the factors. In our model we have established this element by inserted arrows to connect each factor that is included in risk identification.

Additionally, we contextualised the arrows to clarify our thinking and increase the readers comprehension of our model. The third element 'Why', represents the underlying psychological, economic, or social dynamics that justify the selection of factors and the proposed causal relationships (Whetten, 1989, p.491). In line with our degree project, the covid-19 pandemic has been the underlying component, which also became prominent when developing the model. What, how and why combined facilitates the last element; description and explanation (Whetten, 1989, p.491). Altogether we have developed a model including descriptions to explain the model and therefore developed a model that expectantly should be comprehensible for readers.

We have, during the elaboration of the model, identified multiple factors that are essential in order to identify risks in pharmaceutical projects during the covid-19 pandemic. The elaborated model is based upon both aggregated dimensions, second-order codes, and the discussions that we carried out in the previous sections. This model will present both how pharmaceutical projects conduct risk identification the ordinary way during covid-19 pandemic and the exceptional case when unpredictable disruptions appear, and stakeholders govern the risk identification.

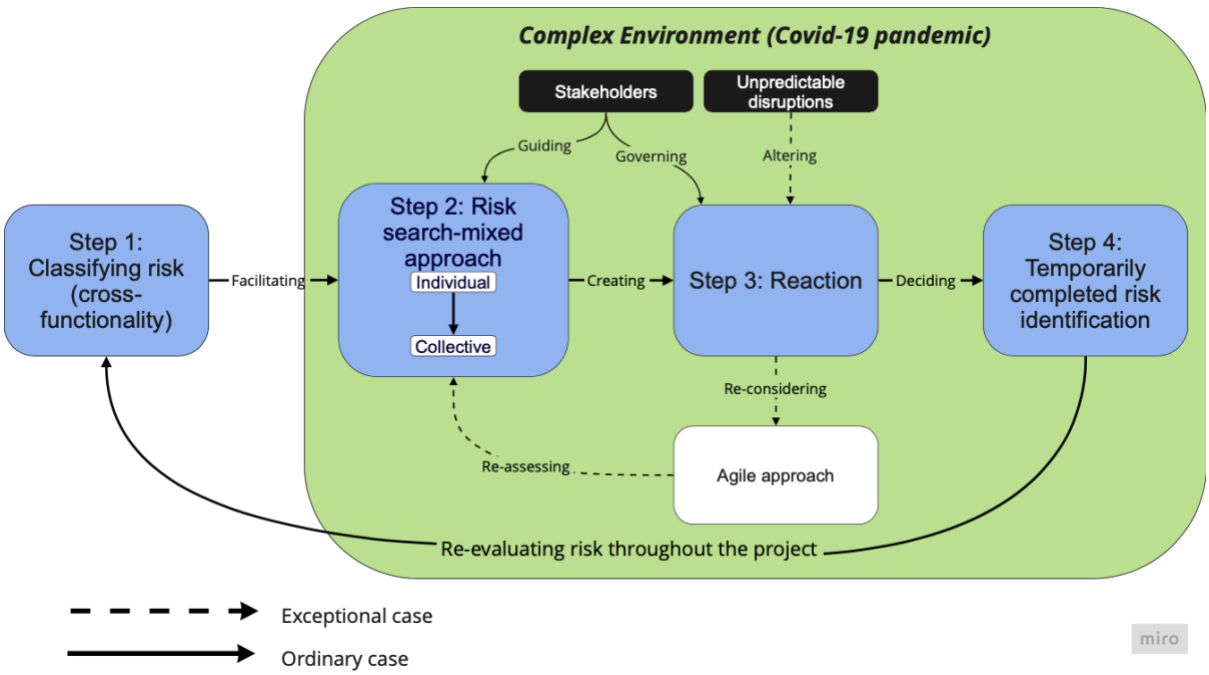

Figure 3: Process model for risk identification during the covid-19 pandemic in pharmaceutical projects

The beginning for identifying risks in pharmaceutical projects starts with *step 1: classifying the risks*. These were the most contradictory findings when we compared our results to existing literature. It was evident that pharmaceutical companies have created such an obvious *cross-functional* structure, that classifying risk is not something one can pinpoint to an event or action. The core of this is the project members' expertise and knowledge within their area of responsibility. However, it is only possible through organisations giving the project members trust and the responsibility needed. The classification of risk and the structure obtained in the projects *facilitated* the next step of identifying risk. This, due to when the structure is set, they know who will search within which category.

The following stage, *step 2: risk search - mixed approach* consists of searching for risks. Firstly, an individual search begins which has been mentioned and is mainly involving the project members previous experience of projects. Afterwards each project member merges their experiences together and conducts a collective risk search within varied groups. Here, *stakeholders* such as regulatory authorities have guidelines that benefit and give *guidance* to the search of risk. They may have suggestions or recommendations that can support the search for risks. For each discovered risk, *step 3: a reaction* is *created* where the stakeholders, especially regulatory authorities, also have a contributing part. Not only do they provide guidance, but they also govern that the guidelines are maintained.

Additionally, due to the long lifetime a pharmaceutical project has, they experience a lot of unpredictable disruptions during the lifetime of the project which alter the reaction of a discovered risk. Especially during the Covid-19 pandemic, unpredictable disruptions have appeared frequently and if the unpredictable disruptions are sufficiently extensive or transformative, pharmaceutical projects need to *reconsider* their discovered risks. Either they might need to modify which risks they prioritise the most, if anything has changed with the already discovered risk, or if the unpredictable disruptions might have caused more risks to be revealed. This creates an agile approach to tackle uncertainties, incentivising pharmaceutical projects to *re-assess* their risk identification.

However, when an unpredictable disruption occurs that is not sufficiently extensive or transformative to the project, it can be *decided* to complete the risk identification, entering the last stage of the process model for risk identification, *step 4: Temporarily completed risk identification.* This decision is also made when unpredictable disruptions are not present, and when guidelines have been adhered to. Despite that, the process model for risk identification during covid-19 pandemic in pharmaceutical projects is not finished. The decision of entering the last stage is only temporary due to the long lifetime of pharmaceutical projects. Thereby, the pharmaceutical project must *re-evaluate* the identified risk throughout the project for two reasons. Either (1) they need to study and investigate if their previously identified risk is still up to date. Otherwise, (2) they re-evaluate the risk identification to discover additional risks that could jeopardise the project.

Our proposed model therefore suggests that the risk identification process is perpetual throughout the lifetime of pharmaceutical projects. Identifying risks is something which therefore needs to be continuously performed to successfully manage risk throughout the project.

7.0 Conclusion and contributions

In this chapter we will present a general conclusion of how we have enabled to answer our research question and met the purpose of this degree project. In addition, we will provide the theoretical contribution this thesis has to offer, followed by practical and societal recommendations. Finally, limitations that this thesis has encountered combined with possible future research area will be displayed.

7.1 Conclusion

The purpose of this degree project was to provide insights into the beginning stages of risk management for projects during Covid-19 in Sweden, within the pharmaceutical industry, which is of crucial importance to our society. We aspired to develop an understanding into how risk identification has changed because of the covid-19 pandemic. Furthermore, we wished to establish an insight that potentially leads to improved risk identification and more effective use of techniques. Through conducting qualitative semi-structured interviews with pharmaceutical project members that had operated in projects during the covid-19 pandemic, these observations could be achieved. By using grounded theory approach and our coding method we could detect how our findings correlate to the existing literature and what new understandings could be achieved. This served as the basis for answering the research question of this degree project being:

- **How do companies conduct risk identification within pharmaceutical projects during the covid-19 pandemic in Sweden?**

Our findings imply that risk identification in pharmaceutical projects consists of four dimensions; 1. Classifying risk through cross-functionality, 2. Risk search - mixed approach, 3. Reacting to disruptions and complexity and lastly, 4. Considering external stakeholders to accommodate demands. Further, these dimensions with their underlying codes generated the proposed process model seen in figure 3, which was shaped by both the findings and the current literature. Our proposed model addresses the key building blocks of how pharmaceutical projects have implemented risk identification during the Covid-19 pandemic and also displays how they are connected. In addition, our model differs from current literature in the following ways: *Firstly*, we detected that pharmaceutical projects classify their risk before the search of risks begins, due to the obvious structure between cross-functional teams. *Secondly*, when the search begins an individual search is carried out first which largely involves studying previously completed projects and later a collective search is completed where brainstorming has been the main activity that our respondents use to allocate possible disruptions. *Thirdly*, when the search has been completed pharmaceutical projects need to create a decision that is governed and altered by stakeholders and unpredictable disruptions. They can then choose to re-assess their risk search through an agile approach or enter the last stage of the model, the temporarily completed risk identification. *Finally*, since pharmaceutical projects tend to proceed during a long period of time, our findings discovered that risk identification is a recurring process. Therefore, after a certain period of time, projects need to re-evaluate their identified risks and carry out the process again.

In conclusion, our results show that these four dimensions as written above represent the most widely used approach to risk identification in pharmaceutical projects during the Covid-19 pandemic. Our conclusion is that these dimensions and their underpinning activities answer the research question.

7.2 Theoretical contributions

Developing new theories or significantly contributing to existing theories is a challenging feat (Shepherd and Sutcliffe, 2011, p.361). Despite this, the research conducted, and the subsequent results developed throughout this thesis has resulted in theoretical contributions.

This study acts as a response to the need for more knowledge about project management within pharmaceutical projects, which is argued to be less developed than other established industries (Chauhan & Srivastava, 2014, p.57). It also gives an insight into the risk identification process for which there has been a lack of development when it comes to explaining how it takes place in terms of searching and classifying.

Our study led to three theoretical contributions. First, it contributed to a new concept regarding the current order in which activities within risk identification take place, which was originally constructed by Chapman & Ward (2003, p.105) who stated that risk identification consists of two activities: (1) searching for risk and (2) classifying risks. After our study, the construction has been modified into switching order on the two activities, resulting in risk identification consisting of (1) classifying the risk and (2) searching for risks. Due to the organisational structure and the subsequent formation of cross-functional teams within pharmaceutical projects, risks are already classified before the searching begins. This can be explained by expertise within one's specific function which means that a project member will identify risks which pertain to their specific area or function. The expertise also facilitates how searching for risk happens on an individual basis before the project group comes together and approaches risk identification collectively.

Second, there are activities within our model that could be considered new for when one is explaining risk identification. The context of the pandemic has enabled us to extend the literature and detect the relationship between pharmaceutical projects and the external stakeholders, especially the regulatory authorities. In our model we have included the relationship stakeholder has to the process of identifying a risk, showing how continuous and imperative the dialogue between pharmaceutical companies and regulatory authorities are. Previous studies (Lofstedt et al., 2000, p.159) has indicated that the Swedish regulatory authorities are one of the strictest, whereas our findings evolves that theory and show how regulatory authorities not only govern but also guide pharmaceutical projects during their development of new products. We have therefore also, at least partially, achieved the purpose of grounded theory, which is to elicit fresh understandings about patterned relationships and how these relationships with the interactions construct reality (Glaser & Strauss, 1967 cited in Cornelissen, 2016, p.378). These results suggest that pharmaceutical project enhances their chance of succeeding when maintaining a dialogue and a cooperation

Finally, our research contributes to the literature of pharmaceutical projects by examining risk identification in the context of the Covid-19 pandemic. This provides insights of how extreme uncertainty and unpredictable disruptions can affect a project and can be partially prevented by incorporating appropriate risk identification. These results indicate the importance of having experience among project members in order to identify risks. This will therefore contribute to settle the reflection Maytorena et al. (2007, p.316) had about whether experience is a contributing factor when it comes to conducting a comprehensive risk identification. Our findings suggest that during the Covid-19 pandemic, experience is perhaps even more important for risk identification than it ever was before.

7.3 Practical recommendations

Based on our empirical findings, we provide some practical recommendations from this study to give some insight for people who are or will be involved in pharmaceutical projects where a risk identification process takes place. These practical recommendations may also in some cases be applicable for others who work within complex projects in other industries.

Firstly, pharmaceutical projects and their members may benefit from being aware of the anatomy of the risk identification process so that they can structure their time and resources in the most efficient way. Knowing that the complex nature of the industry, and the subsequent specialised functions within the project group affects the risk identification process is helpful, especially for project managers. If risks already are classified when project members conduct their risk search, project managers may find the individual search for risks relatively more worth spending time on compared to the collective risk search. This is because from our research, we indicate that experience and one's area of expertise are the largest contributing factors for finding risks. This is not to say, however, that the collective approach should be cast aside. Our results also indicate that project managers and other project members should value the collective search for risks, as several different characteristics and inputs are important for conducting a thorough and comprehensive risk identification process.

Secondly, we also recommend that practitioners within pharmaceutical projects, especially during uncertain times such as the Covid-19 pandemic, maintain a holistic view of the internal and external environments to the project. This will allow them to find important risks which may not be completely obvious. This will also be aided by having a critical mindset when it comes to the project. Our recommendation is therefore to have some optimism when it comes to the predicted success of the project, but to also keep in mind the success rates within the industry, and by maintaining a critical view, be able to identify upcoming obstacles or disturbances to strive for the best result.

Finally, it is our recommendation that pharmaceutical project members and project managers consider step 3 in our model which is the *reaction* step, especially in complex environments such as the Covid-19 pandemic. This suggests that when unpredictable disturbances occur in these environments, the risk identification does not need to be completely re-done. Rather, when disturbances occur, the risk identification process can circle back to step 2, which is the *mixed approach risk search*. The disturbance, which inevitably materialises into a risk can be tackled by this mixed approach - risk search involving the individual, but in this case, mainly the collective approach.

7.4 Societal recommendations

On a larger scale, we will also provide some societal implications and recommendations from our findings regarding *how companies conduct the risk identification process within pharmaceutical projects during the Covid-19 pandemic in Sweden*. This includes the implications for relevant stakeholders as well as some of the contextual factors of this study.

It has become evident during our research that patient safety is an objective of the utmost importance when it comes to the pharmaceutical industry. This has cemented the significance of the risk identification process and how this is conducted within the industry. Thereby, one of the most important stakeholders of pharmaceutical projects, the patients, can become aware of how the risk identification process is conducted. Clinical trial participants, which fall under the scope of patients as a group, can also receive more insight into how the products they will use are developed and the effort that goes into the first step of the risk management process, ensuring their well-being.

This study also has implications for the regulatory authorities within the pharmaceutical industry. By getting further insight into how the risk identification process is conducted within pharmaceutical projects within complex environments, this can be helpful in the understanding of the risk documents they receive in their communication with the projects. Regulatory authorities can also use the findings of this thesis to critically examine how pharmaceutical projects carry out their risk identification processes. More specifically, they may be able to provide input on the structural constellations of pharmaceutical companies and how they deem this to have an either positive or negative effect on how risks are handled. It may also be beneficial for regulatory authorities to be aware of the findings of this thesis for the purpose of communicating with individual projects. For example, if they are aware of step 1 of our model, *classifying risk*, they may be able to ask questions more directly. This may also mean that they can contact the relevant functional departments, and thereby receive answers more quickly.

For the Swedish society at large, this thesis can provide insight into a part of pharmaceutical projects and their anatomy. The pharmaceutical industry is a growing industry within Sweden and has especially been growing during the Covid-19 pandemic (lif, 2022). The Swedish society can gain an insight into parts of how this industry operates, and the seriousness with which pharmaceutical companies in Sweden conduct their projects. The findings from our thesis indicate that within Sweden, and within Europe, the very strict regulatory rules and regulations as enforced by the regulatory authorities ensures some sense of transparency of the industry. However, due to the high level of confidentiality, complete transparency will not be possible. Despite this, these regulatory conditions can contribute to a sense of comfort in knowing that there are immensely high requirements to receive approval to produce and distribute pharmaceutical products on the Swedish and European markets. This is as true for Covid-19 times as it is for ‘normal’ times.

7.5 Limitations and future research

Firstly, in reference to our delimitation in this thesis, risk identification is the catalyst for a much longer management-process, containing mitigation approaches, contingency plans and several other procedures when carefully executing risk management. As a result, it would be valuable to also investigate the other part of the whole risk management process and distinguish how those procedures have been conducted during Covid-19 pandemic within pharmaceutical projects. By assembling knowledge about all parts of risk management during the Covid-19 pandemic in pharmaceutical projects, the industry could improve their success-rate in projects, enabling more effective products on the market and improved support for patients in need.

Secondly, as demonstrated during our degree project, the pharmaceutical industry is highly complex. Nevertheless, there are other high-tech industries that would be interesting to examine. We choose to focus entirely on the pharmaceutical industry, but the covid-19 pandemic has not only affected the pharmaceutical industry. Therefore, it is intriguing to investigate if the industries differ between the consequences of the Covid-19 pandemic. Additionally, we studied solely companies operating within Sweden, although other countries with different regulations and regulatory authorities are an appealing perspective for future research.

Thirdly, future research could expand into other contextual elements, such as other countries or continents. There could also be an expansion of the research into other complex environments as represented by other events which affect the area of study, for example wars. Research into future events may also eventually be able to compare the results of this study and draw conclusions on how different complex environments with different contextual factors affect the risk identification process, or possibly the risk management process as a whole.

Lastly, during our degree project it has been revealed how the industry prioritises and cares for their stakeholders such as patients and regulatory authorities, while also emphasising the importance of obtaining a holistic view when proceeding with pharmaceutical projects. In the spirit of a holistic view, acquiring the stakeholders' perspective on how risk identification is conducted in pharmaceutical projects could be beneficial to gain more perspective. Therefore, also improving their risk identification by letting future research collect the stakeholders' perspective.

8.0 Quality criteria

Within research, it is essential to provide and maintain quality, meaning truthful findings that are in line with reality. To preserve quality, we will present two criteria we have included in our degree project. Normally, validity and reliability are the most common criteria used to evaluate the research (Collis & Hussey, 2014, p.52-54; Saunders et al., 2009, p. 157-158). However, these criteria can seem inapplicable and inappropriate to use to qualitative studies and suits quantitative studies better (Bell et al., 2019, p.48). Therefore, we have instead applied *Trustworthiness* and *Authenticity* as the two criteria which will assess the quality of our thesis (Bell et al., 2019, p.48). Trustworthiness is a criterion which consists of four components: *Credibility, Transferability, Dependability* and *Confirmability.* Whereas authenticity content by five components; *Fairness, Ontological authenticity, Educative authenticity, Catalytic authenticity,* and *Tactical authenticity* (Amin, 2020, p.8-10). In addition, qualitative studies have the tendency to not be as generalisable as quantitative studies (Collis & Hussey, 2014, p.54). Therefore, we will present in accordance with how the authors have placed their study in correlation with the two selected primary quality criteria, which contributes to increased transparency.

8.1 Trustworthiness

Credibility

Starting with credibility within trustworthiness which refers to the truth of the data, or the participants' views and the interpretation and representation of them (Cope, 2014, p.89). In other words, how believable are the findings? This can be compared to internal validity for quantitative studies (Bell et al., 2019, p.48; Korstjens and Moser, 2017, p.121). To ensure credibility we have used a prolonged engagement, meaning that we have spent adequate time with both the respondents and within the research area to learn about the culture, build trust and have time to reflect on potential flaws with the areas of research (Amin et al., 2020, p.2). In addition to prolonged engagement, we have also adopted persistent observation during our research to identify characteristics and elements that are most relevant for our question and issue (Amin et al., 2020, p.3). According to Amin et al. (2020, p.3), prolonged engagement provides scope while persistent observation provides a depth to our research.

Firstly, for the prolonged engagement we provided anonymity to establish a comfortable environment to the respondents. To increase this further, we had a duration of the interviews which allowed respondents to reason with themselves and elaborate their thoughts and experiences by giving examples. When conducting the interviews, we asked follow-up questions to investigate any captivating emerging topic that the respondents might bring up.

Secondly, to ensure credibility, one can see through our practical methodology how we conducted a coding process which reflects upon a persistent observation. We systematically processed the data combined with theories to elaborate codes that developed a model to answer our research question. The data was repeatedly reviewed to create as authentic coding as possible.

Thirdly, we included investigator triangulation (Amin, 2020, p.5). Investigator triangulation means that several researchers are involved when analysing the data using the same technique. Several researchers with the same techniques should reach the same results. However, the reality is not always the same. If the researchers encountered any disagreement of how the data

was interpreted, we discussed the differences and then found common ground for a new interpretation that was better suited.

Transferability

The second criterion within trustworthiness is transferability which refers to how findings can be applied to other settings or groups (Cope, 2014, p.89). In other words, do the findings apply to other contexts? Transferability to qualitative studies can be parallels for external validity in quantitative studies and can therefore also be referred to as generalisability (Bell et al., 2019, p.48). It is important to include transferability, since it is the reader who decides whether the findings are generalisability or not (Cope, 2014, p.89). Therefore, the author should provide sufficient information on the informants and the research context to accredit the reader to evaluate if the findings are transferable (Cope, 2014, p.89). This criterion will therefore be met if the results have meaning to individuals who are not involved in the study and they can associate the result to their own experiences (Cope, 2014, p.89).

Our findings are mainly rooted in the disruption of the society relative to the Covid-10 pandemic. Therefore, our findings might not be generalizable to all scenarios. However, it can be transferable to common settings where complexity and uncertainty is arising. Additionally, since we have gathered data from a high-tech industry the result might be suitable for a broader perspective and several industries, intriguing more individuals to perceive our findings meaningful.

Dependability

Thirdly, the dependability criteria refer to the constancy of data under similar conditions (Cope, 2014, p.89). In other words, are the findings likely to apply at other times? In quantitative studies dependability can be paralleled to reliability (Bell et al., 2019, p.48). Dependability is achieved when another researcher conducts a study with similar characteristics and arrives at similar conclusions, or at least agrees with the conclusions that first researchers stated (Cope, 2014, p.89). Within our thesis, we can make sure to define and present our research process clearly, so that a reader can easily follow the decisions made by us. To meet this criterion, we have strived to be as transparent with our decision and the process to the highest degree possible, both through the theoretical standpoints and the practical methodology. Concluded, the reader can easily detect how our study was executed and what stands behind the choices we made.

Confirmability

The last criterion within trustworthiness is confirmability. Confirmability refers to the researcher's ability to illustrate that the data represent the participants´ answers and not the researcher's biases or viewpoints (Cope, 2014, p.89). The question to be asked is; Has the investigator allowed his or her values to intrude to a high degree? Confirmability can be seen as the criteria of objectivity for quantitative studies (Bell et al., 2019, p.48). To establish objectivity of confirmability to a high degree, we have chosen to display our coding process, leading up to the aggregate dimension thoroughly. However, it can be difficult to ensure entire detachments of one's personal values in business research (Bell et al., 2019, p. 375). To minimise the personal values that interfere with the data, we have ensured that both researchers have been participating during the data collection and the analysis, to enable a dialogue when interpreting the respondents' answers.

8.2 Authenticity

Fairness

Firstly, we will discuss the fairness criteria which falls under authenticity. Fairness has to do with if the research is representative of the respondents' different experienced realities have been taken into account when recounting the responses from the conducted interviews (Amin et al., 2020, p.8). With regard to fairness, all our respondents have been a part of the risk identification process during the Covid-19 pandemic. This was used as a criterion for being able to act as a respondent for the study. For a fair characterisation of the risk identification process, project members of different hierarchical levels and positions within pharmaceutical projects were interviewed. This gave us the opportunity to approach the risk identification process from several lived realities of our respondents. For this reason, it is our opinion that the fairness in this study is high. Furthermore, we only interviewed respondents who had operated under the same contextual circumstances when it came to the pharmaceutical industry in Sweden during the Covid-19 pandemic, to enhance the fairness of our research.

Ontological authenticity

The ontological authenticity relates to how the study has been able to aid parties involved in gaining a deeper understanding of the relevant social setting (Amin et al., 2020, p.9). This study contributes to the understanding of the risk identification within pharmaceutical projects during Covid-19 in Sweden by the model we have developed of the risk identification process. This means that one can gain a deeper understanding of the beginning of the risk management process within pharmaceutical projects. It also means that the organisational influences such as the cross-functional teams and the significance this plays in risk identification within pharmaceutical projects can become clearer. Hence, this study contributes to both practitioners' and researchers' understanding of the social setting.

Educative authenticity

The educative authenticity concerns how the participants of the study have an enhanced awareness and understanding of those outside of their own stakeholder group (Amin et al., 2020, p.9). We deem this criterion to be met, as the respondents in this study have continuously reflected upon the different stakeholders of pharmaceutical projects. There have been elaborate recounts of their relationships with these stakeholders, and the respondents have regularly presented an understanding of, and their relationships with, for example patients and regulatory authorities.

Catalytic authenticity

Catalytic authenticity relates to how the study has served to participate in change, which can mean both clarifying the focus as an issue, moving to eliminate or ameliorate the problem, and/or sharpening values (Amin et al., 2020, p.9). Within our study we have aspired to establish meaningful insights with pharmaceutical risk identification processes and therefore encourage an improved understanding of risk identification within pharmaceutical projects. This may also encourage practitioners to use our theoretical model when they structure the risk management process within pharmaceutical projects.

Tactical authenticity

Tactical authenticity refers to if the participants of the study are able to "*take the action(s) that the inquiry implies or proposes.*" (Amin et al., 2020, p.9). We argue that this criterion is fulfilled since our model gives our respondents and other stakeholders insights into how the risk identification within pharmaceutical projects is conducted. This gives, particularly participants, the opportunity to approach the process from our model's framework.

9.0 Reference list

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10. Appendices

Appendix 1. Keywords search results

Keyword	Search result
Risk identification	5 330 000
Expert opinion risk identification	2 400 000
Pharmaceutical industry	3 210 000
Swedish pharmaceutical industry	115 000
Covid-19 effect on pharmaceutical industry	903 000
Covid-19 effect on Project management	2 220 000
Project management pharmaceutical industry	1 210 000
Pharmaceutical industry risk	2 070 000
Pharmaceutical risk management	2 580 000
Risk identification project management	5 730 000
Unknown risks project management	1 070 000
Failed projects	2 180 000
Riskification	633

Appendix 2. Information form - English

Information form for participants

Risk identification within pharmaceutical projects

We are currently working on a degree project studying the risk identification process within pharmaceutical projects in Sweden. You have been invited to take part in the project.

Before you decide whether to participate in our degree project, please take time to carefully read through the following information about what it means to participate in this study.

What is the purpose of the study?
Our degree project is part of the Business Administration program at Umeå School of Business, Economics and Statistics, Umeå University. Within the program we have explored project management and therefore touched upon risk management. The purpose of this thesis is to provide insights into the beginning stages of risk management for projects during Covid-19 in Sweden, within the pharmaceutical industry, which is of crucial importance to our society. In addition, we aim to elaborate how pharmaceutical companies have managed identifying risks during the pandemic, where uncertainty is consistent. By exploring which strategies and practices are successfully useful for pharmaceutical companies, we desire to bring value for future research and practitioners when identifying risk and proceeding with projects.

Why have I been chosen?
We aim to interview people involved with (a) projects (b) within the pharmaceutical industry (c) in Sweden.

Do I have to participate?
Your participation is voluntary based. Once you agree to participate, you will be given this information sheet to keep and be asked to sign a consent form. Even though you decide to take part, you can still decide to withdraw from the study at any time without an explanation if you do not wish to explain.

If you wish to withdraw from the research after some data have been collected, you will be asked if you are content for the data collected to be retained and included in the study. If you prefer, the data collected can be destroyed and not included in the study. However, you cannot withdraw the data from the study when the research has been completed and data analysis has begun on May 1st, 2022.

If I take part in the research, what do I have to do?
If you decide to take part, we would like to conduct 1 to 2 interviews with you, ideally on Zoom/Teams or via phone call. You will be asked a number of questions regarding (1) yourself and your role within your organisation (2) your take on risk identification within projects (3) your organisation's risk identification processes, before and during Covid-19.

We aim to ask open-ended questions and we can provide the questions in advance if you wish. Each interview will last for around 45 minutes.

What will happen to the information I provide the researchers?
Personal details including your name and contacts will be kept confidential and not revealed to third parties in compliance with academic research ethics and the rules and regulations of processing personal data at Umeå University. More information can be found at:
https://www.umu.se/en/about-the-website/legal-information/processing-of-personal-data/

The consent forms we retrieve from the participants will be preserved in Umeå University OneDrive with password protected. Personal information provided during the interviews such as people's names, places, name of the projects and occupation will be anonymized in the interview transcripts. Specifically, we will assign pseudonyms to people's names that you mention in the interviews. The same pseudonyms strategy applies for places and businesses. Occupation will be replaced by general terms such as Andrew's job as a researcher became 'job in education'. Researchers in our research project are the only ones who possess access to the data. The data we collect from interviews i.e., audio files, transcripts and observation notes will be encrypted and saved similar as the consent form, in a Umeå University OneDrive account, protected by password. Researchers in our research program are the only ones who have access to this data.

Quotes from the interview transcripts will be included in the thesis that we author. Your and your organisation's identities will remain anonymous in the interview quotes that will be used in our papers.

Umeå University will be the organisation processing your personal information. In accordance with the General Data Protection Regulation (GDPR) of the European Union, you have the right to request information once a year, concerning what personal data Umeå University holds on you. If the data that is collected about you is incorrect, you are entitled, as a data subject, to correct it. Additionally, you are authorised to have personal data concerning you erased when it is no longer needed for the purpose for which it was collected. However, the personal data might not always be allowed to be erased due to other legislation that supersedes this rule. Furthermore, you are entitled that the processing of personal data regarding you is limited to a certain specific purpose only. You may complain about the processing of your personal data. If there are no compelling reasons for the university to continue processing the personal data, the university will stop processing.

If you have any request for your personal data, please contact Emma Nydén or Wilma Janzon Hägglund. Our contacts are listed below.
You can also contact the Data Protection Officer at Umeå University, at pulo@umu.se.
If you have any concerns about the university's personal data rights practises you can lodge a complaint to the supervisory authority, Datainspektionen. Information on how to proceed with a complaint is available on their website, www.datainspektionen.se

What if something goes wrong?
Do not hesitate to contact us if you have any concerns or questions. Our contacts are provided below.

How do I get access to the results of the study?
Please feel free to contact the responsible researchers if you have any questions regarding publications or results of the study. If you wish to, we can provide the link or the finished copy of our degree project to you when available.

What happens next?
If you agree to participate in this study, you will find a copy of the consent form below that needs to be signed. You can keep this document and the consent form. We will keep another copy of the consent form.

Thank you for your time!

For further information, please contact:
Wilma Janzon Hägglund
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Appendix 3. Information form - Swedish

Informationsformulär för deltagare

Riskidentifiering inom farmaceutiska projekt

Vi arbetar just nu med ett examensarbete som studerar riskidentifieringsprocessen inom läkemedelsprojekt i Sverige. Du har blivit inbjuden att delta i projektet.

Innan du bestämmer dig för om du vill delta i vårt examensarbete eller inte, ta dig tid att noggrant läsa igenom följande information om vad det innebär att delta i denna studie.

Vad är syftet med studien?
Vårt examensarbete är en del av Civilekonomprogrammet på Handelshögskolan vid Umeå universitet. Inom programmet har vi utforskat projektledning och därför berört riskhantering. Syftet med detta examensarbete är att ge insikter i början av riskhantering för projekt i Sverige. Dessutom strävar vi efter att utveckla hur läkemedelsföretag har lyckats identifiera risker under pandemin, där osäkerheten är konsekvent. Genom att utforska vilka strategier och metoder som framgångsrikt är användbara för läkemedelsföretag vill vi tillföra värde för framtida forskning och praktiker när de identifierar risker och fortsätter med projekt.

Varför har jag blivit utvald?
Vi syftar till att intervjua personer involverade i (a) projekt (b) inom läkemedelsindustrin (c) i Sverige.

Måste jag delta?
Ditt deltagande är frivilligt. När du samtycker till att delta kommer du att få detta informationsblad att behålla och ombeds att underteckna ett samtyckesformulär. Även om du bestämmer dig för att delta kan du när som helst välja att avbryta studien utan förklaring om du inte vill förklara.

Om du vill dra dig ur forskningen efter att viss data har samlats in kommer du att tillfrågas om du nöjer dig med att den insamlade informationen behålls och inkluderas i studien. Om du föredrar det kan de insamlade uppgifterna förstöras och inte inkluderas i studien. Du kan dock inte dra tillbaka data från studien när forskningen är klar och dataanalysen har påbörjats den 1 maj 2022.

Om jag deltar i forskningen, vad måste jag göra?
Om du bestämmer dig för att delta vill vi genomföra 1 till 2 intervjuer med dig, helst på Zoom/Team eller via telefonsamtal. Du kommer att ställas ett antal frågor om (1) dig själv och din roll inom din organisation (2) din inställning till riskidentifiering inom projekt (3) din organisations riskidentifieringsprocesser, före och under Covid-19.

Vi strävar efter att ställa öppna frågor och vi kan tillhandahålla frågorna i förväg om du så önskar. Varje intervju kommer att pågå i cirka 45 minuter.

Vad kommer att hända med informationen jag ger forskarna?
Personuppgifter inklusive ditt namn och dina kontakter kommer att hållas konfidentiella och inte avslöjas för tredje part i enlighet med akademisk forskningsetik och reglerna för behandling av personuppgifter vid Umeå universitet. Mer information finns på:
https://www.umu.se/en/about-the-website/legal-information/processing-of-personal-data/

De samtyckesformulär vi hämtar från deltagarna kommer att bevaras i Umeå universitet OneDrive med lösenordsskydd. Personlig information som lämnas under intervjuerna såsom personers namn, platser, namn på projekten och sysselsättning kommer att anonymiseras i intervjuutskrifter. Specifikt kommer vi att tilldela pseudonymer till personers namn som nämns i intervjuerna. Samma pseudonym strategi gäller för platser och företag. Yrke kommer att ersättas av allmänna termer som att Andrews jobb som forskare blev "jobb inom utbildning". Forskare i vårt forskningsprojekt är de enda som har tillgång till data. De data vi samlar in från intervjuer, till exempel ljudfiler, utskrifter och observationsanteckningar, kommer att krypteras och sparas på samma sätt som samtyckes formuläret, på ett OneDrive-konto vid Umeå universitet, lösenordskyddat. Forskare i vårt forskningsprogram är de enda som har tillgång till denna data.

Citat från intervjuutskrifterna kommer att ingå i den avhandling som vi skriver. Din och din organisations identiteter kommer att förbli anonyma i de intervjucitat som kommer att användas i våra arbeten.

Umeå universitet kommer att vara den organisation som behandlar dina personuppgifter. I enlighet med Europeiska unionens allmänna dataskyddsförordning (GDPR) har du rätt att, en gång per år, begära information om vilka personuppgifter Umeå universitet har om dig. Om uppgifterna som samlas in om dig är felaktiga har du som registrerad rätt att korrigera dem. Dessutom har du rätt att få personuppgifter om dig raderade när de inte längre behövs för det ändamål för vilka de samlades in. Det kan dock hända att personuppgifterna inte alltid tillåts raderas på grund av annan lagstiftning som ersätter denna regel. Vidare har du rätt att behandlingen av personuppgifter om dig är begränsad till endast ett visst specifikt ändamål. Du kan klaga på behandlingen av dina personuppgifter. Om det inte finns några vägande skäl för universitetet att fortsätta behandlingen av personuppgifterna kommer universitetet att upphöra behandlingen av dina personuppgifter.

Om du har någon begäran om dina personuppgifter, vänligen kontakta Emma Nydén eller Wilma Janzon Hägglund. Våra kontaktuppgifter finns nedan.
Du kan också kontakta data skyddsombudet vid Umeå universitet, på pulo@umu.se.
Om du har oro kring universitetets praxis för rätten om personlig information kan du lämna in ett klagomål till tillsynsmyndigheten Datainspektionen. Information om hur du går till väga med ett klagomål finns på deras hemsida, www.datainspektionen.se

Vad händer om något går fel?
Tveka inte att kontakta oss om du har några funderingar eller frågor. Våra kontaktuppgifter finns nedan.

Hur får jag tillgång till resultaten av studien?

Kontakta gärna ansvariga forskare om du har frågor angående publikationer eller resultat av studien. Om du vill kan vi tillhandahålla länken eller den färdiga kopian av vårt examensarbete när det är tillgängligt.

Vad händer härnäst?
Om du samtycker till att delta i denna studie hittar du en kopia av samtyckesformuläret nedan som måste undertecknas. Du kan behålla detta dokument och samtyckesformuläret. Vi kommer att behålla ytterligare en kopia av samtyckesformuläret.

Tack för din tid!

För ytterligare information, vänligen kontakta:
Wilma Janzon Hägglund
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Appendix 4. Consent form - English

Consent form for participants

Risk identification within pharmaceutical projects

Please complete this form after you have been informed about the research project.

Name of the participant:

I hereby confirm that I am over 18 years old and…

I agree to take part in this research,

I have read and understood the study information form and been given the opportunity to ask questions before agreeing to take part in the project,

I understand that I can withdraw from the study at any time without having to give an explanation,

I understand that the interview will be audio-recorded and give permission for the researchers to do so,

I give permission for direct quotes from the interview to be used for academic purposes under the condition that I remain anonymous.

**By signing this consent form, you understand and agree to the terms stated above. **

Date:

Sign:

Appendix 5. Consent form - Swedish

Samtyckesformulär för deltagare

Risk identifiering inom farmaceutiska projekt

Fyll i detta formulär efter att du har blivit informerad om forskningsprojekt.

Namn på deltagaren:

Jag bekräftar härmed att jag är över 18 år och...

Jag går med på att delta i denna forskning,

Jag har läst och förstått information-formuläret och fått möjlighet att ställa frågor innan jag tackar ja till att delta i projektet,

Jag förstår att jag kan dra mig ur studien när som helst utan att behöva ge en förklaring,

Jag förstår att intervjun kommer att spelas in på ljud och ger tillåtelse för forskarna att göra det,

Jag ger tillåtelse att direkta citat från intervjun används för akademiska syften under förutsättning att jag förblir anonym.

**Genom att underteckna detta samtyckesformulär förstår och godkänner du villkoren som anges ovan. **

Datum:

Signatur:

Appendix 6. Interview guide - English

Theme	Questions	Purpose	Theory
Introduction	● Introduce ourselves and the study. ● Ask for permission to record ● Review how their information is handled. (GDPR + anonymous) ● Age, gender	Prepare the respondent for the interview and inform them about their rights. Create a friendly atmosphere. Check that the respondent meets the requirements to participate in the study.	(Saunders et al., 2019)
Background	● Can you tell us a little about your role and the company you work for? ● How long have you worked there? ● How long have you worked as a project manager / within projects? ● What is your education? ● What kind of management training do you have? ● What kind of projects do you work on? ● How involved are you usually in the risk identification process? ● What does risk mean to you as a project manager? How would you define it?	Get information about the person and the company as this is useful for contextualising people's answers.	(Saunders et al. 2019)
Pharmaceutical industry	● What would you say is what characterises the pharmaceutical industry when compared to other industries?	Investigate how the pharmaceutical industry differs from other industries	(Brown & Grundy, 2016)
Pharmaceutical project management	● What would you say is what sets projects in your industry apart from projects in other industries? Are they more or less complex?)	Get an insight into what characterises a project in the pharmaceutical industry	(Chauhan & Srivastava, 2014)

During Covid-19	• How has the pandemic affected your job / role / tasks?	Get an idea of what the pandemic has caused for change + thoughts and feelings about change	(Tirivangani et al., 2021)
Classification of risks	• What would you say are the most common risks in pharmaceutical projects? (How has this been affected by the pandemic?) • After you have identified a risk, do you have any procedure to ensure that the risk is classified correctly? And thus, end up in the right area of responsibility? (Has this required new solutions due to the pandemic?)	Get to know how risks are seen and grouped in projects + how the pandemic has affected the approach	(Mohammad Sabbaghi & Allahyari, 2020; George, 2020; Stulz, 2008).
Risk identification	• Could you tell us a little about how you / your company relate to risk identification? • How do you identify 'common' risks? • How would you say your risk identification in projects has been affected by the pandemic? (Has it / has it been more difficult or easier during the pandemic?)	Get an idea of how risk identification is carried out and how the pandemic has affected the process	(Hoon Kwak and Dixon, 2008)
Risk identification techniques	• Are there any specific risk identification techniques that you usually use? If so, which ones, and why? (Have you had to use new technologies due to the pandemic?)	Understand which techniques are most used in practice and why + the effect of the pandemic	(Brown & Grundy, 2016; Maytorena et al., 2007; Charoo & Ali, 2012)
Experience	• What would you say are the most important characteristics when it comes to identifying risks in the most effective way? (Has this changed during the pandemic?	Create us a perception of how personality versus education / experience is prioritised and an idea of how these factors affect the result of risk identification	(Maytorena et al,. 2007; Hoon Kwak and Dixon, 2008)
Contextualising (Sweden)	• How would you say that regulatory laws and regulations affect	Examine geographical context and whether government and	(Zahra, 2007; Picciotto, 2019;

	projects in the pharmaceutical industry? (Has this changed during the pandemic? If so, how?) ● Do you have any knowledge of whether Sweden differs from other countries when it comes to regulatory laws in the pharmaceutical industry? If so, how do they affect projects and their propensity to take risks? (Have you noticed any difference before / during the pandemic?)	governing actors influence projects and attitudes to risk	Baker and Welter, 2018)
Completion	● If you were to summarise what we talked about in the interview, what would you say are the three most important things when it comes to risk identification? ● How would you sum up that the pandemic has affected pharmaceutical projects and their risk identification? ● Do you have something more you want to add about the subject?	Give space for the respondent to highlight what it considers to be the most important thing to include + Give the respondent the chance to comment freely on the topic.	(Saunders et al. 2019)

Appendix 7. Interview guide - Swedish

Tema	Frågor	Syfte	Teori
Introduktion	● Presentera oss själva och studien. ● Fråga om tillåtelse att spela in ● Gå igenom hur deras uppgifter hanteras. (GDPR+anonymous) ● Ålder, kön	Förbereda respondenten för intervjun och informera om deras rättigheter. Skapa en vänlig stämning. Kontrollera att respondent uppfyller kraven för att delta i studien.	(Saunders et al., 2019)
Bakgrund	● Kan du berätta lite om din roll och företaget du jobbar för? ● Hur länge har du jobbat där? ● Hur länge har du jobbat som projektledare/inom projekt? ● Vad har du för utbildning? ● Vad har du för 'management training'? ● Vad för slags projekt jobbar du inom? ● Hur involverad brukar du vara i riskidentifieringsprocessen? ● Vad betyder risk för dig som projektledare? Hur skulle du definiera det?	Få information om personen och företaget då detta är användbart för att kontextualisera personers svar.	(Saunders et al. 2019)
Farmaceutiska industrin	● Vad skulle du säga att det är som kännetecknar läkemedelsindustrin om man jämför med andra industrier?	Undersöka hur läkemedelsindustrin urskiljer från andra industrier	(Brown & Grundy, 2016)
Farmaceutisk project ledning	● Vad skulle du säga att det är som skiljer projekt i din industri från projekt i andra industrier? (Är de mer eller mindre komplexa?)	Få en inblick i vad som karaktäriserar ett projekt inom läkemedelsindustrin	(Chauhan & Srivastava, 2014)
Under Covid-19	● Hur har pandemin påverkat ditt jobb/din roll/dina arbetsuppgifter? (kan du ge ett exempel?	Få en uppfattning till vad pandemin har orsakat för förändring + tankar och känslor kring förändring	(Tirivangani et al., 2021)

Klassificering av risker	• Vad skulle du säga är de vanligaste riskerna i pharmaceutiska projekt? (Hur har detta påverkats av pandemin, exempel) • Efter att ni har identifierat en risk, har ni något tillvägagångssätt för att säkerhetsställa att risken klassificeras rätt? (exempel) Och därmed hamnar inom rätt ansvarsområde? (Har detta krävt nya lösningar pga pandemin?)	Få kännedom om hur risker ses på och grupperas i projekt + hur pandemin har påverkat synsättet	(Mohammad Sabbaghi & Allahyari, 2020; George, 2020; Stulz, 2008).
Risk identifiering	• Skulle du kunna berätta lite om hur du/ditt företag förhåller er till riskidentifiering? • Hur gör ni när ni ska identifiera 'vanliga' risker? • Hur skulle du säga att eran riskidentifiering inom projekt har påverkats av pandemin? (Är det/har det varit svårare eller lättare under pandemin?)	Få en uppfattning om hur riskidentifiering genomförs och hur pandemin har påverkat processen	(Hoon Kwak and Dixon, 2008)
Risk identifierings tekniker	• Finns det någon/några specifika tekniker för riskidentifiering som du/ni brukar använda er av? Isåfall, vilka, och varför? (Har ni varit tvungna att använda nya tekniker pga pandemin?)	Förstå vilka tekniker som är mest använda i praktiken och varför + pandemins effekt	(Brown & Grundy, 2016; Maytorena et al., 2007; Charoo & Ali, 2012)
Erfarenhet	• Vad skulle du säga är de viktigaste egenskaperna när det kommer till att identifiera risker på mest effektiva sätt? (Har detta förändrats under pandemin?)	Skapa oss en perception om hur personlighet kontra utbildning/erfarenhet prioriteras samt en uppfattning om hur dessa faktorer påverkar resultatet av riskidentifiering	(Maytorena et al,. 2007; Hoon Kwak and Dixon, 2008)
Kontextualisering (Sverige)	• Hur skulle du säga att regulatoriska lagar och regler påverkar projekt i läkemedelsindustrin?	Undersöka geografiskt sammanhang och ifall regering och styrande	(Zahra, 2007; Picciotto, 2019; Baker and Welter, 2018)

	(Har detta förändrats under pandemin? Om ja, Hur?) ● Har du någon vetskap om Sverige urskiljer sig från andra länder när det gäller regulatoriska lagar inom läkemedelsindustrin? Isåfall, hur påverkar dem projekt och benägenheten till risk? (Har du märkt någon skillnad på innan/under pandemin?)	aktörer påverkar projekt och attityden till risk	
Avslutning	● Om du ska sammanfatta det vi har pratat om i intervjun, vad skulle du säga är det tre viktigaste sakerna när det kommer till riskidentifiering? ● Hur skulle du sammanfatta att pandemin har påverkat pharmaceutiska projekt och deras riskidentifiering? ● Har du något mer du önskar tillägga om ämnet?	Ge utrymme till att låta respondenten lyfta fram vad den anse är det viktigaste att ta med + Ge respondenten chansen att kommentera fritt kring ämnet.	(Saunders et al. 2019)

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