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Assessment of the Implementation of a Cloud-Based Software Solution for Drug Registration at a Pharmaceutical Company

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A research proposal submitted to the Faculty of Commerce, Law and Management, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of Master of Business Administration.

Supervisor: Prof. Eric Schaling

Johannesburg, February 2024

➢ DECLARATION

I, Angeline Moodley, hereby declare that this proposal for the Master of Business Administration submitted to the Faculty of Commerce, Law and Management at the University of Witwatersrand has not been submitted previously for any degree at this or another university. It is original in design and in execution, and all reference material contained therein has been duly acknowledged.

Student: Angeline Moodley…….. **Date: 15 February 2024**……

KEYWORDS

Cloud computing, cloud-computing software, drug registration, pharmaceutical company, health authority, drug product submission, submission dossier, regulatory requirements, efficiency, productivity, effectiveness.

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ABSTRACT

This comprehensive research delved into the impact of implementing a cloud-based Regulatory Information Management software solution on the efficiency of drug registration processes within a pharmaceutical company. The study was guided by the hypothesis that the adoption of such a cloud-based solution significantly enhances efficiency by reducing time costs, boosting productivity, and fostering collaboration among cross-functional departments.

Employing a mixed-methods parallel design approach, the research gathered quantitative data by means a survey administered to employees of a pharmaceutical company who are involved in drug registration processes utilizing the implemented software solution, and qualitative data through interviews with key stakeholders in managerial positions directly engaged in drug registration processes at the company. There were 52 respondents to the survey and 10 interviews were conducted providing an adequate representation of the population involved in drug registration processes at the company.

Data analysis, comprising descriptive statistics, thematic analysis, and cross-case comparisons, uncovered patterns, challenges, and benefits. The analysis reveals that the implementation of cloud-based software for drug registration processes would lead to operational efficiencies and positively influences the various functions involved in producing a drug registration dossier and enhances the drug registration processes despite the variations in satisfaction levels and challenges in user adaptation.

The findings contribute valuable insights into the effectiveness of cloud-based software solutions in improving drug registration efficiency, offering evidence-based recommendations for pharmaceutical companies aiming to optimize their processes through cloud-based technologies. Key recommendations include the need for continuous training and support programs and customization to meet evolving business requirements.

CHAPTER 1. INTRODUCTION

1.1 Statement of purpose

Drug registration processes and requirements of health authorities in various markets across the globe have evolved in recent years with requirements becoming more extensive to include large data packages from pharmaceutical manufacturing companies to support drug product registration (Robertson, et al., 2020). An example of such evolution and review of processes at health authorities is illustrated by (Keyter, Gouws, Salek, & Walker, 2018) for South Africa. Pharmaceutical manufacturers have thus employed multiple costly IT systems at a company level for the various functions that support content for drug registration dossiers to be compliant with requirements in the markets in which they seek to gain registration of their products. They are seeking prospects to enhance efficiency in their processes for compliance of regulations that can also be cost effective, which would result in business performance improvements and productivity (Kulkov, 2021). Many of these companies consider IT solutions as a manner to improve efficiencies (Kulkov, 2021), and commentary from pharmaceutical industry leads indicate that cloud-based systems for data management for drug registration requirements have the potential to accelerate and streamline review processes (Robertson, et al., 2020). The impacts of the recent pandemic have also highlighted the need for continued implementation of innovative tools, processes, and cloud-based systems for agility with drug registration requirements (Wegner, 2021).

Thus, the intention of this study is to evaluate whether the implementation of a cloud-based software solution for regulatory data management at Eli Lilly and Company, a multinational pharmaceutical manufacturer, has contributed to improved efficiencies and productivity in all the internal functions that contribute to the data submission package to health authorities for drug registration. This mixed method study will explore the impact of the implementation of Veeva RIM on efficiency and productivity of the company's global regulatory department and

related functions involved in drug registration processes across multiple global markets.

1.2 Background of the study

For any medicine to be available on the market in any country it needs to be accepted by the applicable health authority of that country, and this regulatory process by which an organization is granted permission to launch that product in the market is deemed the drug approval process (Gupta, 2012) (Dailey, 2022). Drug products are evaluated by regulatory agencies for their quality, safety, and efficacy, labelling claims, manufacturing processes and licensing of facilities and distribution channels and involves various functions (Dailey, 2022) (Gupta, 2012). The process of drug evaluation in many countries around the world has evolved over time (Keyter, Gouws, Salek, & Walker, 2018), with the intention to design drug review and approval processes to allow safe and effective medicines to be marketed (Dailey, 2022).

Health authorities or regulatory agencies are responsible to enforce the regulations governing drug approval and issue specific guidance on the requirements for drug registration in their particular markets (Gupta, 2012). These specific guidelines are aimed at assisting organizations to prepare the applicable documents to ensure timely drug registration evaluations (Triveni, Nagabhushanam, Ramakrishna, Sindhu, & Bonthagarala, 2020). Pharmaceutical companies follow these guidance documents and regulations to prepare submission dossiers in a manner that will not result in delays, unnecessary queries, or rejections of applications by the health authority regulatory agencies (Gupta, 2012). Pharmaceutical registration is a demanding task given the diversity of requirements for any market (Badjatya, 2013), and any organization wanting to have drug products registered for use should have thorough knowledge of the regulations and requirements for registration in relevant markets to properly inform regulatory strategy and product launches (Gupta, 2012).

There have been significant efforts from regulatory agencies to improve the pharmaceutical submission process (Suchanek & Ostermann, 2012), which include the move from paper-based submissions to electronic submissions (Sama, Latha, Sathish, Krishna, & Santhosh, 2016) harmonizing the requirements according to regulations (Badjatya, 2013), as well as having harmonized requirements and processes at a regional level for a group of countries (Roey & Haxaire, 2008) (Sithole, Mahlangu, Salek, & Walker, 2020) (Triveni, Nagabhushanam, Ramakrishna, Sindhu, & Bonthagarala, 2020).

For a successful regulatory strategy for drug registration, pharmaceutical companies need to prepare registration dossiers with information related to manufacturing sites and drug product according to the requirements stipulated by the regulatory agencies (Yadav, 2013). The process of dossier preparation entails gathering information and data from different departments within the organization, necessitating effective coordination among various functional areas including production, clinical trials, research and development, quality assurance, quality control, and supply chain management, among others. (Yadav, 2013). Pharmaceutical companies employ various resources in each of these functional areas to manage data and flow of information using in-house IT infrastructure and internal stand-alone systems. This comes at great operational cost to pharmaceutical companies having to maintain and continuously validate these independent computer systems and ensure timely coordination and collaboration in each of the functional areas, to manage large data sets to meet the requirements of the different markets in which they need to register the products and achieve timely submissions and outcomes.

In an effort to improve drug registration processes and timelines, regulatory agencies in many regulated markets have adopted methods for computer-assisted drug registration (World Health Organization, 1998). An example would include the drug registration process in South Africa that used to take a number of years for a new medicine to be registered for use in the country, but with the implementation of improved systems and processes the approval timeline is expected to be drastically shortened (Keyter, Gouws, Salek, & Walker, 2018).

To remain competitive and facilitate easier drug registration mechanisms, pharmaceutical companies have thus also been prompted to re-evaluate their technology to make electronic transfer of information simpler and more accessible between themselves and regulatory authorities (Suchanek & Ostermann, 2012). The recent Covid-19 pandemic has further emphasised the urgent requirement for rapid access to digital information and the necessity for enhancing traditional processes and tools to accommodate greater flexibility through the usage of real-world evidence and cloud-based data systems (Wegner, 2021). Additionally, regulatory authorities must demonstrate increased responsiveness and adopt globally acceptable application procedures to meet the evolving needs of the industry (Wegner, 2021).

In 2017, Eli Lilly and Company, a multinational pharmaceutical manufacturer, conducted internal company surveys related to their internal processes for creating drug registration dossiers and identified challenges such as lack of systems integration and automation, non-standardized processes, trust in source data and duplication of data across multiple systems, insufficient planning tools and lack of workflow communication. In an effort to drive accuracy, transparency, and efficiency throughout their regulatory process and achieve a state of harmonized regulatory systems and processes using best practices and technology, they have implemented Veeva Vault RIM, a cloud-based software solution for data management.

1.3 Research problem

Due to regulatory changes and challenges in the sphere of pharmaceutical drug registration, as well as the evolution of technologies, pharmaceutical companies have been pressed to expand their digital capacities to remain competitive and obtain marketing authorizations in many markets (Global Industry Reports, 2021). Pharmaceutical companies strive to be the first to market with their products to gain market share, and any amount of lead time gained against any competitor would be noteworthy to their competitive advantage (Cha & Yu, 2014). Having lengthy queries from the regulators during the drug registration evaluation process and having to rework the submission dossier accordingly costs the

company time especially if their internal processes are dated and labour intensive.

Having transitioned from paper-based drug registration submission to electronic submissions to health authorities, pharmaceutical companies are now also having to manage increasing data sets to meet diverse registration requirements and ensure quick internal and external communications with various stakeholders for timely marketing authorization approvals globally. In keeping with industry trends, using cloud technology to manage data is expected to provide strong infrastructure and data integrity and achieve greater levels of effectiveness (Global Industry Reports, 2021).

The research gaps considered for this topic include:

1. While there is a growing trend in adopting cloud-based software solutions for data management in drug registration processes, there is a deficiency of comprehensive investigation on the specific outcomes and success of such implementations.
2. There is insufficient understanding of the effectiveness of cloud-based solutions in streamlining the internal and collaborative processes associated with drug registration submission compilation at a pharmaceutical company and also the factors that influence successful implementation and use of the cloud-based software solution for optimal drug registration processes.

The study aims to address these gaps by evaluating the implementation of Veeva Vault RIM at Eli Lilly and Company and assessing its effects on the efficiency and productivity of various functions involved in producing drug registration submission dossiers. The study seeks to provide valuable insights into the extent to which cloud-based solutions contribute to process optimization and efficiency gains and also shed light on the enhancements in workflow communication and coordination achieved through the adoption of cloud-based data management.

The findings will not only inform the specific case of Eli Lilly and Company but also offer valuable guidance to other pharmaceutical companies considering

the implementation of similar cloud-based solutions to enhance their regulatory processes.

1.4 Research objectives

1. To determine the level of efficiencies attained with the implementation of Veeva Vault RIM at Eli Lilly and Company.

2. To assess the impact of the implementation on various functions involved in producing a submission dossier for registration.

3. To evaluate the improvement of drug registration processes following the implementation.

The following research questions are posed for the study:

1. Have tasks related to dossier compilation become easier and quicker to perform following the implementation of Veeva Vault RIM?

2. Has cross functional collaboration improved for processes related to drug registration within the company?

3. Have drug registration submissions and outcomes improved? Is there an improvement to timelines for submission and approval?

1.5 Rationale

Pharmaceutical companies face resource-intensive drug registration processes, but adopting a universally accessible cloud platform for data exchange has the potential to revolutionize the regulatory submissions and approval process. (Robertson, et al., 2020). By implementing a shared data storage structure, companies can alleviate administrative burdens, minimize redundancy, and streamline registration efforts. (Robertson, et al., 2020). Companies aiming for swift market entry of their products prioritize the strategic restructuring of regulatory processes to enhance submission planning and execution efficiency. (Businesswire, 2021).

This is a relatively new practice in the regulatory industry with a growing number of pharmaceutical companies having adopted a cloud-based solution for data management (Businesswire, 2021), thus the rationale for this study is to determine how the implementation of a system such as the Veeva Vault RIM suite impacts the administrative and system issues at a pharmaceutical company in compiling submission dossier for drug registration.

Veeva Systems, the company that provides a cloud-based platform for pharmaceutical companies, reports that many of the top pharmaceutical companies in the world are using their platform for various aspects of their operations, including drug registration processes. It is reported that their platform has been used to manage over 4.5 million regulatory documents. (Veeva, 2023). Using cloud-based solutions that enable more efficient sharing and analysis of data with improved data security and compliance could result in pharmaceutical companies becoming more agile and competitive in an industry where time-to-market and regulatory compliance are critical (Silva, Resende, Amorim, & Borges, 2020).

The conclusions of the study will be useful for the administration of regulatory functions at Eli Lilly and company to measure the ongoing influence of the employment of Veeva RIM in their processes, as well as to other pharmaceutical companies who are considering implementing similar cloud-based software solutions.

1.6 Delimitations of the study

The scope of this study is confined to the functions intimately involved in the regulatory processes for submissions for drug registration at Eli Lilly and Company. These functions include manufacturing, clinical, safety, and marketing affiliate counterparts from around the world. These are the departments that participate in the implementation of the cloud-based software solution to transition from using legacy IT systems and traditional spreadsheet trackers.

This mixed method study involves data collection by means of a survey to Lilly employees that are now using Veeva RIM for data management as well as

interviews with managers and team leads in these functions. The purpose of the survey is to gather information on employee perceptions about the use of the new process and system and ascertain the improvements in their daily work.

Process improvement perceptions are limited to speed and accuracy of compiling a submission dossier internally.

1.7 Definition of terms

Drug registration – process through which pharmaceutical companies submit the information about their drug products for review to comply with the legal requirements of a board of authority to enable the manufacture, import, export, storage, distribution, and sale of a drug product in any country.

Drug registration requirements – guidelines and regulations provided by authorities to guide applicants in preparing documentation required for drug registration.

Electronic submission – format or process by which an applicant can submit regulatory documents to the regulatory authority instead of hard-copy paper documents.

Health authority – government organization that is responsible for medical services for a country to ensure health and well-being of its citizens.

Regulatory agency – division of the health authority responsible for the regulation of medical products intended for human and animal use and are usually tasked

with the efforts for monitoring, evaluating, inspecting, and registering of drug products.

Submission dossier – package of documents to meet the registration requirements and includes all technical information of a pharmaceutical product to be registered for a marketing authorization.

Veeva RIM – software as a service solution on a cloud-based platform that streamlines regulatory processes to improve data quality, visibility, and agility.

Cloud-computing – refers to the delivery of computing services over the internet ("the cloud"). These services include servers, storage, databases, networking, software, analytics, and intelligence.

Cloud-based software – also known as Software as a Service (SaaS), is a type of software that is hosted in the cloud and accessed via the internet, rather than being installed on a local computer. This software delivery model allows users to access applications over the internet through a web browser, without needing to manage the underlying infrastructure or platforms.

1.8 Assumptions

The study will be conducted via a survey to all employees involved with regulatory processes at Eli Lilly and Company, who are familiar with the implementation of the new system. The assumption is that all survey participants will understand the nature of the implementation as well as their specific job functions related to drug registrations for the company.

1.9 Chapter Outline

This chapter highlights the challenges experienced by pharmaceutical companies when trying to prepare product submission dossiers to obtain marketing authorizations across multiple countries given the diverse and increasing requirements mandated by health authorities. It describes the evolution of drug registration processes and the need for pharmaceutical companies to stay

abreast of changes and implement strategic tools and processes to enhance their internal efficiencies to obtain licenses to market their products. Companies that are able to expand their capabilities in a manner that allows them to compile a high-quality submission dossier which will not receive any rejections or many queries from the regulators and which passes technical validation easily, are better positioned to have any advantage against their competitors.

Advancing technological capability is one of the mechanisms to drive process efficiencies at both, the health authority and pharmaceutical company, level. This research study explores the implementation of a cloud-based software solution that helps pharmaceutical companies manage large data sets and facilitates connection amongst the distinct functions that contribute to the preparation of the submission dossier for the company.

In the following section, an extensive literature review is presented with the aim of pinpointing research gaps and providing a rationale for the research objectives of the study. The literature review will highlight the challenges associated with registration processes on a global scale, explore the utilization of cloud computing in healthcare and other industries, and examine the trends and factors influencing the adoption of cloud-based software. Subsequent sections will delve into the research methodology utilized in this study, followed by the presentation of results and their interpretation through a thorough discussion.

The concluding section will include the analysis of the findings in relation to how the data presented may be useful to drug registration policy makers, pharmaceutical companies regulatory functions, scholarly endeavours where gaps in literature may be filled.

CHAPTER 2. LITERATURE REVIEW AND THEORETICAL FRAMEWORK

2.1 Introduction

Drug registration processes can become a laborious task for pharmaceutical manufacturers given the complexity of requirements across multiple markets. The authors Badjatya & Bodla (2013) and Triveni et al. (2020) have explored the varying requirements for drug registration in semi-regulated markets and the Middle East countries, and both have agreed that despite the harmonization efforts in some regions of the world to consolidate the registration requirements, the pharmaceutical manufacturers still need to produce good quality submission dossiers that encompass a wide variety of technical information.

Processes at the regulatory body have undergone changes in recent years. One of the notable changes as described by Ahammad et al. (2019) is the implementation of the electronic submission filing format (eCTD) for registration dossiers. Sama et al. (2016) have also found that the implementation of this submission format in most regulated markets serves to improve and add efficiency to the drug registration process at the regulator, as this type of standardization lends greater consistency in the evaluation process. They also note that the move from paper-based submissions to electronic submissions is occurring in many countries across the world, this is substantiated by (Keyter, Gouws, Salek, & Walker, 2018).

A review of the literature was undertaken in alignment with the themes of the research objectives specified to identify the gaps related to the topic and to determine how cloud-computing software improves processes related to drug registration at pharmaceutical companies.

2.2 Definition of topic or background discussion

As explained by Yadav (2013) and Badjatya (2013), pharmaceutical companies have had to keep abreast of requirements for registration in all the markets in

which they operate. These companies have also needed to build capabilities within their regulatory affairs operations to accommodate the large sets of information required to successfully compile submission dossiers for each market (Yadav, 2013).

Advances in technology within the healthcare environment has led to innovations that can be incorporated in the drug registration process (Rajabion, Shaltooki, Taghikhah, Ghasemi, & Badfar, 2019).

The changes brought about by the Covid-19 pandemic have impacted pharmaceutical companies, influencing their business processes and pushing them to operate within a more digital or virtual framework (Robertson, et al., 2020) (Wegner, 2021).

Pharmaceutical companies have had to consider means in which communication within internal departments becomes more efficient, to ensure seamless transference of information between departments having to contribute to the submission dossier to meet the extensive requirements, as well taking into consideration the ease of which these dossiers can be shared with regulators.

2.3 First research objective: To determine the level of efficiencies attained with the implementation of Veeva Vault RIM at Eli Lilly and Company

2.3.1 *Efficiencies attained with cloud computing.*

The processing and sharing of large volumes of data within the healthcare industry has become significant in recent years and cloud computing has become the popular choice for convenience of handling volumes of healthcare information (Rajabion, Shaltooki, Taghikhah, Ghasemi, & Badfar, 2019). There are advantages associated with cloud computing in relation to availability, speed, databases, and a high level of collaboration possibilities, as well as financial advantages to the organization (Rajabion, Shaltooki, Taghikhah, Ghasemi, & Badfar, 2019). They focused on information handling in terms of patient data and

healthcare systems and not necessarily the drug registration processes that pharmaceutical companies are involved in, but the trend of cloud-based solutions in the industry were aptly articulated.

In describing the top trends with pharmaceutical companies Jardine (2019) explains that the pharma industry is a relatively latecomer in embracing cloud computing technology due to security concerns, disrupting the status quo, or operational hiccups that can influence regulatory compliance or the resources required. Jardine (2019) goes further to explain that there has been a recognition of advantages of cloud computing in the pharmaceutical industry that outweigh the causes for concern and more companies are adopting this technology as it provides optimized security of information, less reliance on in-house IT structures, unparalleled access to and control of data, agility, and scalability.

2.3.2 *Veeva Vault RIM*

For many pharmaceutical companies, coordinating the regulatory information management activities for worldwide submissions can become a multifaceted process and would involve numerous tools for each task which can result in poor visibility of information, disjointed processes, and poor data quality as stated by Veeva (2023). The complexity of this coordination process was reinforced by Yadav (2013) in describing the capabilities required by pharmaceutical companies for successful drug registration.

Veeva Vault RIM is a cloud-based software solution for the life sciences industry that offers end-to-end regulatory information management on a single platform. The suite of applications allows for regulatory data related to submission management to be housed in a single platform which supports the many facets related to preparation and archival of regulatory information for drug registration (Veeva, 2023).

The advantages offered by Veeva to pharmaceutical companies with this suite of applications for regulatory information include greater compliance, unified connectivity for cross functional departments, and speed to market when pharmaceutical companies can respond quicker to changing regulations and

streamline their process (Veeva, 2023). The competitive benefit of speed to market for pharmaceutical companies was explained by Cha & Yu (2014).

In October 2022 Veeva announced that almost 350 pharmaceutical companies have adopted their technology to transform regulatory operations to keep pace with evolving requirements of health authorities and simplify their submission planning, submission development, publishing of submissions and archival of submissions (Veeva, 2023).

2.3.3 *Hypothesis 1*

The implementation of Veeva Vault RIM at Eli Lilly and Company has significantly enhanced the efficiency of the drug registration process by improving data visibility, streamlining processes, and enabling faster response to changing regulatory requirements.

2.4 Second research objective: To assess the impact of the implementation on various functions involved in producing a submission dossier for registration.

2.4.1 *Compiling a drug registration submission.*

The extensive requirements for submission dossiers to meet the standards for marketing authorization approval in international markets have been described by Ahammad et al.(2019), Badjatya (2013), and (Keyter et al. (2018) revealing the time consuming and arduous process it becomes to pharmaceutical manufacturers.

Pharmaceutical companies have had to adapt and build internal capabilities to fulfil the dossier preparation tasks to ensure successful submission and minimize the questions and comebacks from regulators. Dossier preparation requires information from areas of production, quality control, R&D, labelling, and other related functions of the organization (Dailey, 2022). There is a need for excellent communication and collaboration and coordination between all these

departments of the internal organization to produce a high-quality submission dossier (Yadav, 2013).

Regulatory submissions consist of hyperlinked documents and information of company generated data that is collated and presented in a standard template and then modified to meet the varying requirements of different markets and regulators which amounts to a resource intensive process. Utilizing a shared platform for storing information can alleviate the administrative burden on individuals involved in preparing the dossier. (Robertson, et al., 2020).

2.4.2 *Hypothesis 2*

User perceptions influence the extent of use and level of efficiencies attained with cloud computing in drug registration processes.

2.5 Third research objective: To evaluate the improvement of drug registration processes following the implementation.

Rajabion et al. (2019) reviewed the advantages of using cloud computing as an internet-based software solution to manage large data in healthcare systems but have also emphasised that discussion in this field is still rare. The review by Gao & Sunyaev (2019) and El-Gazzar (2014) have also included insight on the elements shaping the adoption of cloud computing systems in healthcare and other industries. Neicu et al. (2020) have expanded on this aspect and quantified the perception of users who are now employing cloud-based technology in small to medium enterprises and have concluded that a positive perception of use of this technology exists among current users.

The learnings from the pandemic and the trends in the pharmaceutical industry in using technological advances, is leading to expanded use of cloud computing across the wider organizations as described by Champagne et al. (2015), Jardine (2019), Robertson, et al. (2020) and Wegner (2021). This use is extending to the drug registration processes by employing vendor services to manage the related regulatory information (Veeva, 2023).

2.5.1 *Hypothesis 3*

Cloud-based features and the selection of vendor, as well as internal organizational and technical factors can contribute to the benefits and challenges of successful implementation of cloud technology in drug registration processes.

2.6 ANALYTICAL FRAMEWORK

The literature reviewed illustrates that there has been an evolution in business operations of the healthcare or life sciences industry in an effort to adjust to the evolving surroundings. It is purported that technology advances such as cloud computing can improve management of data in the life sciences industry and produce efficiencies within its structures.

There are various phenomena that influence the success of adopting new technologies in an industry. Aside from the perceptions of users themselves or external environmental contributors, there could be other variables such as cultural challenges that impede the adoption of technology.

As the implementation of cloud-based software for the purposes of drug registration processes is still relatively new, this research aims to explore the value created within the drug registration functions of a pharmaceutical company and to investigate the aspects that impact the acceptance and continued use of such technology. The intention is to investigate the impact it has made on producing efficiency with the tasks involved, to determine the effect it has on collaboration between departments and to understand if the use of cloud-based software has resulted in improved outcomes in the drug registration approval process entirely.

The inter-related concepts to be explored with this topic then include perceptions of users around technological advances related to their job function, challenges experienced in adopting new technology, value creation in relation to work being made simpler, whether the cloud-based system improves collaboration within departments and creates efficiency in producing a submission dossier for registration.

Systems Theory and Total Quality Management (TQM) in Assessing Cloud Computing Implementation for Drug Registration

The assessment of cloud computing implementation for drug registration processes at a pharmaceutical company can be effectively guided by systems theory and total quality management.

Systems theory offers a holistic approach, viewing the organization as an interconnected system where technological, human, and procedural subsystems interact and impact one another. As substantiated by Mele et al. (2010) this theory emphasizes understanding these interdependencies, feedback loops, and the system's adaptive capabilities to identify how cloud computing influences the overall drug registration process.

In parallel, TQM provides a structured framework focused on continuous improvement, customer satisfaction, employee involvement and process optimization. By integrating TQM principles, emphasis is placed on the importance of high-quality standards, regular monitoring, and iterative enhancements in the cloud-computing system (Richbell & Ratsiatou, 1999).

Together, these frameworks allow for a comprehensive evaluation of the cloud computing system implementation, that it not only aligns with organizational goals but also drives efficiency, accuracy, and regulatory compliance in drug registration.

2.6.1 *Theoretical Framework*

The Technology Acceptance Model (TAM) and the Technology-Organization-Environment (TOE) frameworks are particularly pertinent theories for this study, providing insights into concepts associated with the organizational implementation of cloud computing technology.

The Technology Acceptance Model is a useful and widely used theoretical framework to describe how users perceive and adopt new technologies. It provides a conceptual structure for understanding and explaining the relationship between technology and user behaviour. This theory explains that acceptance of

a technology is primarily driven by two factors: perceived usefulness and perceived ease of use (Lee, Kozar, & Larsen, 2003). It was used to clarify the association between technology reception in users and implementation and the intent to use it (Palos-Sanchez, Arenas-Marquez, & Aguayo-Camacho, 2017). In the perspective of cloud computing, the Technology Acceptance Model can be functional to comprehend user attitudes and behaviours towards cloud-based services (Holden & Karsh, 2010).

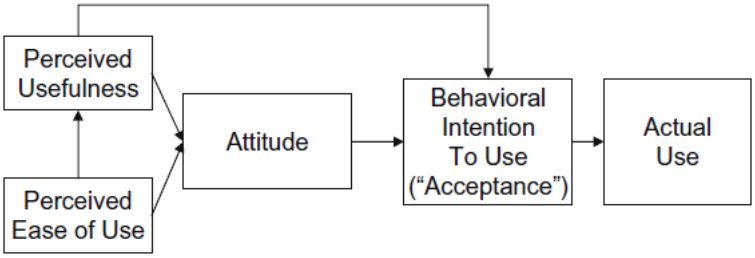


Figure 1: Illustration of the Technology Acceptance Model (TAM)

(Sourced (Holden & Karsh, 2010)

The Technology-Organization-Environment (TOE) framework is another on ICT adoption which proposes that the adoption of technology is also influenced by three additional factors which includes the context of the organization in relation to resources and internal features; the environmental context which relates to the space in which business processes are conducted; and the internal and external technologies in the market (Palos-Sanchez, Arenas-Marquez, & Aguayo-Camacho, 2017). This framework offers an indication of technology implementation and relevance and envisages the influence on value chain behaviour and the ensuing distribution of the factors that impact business choices (Palos-Sanchez, Arenas-Marquez, & Aguayo-Camacho, 2017) (Tweneboah-Koduah, Endicott-Popovsky, & Tsetse, August 2014).

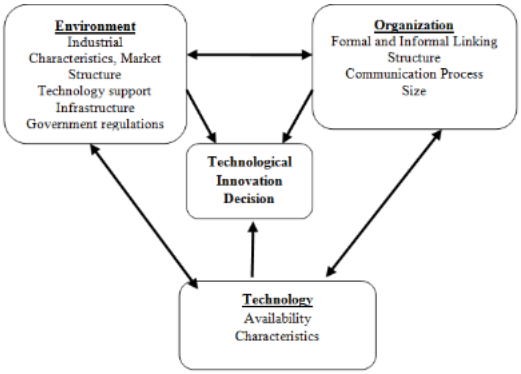


Figure 2: Illustration of the Technology-Organization-Environment (TOE) Framework.

(Tornatzky and Fleischer 1990) (*sourced (Tweneboah-Koduah, Endicott-Popovsky, & Tsetse, August 2014)*

2.6.2 *Conceptual Framework*

To enable the exploration of the advantages and challenges of cloud computing adoption at a pharmaceutical company, and to ascertain the extent of cloud computing use and its impact on drug registration processes, the key constructs as viewed through the lens of the TAM and TOE theoretical frameworks include evaluating the user perception of use of the cloud computing solution adopted, such as ease of use, reliability, performance; organizational factors such as organization size, structure and culture; economic and legal factors such as regulatory compliance, risk perception and data privacy; vendor selection such as pricing, reputation, product features; and integration with existing systems and interoperability.

The conceptual map depicted in Figure 3 below, demonstrates the interrelation of the multiple variables in cloud computing and drug registration. All these factors can influence the adoption and success of cloud-based technologies in drug registration. It is also important that the cloud-based technologies are used in a manner that meets regulatory requirements.

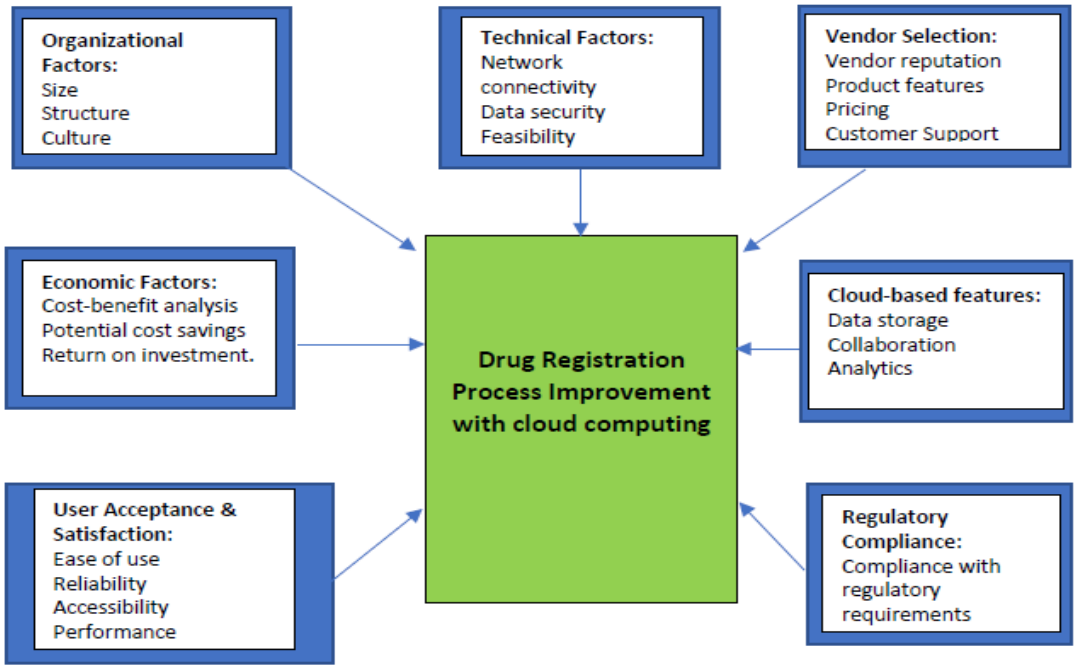


Figure 3: Conceptual Map for Cloud Computing in Drug Registration.

(Source: researcher)

By evaluating and understanding these constructs and their relationships, pharmaceutical companies can gain insights into the advantages and challenges related to cloud computing adoption, and also its impact on drug registration processes. There are several dependent and independent variables to consider.

The dependent variable is the adoption and success of cloud-based technologies in drug registration. This is the primary outcome variable, measuring the level of acceptance and effectiveness of cloud computing solutions in the company's drug registration processes. It encompasses factors such as improved efficiency, accuracy, and timeliness in the registration procedures.

The independent variables include:

User perception of use of cloud computing – the ease of use in how easily users can utilize the cloud computing solution, the perceived reliability and availability of the cloud system, and the users perception of the system's speed and responsiveness.

Organizational factors – the size, structure and culture of the organization which can influence its ability to adopt and integrate cloud computing.

Economic and legal factors – which involves regulatory compliance and the degree to which the cloud computing solution adheres to the industry regulations and requirements.
Vendor selection – the functionality and capabilities offered by the cloud computing solution.

By examining the relationship between these variables, the researcher will gain insight into the benefits, challenges, and overall impact of cloud computing adoption in the pharmaceutical industry's drug registration procedures.

2.7 Conclusion of the Literature Review

The literature reviewed in this chapter include contributions that describe the multitude of requirements of health product regulators from different regions and countries of the world. There is commonality amongst the research reviewed that each region or country has some unique requirements for submission dossiers and there have been efforts to harmonize these requirements across regions or according to leading market processes to facilitate easier evaluation timelines to ensure quicker registration given that regulators have also evolved their processes.

The review is also indicative that pharmaceutical companies make efforts to adapt to advances in the environment and the trends exist to improve efficiency with the adoption of technological capabilities. The review includes adoption of cloud-based solutions in some sectors of the life sciences industry as well as commentary insight on the value that this technology could create in the drug regulatory environment.

Based on the literature review carried out, it becomes evident that there is a scarcity of research examining the influence of cloud-based software solutions on drug registration processes within pharmaceutical companies. Therefore, the objective of this study is to explore the real impact of enhancing the compilation of submission dossiers through the implementation of cloud technology. Additionally, the study aims to collect user perceptions and identify any

challenges encountered in the process. To achieve this, a mixed method survey will be conducted among the current users of the system involved in the drug registration process.

2.7.1 *Hypothesis 1*

The implementation of Veeva Vault RIM at Eli Lilly and Company has significantly enhanced the efficiency of the drug registration process by improving data visibility, streamlining processes, and enabling faster response to changing regulatory requirements.

2.7.2 *Hypothesis 2*

User perceptions influence the extent of use and level of efficiencies attained with cloud computing in drug registration processes.

2.7.3 *Hypothesis 3*

Cloud-based features and the selection of vendor, as well as internal organizational and technical factors can contribute to the benefits and challenges of successful implementation of cloud technology in drug registration processes.

CHAPTER 3. RESEARCH METHODOLOGY

The hypotheses following the critical literature review on the theme of cloud computing use in the processes of drug registration, revealed that a need exists to explore the impact of cloud computing software used in drug registration processes at pharmaceutical companies. The intention of this study was aimed at generating evidence-based insights which will inform practice and policy.

This section outlines the research approach undertaken to determine the extent of cloud computing use at the pharmaceutical company, the gains and challenges of cloud computing adoption and the overall effect on drug registration processes. The research design is outlined with the data collection methods, population and sample, and the data analysis strategies.

3.1 Research approach

In order to explore the impact of cloud computing on the efficiency of drug registration processes at pharmaceutical companies, the primary research questions focus on the extent of cloud computing use, the advantages and challenges encountered by users in the adoption, and the overall impact on the drug registration process.

The research on this topic was a mixed methods approach to collecting data to understand opinions and perceptions of using cloud-based software in drug registration processes at a pharmaceutical company. The approach helped to identify the extent of cloud computing use, and if the implementation of a cloud computing application had improved individual tasks in providing any efficiency of those involved in drug registration processes. It also served to recognize the perceptions of using a new system in the workplace and helped to investigate the challenges and benefits of using cloud-based software to accomplish work in the regulatory department.

The assumptions are based on literature reviewed that cloud-computing offers multiple advantages and is a growing trend within the life sciences industry.

Data was gathered through the use of a survey to employees working within the regulatory function at a pharmaceutical company which has recently adopted cloud computing software for drug registration processes. Data was also collected via interviews with senior management of the regulatory department.

For analysis of data collected, statistical methods were used to analyse quantitative data and a thematic approach was employed for qualitative data. Following this analysis, conclusions about the impact of cloud computing on drug registration processes at a specific pharmaceutical company were drawn and recommendations made.

3.2 Research Paradigm

The research paradigm for this study is a combination of interpretivism and pragmatism.

In this study, interpretivism is reflected in the qualitative data collection methods, such as interviews, which aim to gather insights and understand perceptions and experiences of users of cloud-based software in drug registration processes. The focus is on exploring individual perspectives, opinions, and the impact of the software on their work.

Pragmatism, emphasizes practicality and usefulness of knowledge, is reflected in the mixed-methods approach which combines qualitative and quantitative data collection methods. The quantitative survey provides numerical data to assess the extent of cloud computing adoption and the benefits and challenges experienced, while the qualitative interviews provide in-depth understanding and insights into the impact on drug registration processes.

By employing both interpretivism and pragmatism, the research paradigm allows for a complete exploration of the research topic. It acknowledges the importance of understanding individual experiences and perceptions while also aiming to generate practical knowledge that can inform practice and policy in the pharmaceutical industry.

3.3 Research design

The research design follows on the approach of a mixed methods study using grounded theory principles to establish user perceptions and experiences of employees within the pharmaceutical company using the cloud-based software. Grounded theory involves systematically collecting and analysing data to uncover patterns, categories, and relationships. The research will utilize an inductive approach, enabling themes, concepts, and theories to surface organically from the collected data.

In this study, a parallel mixed methods design is chosen to leverage the strengths of both qualitative and quantitative approaches, enabling a comprehensive exploration of the research problem. This design is appropriate for this study as it allows for the simultaneous collection of survey data to capture broad trends and in-depth interviews to provide contextual understanding. A parallel design provides a more comprehensive understanding of the research problem by capturing different dimensions of the phenomenon at the same time. This is useful when exploring multifaceted issues that require both statistical trends and personal experiences or perceptions.

A survey was undertaken to gather quantitative information regarding the extent of cloud computing adoption as well as the associated benefits and challenges. Additionally, interviews were conducted to collect data on the impact of cloud computing on drug registration processes.

The data collected then established the relationship between the software solution and the perceived benefits. This design was helpful in building knowledge on this particular topic, as the literature review did not reveal too much information regarding the use of cloud-computing software for drug registration processes currently. This will help inform future policies and practices.

Grounded theory offers a flexible approach to investigate a wide variety of questions and will be useful to explain the relationships among variables such as productivity and efficiency, specifically in connection to the ease of use and value added by the software implementation.

3.4 Data collection methods

The method for collecting data encompassed the following:

Survey data collection:

The target population included employees at the pharmaceutical company involved in drug registration processes. Ethical approvals and permissions were sought to administer the survey and confidentiality and anonymity of the respondents were ensured. A structured survey questionnaire based on the research objectives was developed and administered to the identified participants online. The completed surveys were collected to then analyse the data.

Interview data collection:

Key stakeholders such as regulatory managers and senior division leaders involved in the drug registration processes were identified from the organization and informed consent to participate was sought. A semi-structured interview guide was created to delve into participants experiences, perceptions, and insights. Virtual interviews with the selected participants were scheduled and recorded with the participants permission. The transcribed recorded interviews were used for data analysis.

By employing multiple data collection methods, the study gathered a rich and diverse dataset which allowed for a comprehensive analysis of the study questions and objectives.

3.5 Population and sample

3.5.1 *Population*

Table 1 below illustrates the total number of current and active users of the Veeva Vault RIM solution at the company related to the specific functions they perform according to the security profiles they fall under. For the purpose of this study which is centred on drug registration processes at the company, the population included those listed as Affiliate users and a portion of the Functional users who

are directly involved in drug registration processes to respond to the survey. Affiliate users are defined as those employed as regulatory personnel at marketing country offices of the company spread across the various countries in which the company operates, Functional users are defined as those personnel employed at manufacturing sites located in several parts of the world that contribute to the content of the regulatory submission dossier for the various countries. These are the functions directly involved in registration dossier preparation and submission to health authorities and they were able to provide input on the benefits and challenges and also assisted the study in assessing the degree to which the implemented cloud computing solution is utilized.

Interviews were conducted with senior management of the regulatory function to collect data on the impact of the cloud computing adoption, and this includes the Geo profile listed in Table 1.

The population considered for this study amounted to an estimated 520 employees of the organization.

Table 1: Total number of active Veeva Vault RIM users at Eli Lilly & Co. as of 28 April 2023

Security Profile	# of Users
Affiliate User	599
Business System Support	9
Document Publisher	21
Document User	5104
Document Viewer	21
eCTD Submission Coordinator	72
Focused Global Viewer	2
Focused Universal Viewer	0
Functional Data Steward	7
Functional User	263
Geo	9

Security Profile	# of Users
Global Viewer	934
IT Support	14
Limited Document User	308
Product Focused Functional User	2
Project Manager	106
Universal Viewer	199
Vault Owner	21
Grand Total	**7691**

3.5.2 *Sample and sampling method*

A simple random sampling method was used in this study. A sample of respondents representative from each relevant functional area of the population were selected to respond to the survey. This method allowed for an unbiased representation of the population.

For the qualitative component, purposive sampling was used which involved selecting participants at managerial level roles for their specific experiences or perspectives from a leadership position to share insights on the implementation and the progress they have witnessed.

The survey was distributed to employees within the organization and are thus easily distinguishable from the internal Veeva Vault RIM user list and also readily accessible via internal email and communication channels of the company.

3.6 The research instrument.

As a mixed methods approach was employed in this study, research instruments to collect both quantitative and qualitative data were used. The following research instruments will be utilized:

a) **Survey Questionnaire**

A structured questionnaire was developed to collect quantitative data related to the extent of cloud computing adoption, perceived benefits, and challenges. The questionnaire included close-ended questions with options for participants to select their responses on a Likert scale and covered topics such as demographic information (age, job position, years of experience); usage of the software to complete daily work; perceived benefits (efficiency, accessibility, collaboration); challenges (technical issues, integration challenges, resistance to change); and overall satisfaction.

b) Interview Guide

A semi-structured interview guide was developed to gather qualitative data through in-depth interviews with key stakeholders. The interview covered topics such as participants experiences and observations regarding the adoption and usage; choice of vendor; perceived benefits and challenges; impact on drug registration process (efficiency, productivity, decision-making); and suggestions for improvement.

By employing these research instruments in a complementary manner, the study obtained both quantitative and qualitative data to triangulate the findings, and thus led to a comprehensive understanding of the impact of cloud computing in drug registration processes.

The sample survey and interview guide are attached as Appendix A.

3.7 Procedure for data collection

Surveys were sent via email to the identified employees working within the drug registration function of the pharmaceutical company. Virtual interviews were conducted with senior management of the regulatory function of the same pharmaceutical company.

3.8 Data analysis strategies and interpretation

The following data analysis strategies and interpretation were used.

a) Quantitative Data Analysis:

   Descriptive statistics were employed to compute frequencies, percentages, means and standard deviations, providing a detailed depiction of the demographic characteristics of the respondents and the extent of cloud computing adoption.

   Inferential statistics were used to examine the relationships between variables, such as the association between cloud computing adoption and the perceived benefits or challenges.

   Regression analysis was used to investigate how cloud computing influences outcomes such as efficiency or productivity.

b) Qualitative Data Analysis:

   A thematic analysis was used to analyse interview transcripts and qualitative data to identify common patterns, categories, and themes. This process included coding the data, organizing codes into thematic categories, and examining the relationships among these themes.

c) Integration of Quantitative and Qualitative Data:

   A triangulation approach was used to compare and integrate quantitative and qualitative findings to corroborate or validate each other. This provided a deeper understanding of the research topic and generated new insights.

d) Interpretation:

   The interpretations of the findings were made by connecting them back to the study objectives and theoretical framework. Conclusions were derived on the basis of the analysis, highlighting the key findings and their implications for cloud computing adoption in drug registration processes, discussing their practical implications for policy, practice, and future research.

3.9 Possible limitations and challenges of the study

Some of the probable limitations and challenges of the study included the following:

Generalizability: The study's findings may be limited to the specific pharmaceutical company included in the research sample, making it challenging to generalize the results to the broader pharmaceutical industry. The unique context, organizational culture and infrastructure of the company may influence the findings.

Reliance on Self-Reported Data: The study relies on self-reported data from surveys and interviews, which may be subject to recall bias or individual interpretation. Participants may not accurately recall or articulate their experiences or may provide biased responses, affecting the reliability of the data.

Response bias: Participant's responses to the survey or interviews may be subject to response bias, where they provide socially desirable answers, or their responses may not fully reflect their true experience or perceptions. This bias will be mitigated through anonymous responses and promoting an open and honest environment during interviews.

3.10 Quality Assurance

3.10.1 *External validity and transferability*

In order to maximize the external validity and transferability of this study, the following measures will be ensured:

Sampling: Participants selected will be relevant stakeholders involved in the drug registration processes at the pharmaceutical company. They will include participants from different roles, with varying levels of experience and organizational contexts.

Data collection: Rigorous data collection methods will be employed. The data collection instrument will be well-designed, reliable, and valid to enhance the credibility and transferability of the findings.

Triangulation: By utilizing multiple data sources by means of collecting quantitative and qualitative data, it will provide a thorough understanding of the research topic. The use of triangulation will enhance the transferability of the findings by considering diverse perspectives and capturing different dimensions of topic.

3.10.2 *Internal validity and credibility*

Internal validity refers to the degree to which a study accurately measures the cause-and-effect relationship between variables, while credibility refers to the believability and trustworthiness of the findings (Kumar, 2011).

To ensure internal validity/credibility in this study, the appropriate sampling techniques will be administered to participants that represent the target population. The appropriate statistical analysis techniques using established statistical software will be employed for quantitative data. Thematic analysis will be used as the recognized qualitative analysis method to analyse the qualitative data.

The quantitative and qualitative data will be compared and integrated to ensure consistency and convergence. The findings will be presented clearly with appropriate visuals to enhance the credibility and transparency of the results.

3.10.3 *Reliability and dependability*

To ensure reliability and dependability in this study, the following will be considered:

Standardized data collection procedures will be followed to ensure consistency and the data collection process will be clearly documented.

Well established data analysis techniques appropriate for a mixed method study will be utilized, and transparent and systematic procedures will be followed during data analysis to ensure consistency and reliability in the interpretation of the findings.

Detailed documentation of the research process, including raw data, coding schemes, and analytical decisions will be maintained to serve as an audit trail, to allow for the verification and replication of the study's findings by external researchers.

3.11 Ethical considerations

The following ethical considerations will be considered in this study:

Informed consent: informed consent will be obtained from participants to ensure they have a strong understanding of the study's purpose, procedures, and their risks as participants. Participation is voluntary and will be without coercion, and consent will be documented in the online survey.

Participant confidentiality: the privacy and confidentiality of participants personal information and data collected during the study will be safeguarded. Participant identities will not be required for the purpose of the study and will be anonymized.

Data protection: permissions and approvals for data collection will be obtained from the organization in the study, ensuring compliance with legal and ethical requirements.

Transparency and full disclosure: transparency in the reporting of research findings will be maintained by accurately representing the data collected and avoiding selective reporting.

Conflict of interest: to maintain research integrity, necessary measures will be taken to address and manage any conflicts of interests such as personal relationships or biases that could influence the research process or findings.

3.12 Proposed schedule and timelines

Research proposal submission	28 May 2023
Ethical approval	07 August 2023
Data collection (survey dissemination and interviews)	01 September 2023
Data analysis	November 2023
Communication of findings	29 February 2024

CHAPTER 4. DATA ANALYSIS AND RESULTS DISCUSSION

4.1 Introduction

The focus of this study was to assess the implementation of a cloud-based software solution for drug registration processes at a pharmaceutical company. This chapter delves into the heart of a mixed methods study, offering a comprehensive analysis of both quantitative and qualitative data gathered during the investigation. The intertwining of numerical metrics and narrative insights aims to provide a nuanced understanding of the multifaceted implications and outcomes associated with the adoption of this innovative technology.

The Research Objectives:

1. To determine the level of efficiencies attained with the implementation of Veeva Vault RIM at Eli Lilly and Company.
2. To assess the impact of the implementation on various functions involved in producing a submission dossier for registration.
3. To evaluate the improvement of drug registration processes following the implementation of cloud computing technology.

The chapter begins by elucidating the procedures employed in preparing, processing, and interpreting the quantitative data, followed by a detailed exploration of the statistical findings. Subsequently, the qualitative component is addressed, illuminating the emergent themes, patterns, and rich contextual perspectives gleaned from the interviews.

The chapter concludes with an integration of the quantitative and qualitative results, synthesizing the varied threads of evidence to construct a comprehensive narrative that offers valuable insights for both practitioners and researchers in the pharmaceutical industry.

4.2 Quantitative Data Analysis

4.2.1 Data Preparation

An online questionnaire was administered to employees of Eli Lilly and Company who are actively involved in drug registration processes for the company and who are registered users of Veeva Vault RIM. Participation was voluntary and a total of 52 responses were collected.

This dataset captures insights from individuals actively engaged in drug registration processes across various geographical regions and functional areas. By delving into their experiences, duration of cloud computing utilization, frequency of platform usage, and overall satisfaction levels, we aim to unravel the nuanced dynamics surrounding the impact of Veeva Vault RIM on work processes.

The collected data was reviewed and cleaned to remove any personal identifiers to maintain anonymity. The software, IBM SPSS, was then used to analyse the responses.

4.2.2 Descriptive Statistics

The survey contained 12 questions asking respondents about their geographic location, functional area, length of time using the software, and their ratings of using the software to accomplish their tasks. Based on the response from 52 respondents, the following statistics were described.

The tables presented below are outputs gathered from the statistical analysis using IBM SPSS software. The Percent column represents the percentage of the total number of cases in each category. The Valid Percent column is similar to the Percent but considers only valid cases in case there might have been missing or invalid values. The Cumulative Percent provides the cumulative percentage of responses up to a particular category. (OpenAI, 2024).

In which geographical region of the organization are you located?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Africa	1	1.9	1.9	1.9
	Asia/Pacific	17	32.7	32.7	34.6
	CIS Balkans	1	1.9	1.9	36.5
	Europe	14	26.9	26.9	63.5
	Middle East	5	9.6	9.6	73.1
	North America	14	26.9	26.9	100.0
	Total	52	100.0	100.0	

The largest number of respondents were in the Asia/Pacific region.

Which functional area of the drug registration process are you involved in?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Affiliate	28	53.8	53.8	53.8
	CMC	19	36.5	36.5	90.4
	Management	5	9.6	9.6	100.0
	Total	52	100.0	100.0	

Of the respondents actively involved in the drug registration processes, the most common functional areas included affiliate end users and CMC functional users.

How long have you been using cloud computing (Veeva Vault RIM) for drug registration activities?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1-3 Years	35	67.3	67.3	67.3
	3-5 Years	6	11.5	11.5	78.8
	Less than 1 year	8	15.4	15.4	94.2
	More than 5 years	3	5.8	5.8	100.0
	Total	52	100.0	100.0	

The average duration of using Veeva Vault RIM for drug registration activities is approximately 2 years where the range of usage was less than 1 year to more than 5 years.

How frequently do you use Veeva Vault RIM to execute your work?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Daily	40	76.9	76.9	76.9
	Four times a week	5	9.6	9.6	86.5
	Once a week	4	7.7	7.7	94.2
	Twice a week	3	5.8	5.8	100.0
	Total	52	100.0	100.0	

76.9% of respondents are using the system daily to execute their work for drug registration activities.

How would you rate the overall effectiveness of using Veeva Vault RIM in improving the efficiency of your work in drug registration?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Effective	25	48.1	48.1	48.1
	Ineffective	7	13.5	13.5	61.5
	Neutral	9	17.3	17.3	78.8
	Very effective	9	17.3	17.3	96.2
	Very ineffective	2	3.8	3.8	100.0
	Total	52	100.0	100.0	

With 48.1% of respondents indicating that Veeva Vault RIM is effective in improving the efficiency of their work, thus reflecting that the average effectiveness rating is moderately effective where the range was ‘very ineffective’ to ‘very effective’. Overall, respondents rate Veeva Vault RIM as effective, with some considering it very effective, while others have a neutral opinion.

What the main benefits you have experienced from using Veeva Vault RIM in your executing your work?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Faster processing times;	2	3.8	3.8	3.8
	Faster processing times; Improved collaboration;	2	3.8	3.8	7.7
	Faster processing times; Improved decision making process;Improved collaboration;	1	1.9	1.9	9.6
	Faster processing times; Improved decision making process;Increased productivity;Improved collaboration;	3	5.8	5.8	15.4
	Faster processing times; Increased productivity;	1	1.9	1.9	17.3
	Faster processing times; Increased productivity; Improved collaboration;	1	1.9	1.9	19.2
	Faster processing times; Increased productivity; Improved collaboration; Improved decision making process;	1	1.9	1.9	21.2
	Improved collaboration;	21	40.4	40.4	61.5
	Improved collaboration; Faster processing times;	1	1.9	1.9	63.5
	Improved collaboration; Faster processing times; Increased productivity;	1	1.9	1.9	65.4
	Improved collaboration; Improved decision making process;	1	1.9	1.9	67.3
	Improved collaboration; Increased productivity;	3	5.8	5.8	73.1
	Improved collaboration; Increased productivity; Faster processing times;	1	1.9	1.9	75.0
	Improved decision making process;	3	5.8	5.8	80.8
	Improved decision making process;Improved collaboration;	2	3.8	3.8	84.6
	Improved decision making process;Increased productivity;Improved collaboration;	1	1.9	1.9	86.5
	Increased productivity;	2	3.8	3.8	90.4
	Increased productivity; Improved collaboration;	3	5.8	5.8	96.2
	Increased productivity; Improved collaboration; Improved decision making process;Faster processing times;	1	1.9	1.9	98.1
	Increased productivity; Improved decision making process;Improved collaboration;	1	1.9	1.9	100.0
	Total	52	100.0	100.0	

Improved collaboration, faster processing times, increased productivity, and better decision-making process are the main benefits reported by respondents.

Please rate the level of challenges experienced with the adoption of Veeva Vault in executing your tasks for drug registration processes.

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Major challenge	2	3.8	3.8	3.8
	Minor challenge	15	28.8	28.8	32.7
	Moderate challenge	22	42.3	42.3	75.0
	Not a challenge	1	1.9	1.9	76.9
	Significant challenge	12	23.1	23.1	100.0
	Total	52	100.0	100.0	

The challenges reported include both minor and moderate challenges, with some respondents indicating significant challenges in adopting Veeva Vault RIM for executing their tasks.

On a scale of 1 to 5, how satisfied are you with the overall performance of Veeva Vault RIM to execute your work?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2: Dissatisfied	9	17.3	17.3	17.3
	3: Neutral	8	15.4	15.4	32.7
	4: Satisfied	30	57.7	57.7	90.4
	5: Very satisfied	5	9.6	9.6	100.0
	Total	52	100.0	100.0	

Most respondents reported to be satisfied with using RIM to execute their work, but the satisfaction levels do vary.

Veeva Vault RIM has positively impacted your productivity compared to the traditional process?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Agree	25	48.1	48.1	48.1
	Disagree	10	19.2	19.2	67.3
	Neutral	10	19.2	19.2	86.5
	Strongly agree	4	7.7	7.7	94.2
	Strongly disagree	3	5.8	5.8	100.0
	Total	52	100.0	100.0	

The majority of respondents believe that Veeva Vault RIM has positively impacted their productivity compared to traditional processes.

To what extent has cloud computing improved collaboration and communication among team members involved in drug registration?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Minimal improvement	4	7.7	7.7	7.7
	No improvement	2	3.8	3.8	11.5
	Significant improvement	22	42.3	42.3	53.8
	Some improvement	20	38.5	38.5	92.3
	Substantial improvement	4	7.7	7.7	100.0
	Total	52	100.0	100.0	

Cloud computing (Veeva Vault RIM) is perceived to have improved collaboration and communication to varying extents. 42.3% of respondents indicate that there

is significant improvement and 38.5% of respondents believe that there is some improvement.

Please rate the extent to which cloud computing has enhanced the accuracy and quality of your work in drug registration:

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Completely	1	1.9	1.9	1.9
	Moderately	21	40.4	40.4	42.3
	Not at all	2	3.8	3.8	46.2
	To a great extent	19	36.5	36.5	82.7
	To a small extent	9	17.3	17.3	100.0
	Total	52	100.0	100.0	

Respondents generally agree that cloud computing has enhanced the accuracy and quality of their work in drug registration.

How would you rate the overall impact of cloud computing on the timeliness of completing drug registration tasks?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Negative	12	23.1	23.1	23.1
	Neutral	15	28.8	28.8	51.9
	Positive	21	40.4	40.4	92.3
	Very positive	4	7.7	7.7	100.0
	Total	52	100.0	100.0	

Cloud computing is reported to have a positive impact on the timeliness of completing drug registration tasks.

The data suggests that overall respondents have a positive perception of Veeva Vault RIM, citing improved efficiency, collaboration, and productivity, However, challenges and variations in satisfaction levels exist.

4.2.3 Inferential Statistics

Using some variables of the quantitative dataset, the following inferences were made about the population based on the sample of data.

Regression Analysis

Regression analysis is a valuable statistical technique used to examine the relationship between one or more independent variables and a dependent

variable. It is useful to understand how changes in one variable are associated with changes in another and allows testing of hypotheses about the relationship between variables. (OpenAI, 2024).

Variables Entered/Removed[a]

Model	Variables Entered	Variables Removed	Method
1	Usage duration[b]	.	Enter

a. Dependent Variable: Rate the effectiveness of RIM

b. All requested variables entered.

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.277[a]	.077	.058	1.01966

a. Predictors: (Constant), Usage duration

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	4.323	1	4.323	4.158	.047[b]
	Residual	51.985	50	1.040		
	Total	56.308	51			

a. Dependent Variable: Rate the effectiveness of RIM

b. Predictors: (Constant), Usage duration

Coefficients[a]

Model		Unstandardized Coefficients B	Unstandardized Coefficients Std. Error	Standardized Coefficients Beta	t	Sig.
1	(Constant)	2.763	.441		6.265	<,001
	Usage duration	.410	.201	.277	2.039	.047

a. Dependent Variable: Rate the effectiveness of RIM

The overall model is statistically significant, suggesting that there is evidence that length of duration of usage is associated with the rating of the effectiveness of Veeva Vault RIM.

- The positive coefficient for Usage duration (0.410) indicates that as Usage duration increases, the perceived effectiveness of RIM also tends to increase.
- The R Square is relatively low, indicating that the model explains only a small portion of the variability in the effectiveness of RIM.

• The p-value for the F-statistic is below the significance level, supporting the overall significance of the model.

In summary, the analysis suggests that there is a statistically significant relationship between length of duration of usage of the cloud-based software and the perceived effectiveness of Veeva Vault RIM in improving the efficiency of drug registration tasks.

Correlations

1. Relationship between Frequency of Use of RIM and Impact on Timeliness of completing drug registration tasks.

Correlations

		How Frequently do you use RIM	Timeliness Impact
How Frequently do you use RIM	Pearson Correlation	1	.198
	Sig. (2-tailed)		.160
	N	52	52
Timeliness Impact	Pearson Correlation	.198	1
	Sig. (2-tailed)	.160	
	N	52	52

The correlation coefficient of 0.198 indicates a weak positive correlation between "How Frequently do you use RIM" and "Timeliness Impact." In other words, there is a tendency for individuals who report using RIM more frequently to also report a slightly higher impact on timeliness for completing tasks for drug registration.

2. Relationship between Frequency of Use of RIM and Positive Impact on Productivity

Correlations

		Positive impact compared to traditional process	How Frequently do you use RIM
Positive impact compared to traditional process	Pearson Correlation	1	.091
	Sig. (2-tailed)		.521
	N	52	52
How Frequently do you use RIM	Pearson Correlation	.091	1
	Sig. (2-tailed)	.521	
	N	52	52

The correlation coefficient of 0.091 indicates a very weak positive correlation between "Positive impact compared to traditional process" and "How Frequently do you use RIM." In other words, there is a slight tendency for individuals who report using RIM more frequently to also report a slightly more positive impact productivity compared to the traditional process.

4.2.4 Summary of Quantitative Findings

- **Demographic Overview:**
  - The majority of respondents were from the Asia/Pacific region.
  - Common functional areas of respondents involved affiliate end users and CMC functional users.
- **Duration of Usage:**
  - The average duration of using Veeva Vault RIM for drug registration activities is around 2 years.
  - Usage ranges from less than 1 year to over 5 years.
- **Frequency of Usage:**
  - 76.9% of respondents use Veeva Vault RIM daily for drug registration activities.
- **Effectiveness Ratings:**
  - Approximately 48.1% of respondents find Veeva Vault RIM effective in improving the efficiency of their work.
  - Overall, respondents rate Veeva Vault RIM as moderately effective, with some expressing a very effective opinion.
- **Benefits and Challenges:**
  - Reported benefits include improved collaboration, faster processing times, increased productivity, and better decision-making.
  - Challenges vary, with some respondents facing significant challenges in adopting Veeva Vault RIM.
- **Satisfaction Levels:**
  - Overall satisfaction levels vary, with most respondents reporting satisfaction, but with differences in degrees.
- **Impact on Productivity:**

    - Respondents believe that Veeva Vault RIM has positively impacted their productivity compared to traditional processes.
- **Improvements in Collaboration and Communication:**
    - Cloud computing (Veeva Vault RIM) is perceived to have improved collaboration and communication to varying extents.
- **Accuracy and Quality:**
    - Respondents generally agree that cloud computing has enhanced the accuracy and quality of their work in drug registration.
- **Timeliness of Completion:**
    - Cloud computing is reported to have a positive impact on the timeliness of completing drug registration tasks.
- **Regression Analysis:**
    - The analysis indicates a statistically significant relationship between the length of duration of usage of Veeva Vault RIM, that is how long the user has been using the system since implementation, and the perceived effectiveness in improving the efficiency of drug registration tasks.
- **Correlations:**
    - There is a weak positive correlation between the frequency of RIM usage and the impact on the timeliness of completing drug registration tasks.
    - A very weak positive correlation exists between the frequency of RIM usage and the positive impact on productivity compared to the traditional process.

In summary, the quantitative findings suggest an overall positive perception of Veeva Vault RIM, with respondents experiencing improved efficiency, collaboration, and productivity. However, challenges and variations in satisfaction levels highlight the complexity of implementing cloud-based solutions in drug registration processes. The regression and correlation analyses provide valuable insights into the relationships between usage patterns and perceived effectiveness.

4.3 Qualitative Data Analysis

A total of ten interviews were conducted with employees of the pharmaceutical company who are employed in senior leadership positions involved in drug registration processes. Data collection relied on a semi-structured interview composed of six questions designed to gather insights on the motivation to implement Veeva Vault RIM for drug registration processes, the benefits and challenges experienced, the success factors for adoption and the future expectations.

4.3.1 Data Coding and Categorization

The qualitative phase of the study involved a meticulous process of data coding and categorization to extract meaningful insights from the textual data obtained through the interviews. Grounded in the principles of thematic analysis, initial coding was conducted inductively, allowing themes to emerge organically from the data and a coding scheme was iteratively developed. Codes were assigned to segments of data representing key concepts, ideas, and recurring motifs. The coding process facilitated the identification of commonalities and differences in the participants experiences.

Categories were established to encapsulate shared patterns of responses. This approach allowed to discern the distinct differences in the adoption and perception of the implementation of Veeva Vault RIM as the cloud-based software, shedding light on contextual factors influencing its effectiveness. This exploration formed the foundation for the subsequent thematic analysis.

4.3.2 Thematic Analysis

Thematic analysis was utilized to uncover the patterns and recurring themes embedded within the qualitative data. Initial codes generated during data coding and categorization were then grouped into overarching themes that encapsulated the essence of participants' experiences and perceptions. The identification of themes was an iterative process to ensure a robust and reliable presentation of

the qualitative data. Each theme was characterized by a coherent and internally consistent set of codes.

Several emergent themes surfaced from the analysis. These included but were not limited to participants perceptions of the software's impact on workflow efficiency, challenges encountered during the implementation process, user experience with the interface, and the evolving role of organizational culture in shaping attitudes towards technological innovation. Table 2 below provides an example of the key categories and dominant themes emanating from the data. The thematic analysis not only facilitated a deeper understanding of individual perspectives but also allowed for a holistic synthesis of qualitative findings.

Categories	**Themes**
Data management Efficiency improvement Data quality Data integration Compliance control Seamless reporting System integration User adoption Challenges Data centricity Training and capability	Data quality improvement Centralization and standardization Visibility and traceability Confidence in data and documentation Streamlined processes and Efficiency. System adaptation User Adoption and Learning Curve Areas for Improvement Data Governance and Roles
System capabilities Flexibility and Development Global collaboration Vendor selection and system adjustability Communication and Training Usability User-friendly Automation Complexity and Resistance Satisfaction and Productivity	Enhanced functionality and flexibility Performance improvement and cloud-based solutions Communication, Training and User Capability Global Collaboration and Accessibility Organizational Change Management Vendor Responsiveness and Customization Efficiency and Automation Positive Aspects and Benefits

Table 2: Thematic Analysis - Major Categories and Themes

The ensuing sections will delve into specific themes, providing a detailed exploration of the qualitative dimensions that emerged from the participants accounts.

4.3.3 Summary of Qualitative Findings

The discussion on the motivating factors and decision-making process that led to the company adopting Veeva Vault RIM for drug registration processes were centered around the following themes:

Data integration and Data Quality

There were concerns about data integrity and data quality, and there was a need for a unified platform to consolidate data from multiple systems to ensure continuous and consistent information flow.

Compliance Control

The need to address compliance gaps, improve compliance control throughout operations, and ensure consistency of information across units globally.

Global Collaboration and Accessibility

The importance of having a system where global teams and affiliates can work together, share documents, and have access to registered information across different countries.

Streamlined Processes and Efficiency, Performance Improvement and Cloud-based Solutions.

The desire for a more seamless workflow, reducing the need to access multiple systems for reports and allowing regulatory associates to work more efficiently within a single integrated platform. Moving from location-dependent performance to a more consistent user experience by adopting cloud-based solutions to ensure uniform access and performance for all users regardless of their location.

Enhanced Functionality and Flexibility

Veeva Vault's RIM capabilities were highlighted, offering more functionalities compared to previously employed legacy systems, including better document management, tracking, and archiving of submissions, and the ability to make modifications as needed. Veeva Vault RIM's modular design allows companies

to choose and utilize specific parts of the system according to their needs rather than mandating the use of the entire system at once.

The questions that revolved around the challenges and obstacles encountered during the implementation and utilization of Veeva Vault RIM revealed the following themes:

Data migration

Moving data from legacy systems posed significant challenges due to volume and complexity. Automating this process required vendor support and extensive mapping, resulting in the allocation of substantial resources.

System adaptation

The initial software capabilities did not align with expectations, necessitating discussions with Veeva to enable essential functionalities. While a workable solution was achieved, it required compromise, and the granularity of the system made data entry time consuming.

User Adoption and Learning Curve

Transitioning from previous systems required a steep learning curve. The terminology, complexity, and structural differences made it challenging for users to adapt, resulting in increased time for processes, bureaucratic hurdles, and an overall increased workload.

Usability and User-Friendliness

The system's complexity made it less user-friendly for some individuals, creating a divide between those more technology-driven and those accustomed to traditional paperwork-based processes. The need for extensive clicks and navigation for information retrieval added to the usability challenges.

Organizational Change Management (OCM)

Implementing changes across the organization, including training power users, submission coordinators, process owners, and functional data stewards provided

essential support. Integrating multiple tools into one system required significant data input, leading to challenges in allocating time and resources for effective utilization of the system. Consistent communication about the benefits of the system, on-the-job training, and creating reports were essential strategies to manage the adoption challenges.

Vendor Responsiveness and Customization

The responsiveness of the vendor team was crucial in addressing system inadequacies and customizing solutions to meet the needs of the company. However, it required ongoing adjustments and workarounds to fit real-life scenarios.

When asked about the benefits and advantages of implementing the cloud-based software, Veeva Vault RIM, for drug registration processes at the company, the following themes became evident:

Data Quality Improvement

The implementation of Veeva Vault RIM led to a significant improvement in data quality. Efforts were made to consolidate, clean up, organize, and maintain critical data within one system, leading to better accuracy and reliability of information.

Efficiency and Automation

While initial phases focused on compliance benefits, there is a noticeable anticipation of future efficiency gains through automation. Streamlining repetitive tasks and standardizing global processes are expected to enhance overall submission timelines.

Centralization and Standardization

The system brought about centralization of information, enabling easy access to documents, standardized processes, and reducing reliance on disparate tools or databases. It promoted a sense of control, compliance, and consistency across teams.

Confidence in Data and Documentation

The system instilled confidence in the accuracy and accessibility of data. Having a single source of truth, where there is only one authoritative and reliable source for particular information within the organization and having a centralized and consistent data repository for submissions, approvals, and commitments improved oversight, especially during regulatory inspections or audits.

Visibility and Traceability

The system facilitated better visibility and traceability of processes, submissions, and approvals across different markets. Real-time tracking and archiving of documents enhanced oversight and accountability.

Challenges and Areas for Improvement

Some challenges were highlighted, including potential delays caused by the content plan verification process, the need for more time to leverage the tool fully, and a need for greater customization or flexibility in reporting.

When asked about the learnings of key success factors for implementing such a system for drug registration processes, the following themes emerged:

Data Centricity and Standardization

Ensuring a clear understanding of data flows, definitions, and terminologies across different departments and partners is crucial. Establishing standardized data practices helps connect the enterprise and improve efficiencies. Master data management is also crucial, identifying sources of truth for data and stewardship become critical as multiple data pieces intersect across functions.

Data Governance and Roles

Establishing robust data governance, clear roles, and responsibilities for managing foundational data is essential. Central roles can aid users in understanding system integration.

Vendor Selection and System Adjustability

The selection of a vendor should involve consultation with different functions that interface with the system. The system's adjustability to accommodate specific needs and changes is crucial.

Training and User Capability

Having a well-trained specialized group of users in the system, such as power users, is vital for successful implementation. Training initiatives, face-to-face meetings, and on-the-job training play significant roles in user adoption.

Phased Implementation

Implementing changes in phases allows for a smoother transition, easing users into the new system. However, a prolonged transition period may confuse users working with parallel systems for an extended time.

Communication and OCM (Organizational Change Management)

Effective communication and OCM strategies help set expectations and promote adoption. Face-to-face training and early promotion of adoption are seen as beneficial.

Adaptability and Continuous Improvement

The system must evolve to meet changing needs. Incorporating customer feedback and being proactive with system updates and releases is crucial for continuous improvement.

The final questions centered on the perceptions of the adoption of Veeva Vault RIM and how employees have responded to the implementation. The following themes were noted:

Initial Resistance and Complexity

There is a prevalent theme of initial resistance due to the complexity of the tool. Employees who were accustomed to legacy systems faced a steep learning curve and perceived the adoption as disruptive to performing their daily tasks.

Satisfaction and Productivity Challenges

The satisfaction levels have not notably increased, and productivity challenges persist. Employees complain about the system's impact on their productivity, particularly regarding delays in tasks, dependencies on others, and increased workload in having to upload documents to the system and include metadata.

Positive Aspects and Benefits

Despite the challenges, certain groups, like power users and submission coordinators, spread positivity about the tool. Over time, familiarity with the system has led to a better understanding of its benefits, such as improved clarity, better archiving, and support for global submissions.

Varied User Perceptions

Different user groups have varying perceptions. Some find the system efficient, while others, especially some affiliate end users, feel they are spending more time in the system and struggle to justify the additional time required for data entry and learning the system.

Ongoing Improvement and Adoption

Efforts to improve the system and enhance adoption are ongoing. While there is recognition of progress and improved familiarity, there is also acknowledgement of the need for further enhancements, automation of tasks, and better training.

4.4 Integration of Quantitative and Qualitative Results

The assimilation of quantitative and qualitative findings provides a thorough and nuanced comprehension of the adoption and impact of Veeva Vault RIM in drug registration processes at Eli Lilly and Company. The convergence of numerical metrics and narrative insights enriches the discussion, providing a holistic perspective on the multifaceted implications of implementing this cloud-based software solution.

Themes Alignment and Validation

The qualitative themes align well with certain quantitative findings, validating and expanding upon the numerical data. For instance, the qualitative emphasis on the importance of data quality improvement, where the accuracy, completeness, consistency, and reliability of data is enhanced, resonates with the quantitative observation that a significant percentage of respondents perceive Veeva Vault RIM as positively impacting the accuracy and quality of their work in drug registration. This alignment strengthens the validity of the overall findings.

Duration of Usage and Effectiveness

The regression analysis highlights a statistically significant relationship between the length of duration of usage, that is how long a user has been using the system since its implementation, and the perceived effectiveness of Veeva Vault RIM to accomplish their tasks. This aligns with qualitative insights indicating that over time, users have become more familiar with the system, leading to increased satisfaction and recognition of its benefits. The qualitative data further enriches this finding by offering insights into the challenges faced during the initial phases of implementation.

Collaboration and Communication

The quantitative data suggests that cloud computing (Veeva Vault RIM) is perceived to have improved collaboration and communication to varying extents. The qualitative findings provide depth to this observation by highlighting the importance of global collaboration and accessibility as motivating factors for adopting the software. The qualitative data emphasizes the need for a system that enables teams across different countries to work together seamlessly.

Benefits and Challenges

Quantitative findings indicate that improved collaboration, faster processing times, increased productivity, and better decision-making are reported benefits, while challenges vary. The qualitative data enriches these findings by providing detailed accounts of the specific benefits experienced, such as efficiency gains

through automation, centralization and standardization of processes, and confidence in data and documentation. Similarly, the challenges outlined in the qualitative data, such as data migration, system adaptation, and user adoption, align with the reported challenges in the quantitative survey.

Satisfaction Levels

Quantitative data reveals variations in satisfaction levels, with most respondents reporting satisfaction but with differences in degrees. The qualitative data adds depth by uncovering the reasons behind these variations. The initial resistance and complexity noted in the qualitative findings shed light on the challenges faced by employees transitioning from legacy systems, providing context to the reported satisfaction levels. This integration allows for an added interpretation of the aspects shaping satisfaction in the adoption process.

Continuous Improvement

Both quantitative and qualitative data point towards ongoing efforts for improvement. The quantitative findings suggest that respondents believe in the positive impact of Veeva Vault RIM on productivity, and the qualitative data reveals that these efforts include addressing challenges such as data migration, system adaptation, and user adoption. The integration emphasizes the fluid character of the implementation process and the importance of continuous refinement in response to user feedback and evolving needs.

Varied User Perceptions

The qualitative findings highlight varied user perceptions, with some finding the system efficient, while others express concerns about increased workload. This aligns with the quantitative data, where respondents have varying opinions on the effectiveness of Veeva Vault RIM. The integration of both data types allows for a more nuanced understanding of the diverse user experiences, emphasizing the need for targeted strategies that acknowledge and address the varied perspectives within the user community.

In conclusion, the integration of quantitative and qualitative findings enhances the overall understanding of the adoption and impact of Veeva Vault RIM in drug registration processes. The convergence of statistical evidence with contextual narratives provides a more holistic and nuanced perspective, offering valuable insights for both practitioners and researchers in the pharmaceutical industry. The identified themes, correlations, and relationships contribute to the broader discourse on cloud-based solutions, guiding future research and informing industry practices.

CHAPTER 5. DISCUSSION AND ANALYSIS

5.1 Summary of Findings

The comprehensive integration of quantitative and qualitative data in this study has yielded valuable insights into the adoption and impact of Veeva Vault RIM in drug registration processes at Eli Lilly and Company. The synthesis of numerical metrics and narrative insights has provided a nuanced understanding of various aspects of the implementation, offering a holistic view of the multifaceted implications of cloud-based technology in the pharmaceutical industry.

Key Themes and Alignments

The alignment between quantitative and qualitative themes serves as a foundational aspect of the findings. Key themes, such as the emphasis on data quality improvement, collaboration, and communication enhancements, are supported by both types of data. This alignment enhances the validity of the overall findings and provides a deeper understanding of the observed patterns.

Duration of Usage and Evolution of Perceptions

The study reveals a statistically significant relationship between the duration of usage, that is how long a user has been using the system since its implementation, and perceived effectiveness to accomplish tasks, corroborated by qualitative insights into users evolving perceptions over time. The challenges faced during the initial phases of implementation, as highlighted in qualitative data, contribute to a comprehensive understanding of the system’s evolution and user satisfaction.

Collaboration and Communication Enhancements

Quantitative data indicates varying degrees of improvement in collaboration and communication, and qualitative findings underscore the importance of global collaboration and accessibility. The integration of both data types provides a human context to statistical insights, emphasizing the need for seamless collaboration across different countries in the pharmaceutical industry.

Benefits, Challenges, and User Satisfaction

The integration of quantitative benefits and challenges with qualitative narratives offers a detailed account of the experiences of users. Reported benefits such as improved collaboration, faster processing times, and better decision making are enriched by qualitative details, providing a comprehensive picture of the complexities involved, including data migration and system adaptation challenges. Varied user perceptions, as revealed in both data types, underscore the need for targeted strategies to address diverse perspectives and enhance overall satisfaction levels.

Continuous Improvement and Future Recommendations

The study highlights ongoing efforts for continuous improvement, with respondents expressing belief in the positive impact of Veeva Vault RIM on productivity. Qualitative insights reveal specific areas for improvement, such as addressing challenges in data migration, system adaptation, user adoption, and automation. The integration emphasizes the dynamic nature of the implementation process and provides practical recommendations for targeted training programs and user support during the initial phases of adoption.

5.2 Discussion of Results

As we delve into the analysis of the results of the quantitative and qualitative findings, which has shed light on various dimensions of the adoption and impact of Veeva Vault RIM on drug registration activities at Eli Lilly and Company, we explore key themes, alignments, and implications, with focus on the emerging needs for automation identified through both data types.

Alignment and Validation of Themes

The alignment between qualitative and quantitative themes serves as a cornerstone for understanding the holistic impact of Veeva Vault RIM. The emphasis on data quality improvement, collaboration enhancements, and communication streamlining aligns closely with both data sets. However, a notable emergent theme revolves around the increasing need for automation to further streamline processes and enhance overall efficiency.

Duration of Usage and Evolution of Perceptions

The statistically significant relationship between the duration of usage and perceived effectiveness, as indicated by both quantitative regression analysis and qualitative insights, reveals an evolving landscape. Users familiarity with Veeva Vault RIM over time has led to increased satisfaction, but this evolution also highlights an emerging demand for increased automation to optimize repetitive tasks and minimize manual intervention.

Collaboration and Communication Enhancements

The integration of quantitative data indicating varied improvements in collaboration and communication, with qualitative findings emphasizing global collaboration and accessibility provides a comprehensive understanding of the software's impact. The human context provided by qualitative narratives enriches statistical insights indicating that there is seamless collaboration across teams distributed globally.

Benefits, Challenges, and User Satisfaction

The combined analysis of quantitative benefits and challenges with qualitative narratives presents a detailed and nuanced picture of the experiences of users. The reported benefits, such as improved collaboration and faster processing times, are enriched by qualitative details, offering a more comprehensive understanding of the complexities involved. Varied user perceptions, reflected in both data types, underscore the importance of tailored strategies to address diverse perspectives and enhance overall satisfaction levels.

Automation Needs

The emergent theme of automation needs becomes increasingly pronounced in the discussion of results. Users and stakeholders alike recognize that the full potential of Veeva Vault RIM could be unlocked through strategic automation. Whether it be in data processing, document management, or communication workflows, there is a shared sentiment that targeted automation could significantly enhance the system's efficiency and overall impact on drug registration processes.

Relating Findings to Research Objectives

Three research objectives guided the investigation:

1. **Efficiencies Attained with Veeva Vault RIM Implementation:**
   The quantitative data reveals a positive perception of Veeva Vault RIM, with almost half of the respondents finding the software effective in improving the efficiency of their work. The thematic analysis from qualitative interviews aligns with this, emphasizing efficiency gains through automation and streamlined processes. This convergence supports the hypothesis that the implementation of Veeva Vault RIM would lead to improved operational efficiencies.
2. **Impact on Various Functions in Submission Dossier Production:**
   The quantitative findings outline benefits such as improved collaboration, faster processing times, increased productivity, and better decision-making, corroborated by qualitative themes like global collaboration, enhanced functionality, and centralization. These align with the hypothesis that the implementation of cloud-based technology positively influences various functions involved in producing a submission dossier for registration.
3. **Evaluation of Improvement in Drug Registration Processes:**
   Quantitative data suggests a positive impact on productivity, collaboration, communication, accuracy, and timeliness in drug registration tasks. Qualitative insights further elaborate on improvements in data quality, efficiency, centralization, and confidence in documentation. The alignment between quantitative and qualitative outcomes supports the hypothesis that the adoption of Veeva Vault RIM leads to enhanced drug registration processes.

5.3 Comparison with Previous Research

The literature reviewed in relation to this study included research related to global registration requirements, technological advances related to the pandemic impact, communication and collaboration within pharmaceutical companies, cloud computing in healthcare and Veeva implementation.

Global Variation in Registration Requirements

The literature review emphasizes diverse and evolving requirements for drug registration across different markets as substantiated by Badjatya (2013) and Yadav (2013) iterated that pharmaceutical companies need to build system capabilities.

This study focuses on the impact of Veeva Vault RIM on drug registration processes at Eli Lilly and Company without direct emphasis on global variations of requirements. However, this study may indirectly address the need for a unified platform to handle varied regulatory requirements.

Technological Advances and Digital Transformation Trends

The literature review included discussions that recognized the transformative influence of technological advances and the Covid-19 pandemic on pharmaceutical companies as described by Wegner (2021), prompting a shift towards digital frameworks. The literature underscores the industry's need to embrace innovative solutions and adapt to the evolving landscape, emphasizing the importance of digitalization in various aspects of pharmaceutical operations which were highlighted by Champagne et al. (2015) and Robertson, et al. (2020).

While this study establishes a connection between the adoption of Veeva Vault RIM and technological advances, it does not explicitly delve into the specific impact of Covid-19 pandemic on the decision to implement this system. This study, however, implicitly aligns with the broader trend of leveraging technological solutions for enhancing pharmaceutical processes, contributing to the ongoing digital transformation in the industry.

Cloud Computing in Healthcare

The literature review describes cloud computing as a significant technology for handling healthcare information, noting the industry's initial cautious approach. (Rajabion, Shaltooki, Taghikhah, Ghasemi, & Badfar, 2019), (Jardine, 2019) (Gao & Sunyaev, 2019) (El-Gazzar, 2014).

This study focuses on the adoption and impact of Veeva Vault RIM, a cloud-based regulatory information management solution, providing advantages such as compliance, connectivity, and speed to market.

Veeva Vault Implementation

The literature review introduces Veeva Vault RIM as a cloud-based solution for regulatory information management, emphasizing its adoption by numerous pharmaceutical companies (Veeva, 2023).

This study specifically investigates the implementation of Veeva Vault RIM at Eli Lilly and Company, discussing its impact on drug registration processes, user satisfaction, and challenges.

Integration of Technological Adoption Frameworks

The Technology Acceptance Model (TAM) and the Technology-Organization-Environment (TOE) framework provides a valuable lens for understanding the dynamics of implementing cloud-based solutions in pharmaceutical settings. The TAM, emphasizing perceived usefulness and ease of use, aligns with the user-centric perspective explored in this study. The positive reception reported in the findings echoes TAM's principles, suggesting that users perceive Veeva Vault RIM as beneficial and user-friendly. Furthermore, the TOE framework, encompassing organizational and environmental factors, finds resonance in this study's emphasis on collaboration, communication, and the broader organizational context. The challenges and benefits identified in this study contribute empirical insights that complement and affirm the theoretical foundations, illustrating how user perceptions, organizational characteristics, and external factors play crucial roles in shaping the success of technological adoption in the pharmaceutical industry.

Overall Comparison

This study provides a specific and focused examination of the implementation of Veeva Vault RIM at Eli Lilly and Company, validating or refining hypotheses proposed in the literature review. It addresses the practical implications and impact of cloud technology in the pharmaceutical industry, offering a case study perspective that complements and extends the insights provided by the broader

literature. The findings from this study contribute context-specific evidence to the existing knowledge on cloud-based solutions and their role in drug registration processes.

5.4 Limitations of the study

It is crucial to acknowledge the limitations of this study. The reliance on self-reported data, potential respondent bias, and the specific context of Eli Lilly and Company may limit the generalizability of the findings.

5.5 Recommendations

The comprehensive analysis of the implementation of Veeva Vault RIM at Eli Lilly and Company provides a foundation for actionable recommendations that cater to the specific needs of the company, contribute to advancements in the pharmaceutical industry, and guide future research endeavors. These recommendations aim to guide Eli Lilly and Company in optimizing their use of Veeva Vault RIM, contribute to the advancement of cloud-based technologies in the pharmaceutical industry, and inspire future research initiatives that delve deeper into the complexities of technology adoption and its implications.

5.5.1 *Recommendations for Eli Lilly and Company*

Continuous Training and Support Programs

Develop ongoing training programs to address the learning curve associated with transitioning from legacy systems to Veeva Vault RIM. Incorporate both online resources and hands-on training sessions to cater to diverse learning styles. Continuous support mechanisms, such as helpdesk services and user communities, can be established to assist employees in real-time.

Data Quality Assurance Initiatives

Implement initiatives focused on data quality assurance to address concerns related to data integrity and consistency. Establish clear data governance

protocols, ensuring standardized practices for data entry, verification, and stewardship. Regular audits and quality checks should be incorporated to maintain a high standard of data accuracy within the system.

Customization and System Adaptation

Collaborate closely with Veeva to ensure that the system aligns seamlessly with the specific needs and expectations of Eli Lilly and Company. Prioritize customization options that enhance user experience and meet evolving business requirements. Regular feedback loops should be established to address any gaps in system capabilities promptly.

Organizational Change Management (OCM) Strategies

Strengthen OCM strategies to manage organizational shifts effectively. Communicate the benefits of Veeva Vault RIM transparently, addressing concerns and resistance. Leverage champions within the organization to advocate for the system and ensure that employees across different functions are informed and engaged throughout the adoption process.

Phased Implementation Planning

Consider a phased implementation approach for any future updates or additional functionalities of Veeva Vault RIM. This will allow for a smoother transition and facilitate users in adapting to new features incrementally. A well-structured roadmap should be communicated to all stakeholders, outlining the timeline, and expected impacts on daily operations.

5.5.2 *Industry-wide Recommendations*

Collaborative Knowledge Sharing

Encourage collaborative knowledge sharing among pharmaceutical companies regarding the implementation of cloud-based solutions. Establish industry forums, webinars, or conferences where organizations can share best practices, challenges, and success stories. This collective approach will foster a more informed and connected pharmaceutical community.

Standardization Efforts

Collaborate with industry associations and regulatory bodies to work towards standardization of cloud-based solutions in drug registration processes. Establishing common frameworks and interoperability standards will facilitate seamless collaboration among pharmaceutical companies, regulatory agencies, and other stakeholders.

Data Security and Compliance Guidelines

Develop and disseminate industry-specific guidelines for ensuring data security and compliance when adopting cloud-based technologies. This includes recommendations for secure data storage, transmission, and access control. Such guidelines will provide a roadmap for companies navigating the complex landscape of regulatory compliance.

5.5.3 *Recommendations for Future Research*

Longitudinal Studies on Technology Adoption

Conduct longitudinal studies to track the long-term impact of cloud-based technology adoption in pharmaceutical companies. Assess how organizations evolve in terms of efficiency, productivity, and data quality over an extended period, considering factors such as technological advancements and changing industry landscapes.

Comparative Analyses Across Cloud Solutions

Undertake comparative analyses across different cloud-based solutions used in the pharmaceutical industry. Explore how various platforms contribute to operational efficiencies, collaboration, and data quality. Such studies can provide insights into the strengths and weaknesses of different technologies, aiding companies in informed decision-making.

User Experience Studies

Conduct in-depth user experience studies to understand the nuances of employee perceptions and challenges during the adoption of cloud-based systems. Explore ways to enhance user-friendliness, reduce learning curves, and address specific concerns raised by different user groups.

Evaluating Industry-wide Impact

Investigate the industry-wide impact of cloud-based solutions on regulatory processes and interactions with regulatory agencies. Assess how the adoption of such technologies influences regulatory timelines, submission quality, and overall compliance. This research can contribute to shaping regulatory frameworks and industry practices.

5.6 Conclusion

In this chapter, the comprehensive analysis of both quantitative and qualitative data has illuminated the intricacies of adopting Veeva Vault RIM in drug registration processes at Eli Lilly and Company. The alignment of literature, quantitative metrics, and qualitative insights has unraveled a nuanced narrative, showcasing the interplay between technological implementation, user experiences, and the broader implications for pharmaceutical practices. The correlation between the length of usage and perceived effectiveness, the positive impact on collaboration, and the identified benefits and challenges collectively underscore the significance of cloud-based solutions in transforming drug registration workflows. As we move forward, the synthesis of these findings sets the stage for a robust conclusion that consolidates key takeaways and implications for the pharmaceutical industry.

CHAPTER 6. CONCLUSION

The culmination of this comprehensive study on the implementation of Veeva Vault RIM at Eli Lilly and Company provides a nuanced understanding of the adoption, impact, and implications of cloud-based technology in the pharmaceutical industry. The convergence of quantitative and qualitative data, coupled with an exploration of relevant literature, offers valuable insights for both practitioners and researchers.

6.1 Recapitulation of Findings

The research began by examining the technological landscape within the pharmaceutical industry, acknowledging the influence of digital frameworks and the impact of the COVID-19 pandemic. A review of the literature emphasized the increasing trend of adopting cloud-based solutions, aligning with the findings of this study.

The quantitative analysis, based on responses from 52 participants actively engaged in drug registration processes, revealed positive perceptions of Veeva Vault RIM. The majority of users reported improved efficiency, collaboration, and productivity. However, variations in satisfaction levels, challenges in user adaptation, and diverse user perceptions illuminated the complexity of implementing cloud-based solutions.

The qualitative phase, comprising ten interviews with senior leadership, enriched the quantitative findings. Themes such as data integration, compliance control, global collaboration, and streamlined processes emerged as driving factors for adopting Veeva Vault RIM. Concurrently, challenges related to data migration, user adoption, and system adaptation were identified.

The integration of both data types facilitated a holistic understanding of the adoption process. Themes aligned, validating, and expanding upon quantitative observations. Duration of usage emerged as a significant factor influencing perceived effectiveness, reinforcing the importance of continued user engagement and familiarity.

6.2 Implications and Contributions

The study enhances the current body of knowledge by offering experiential insights into the adoption of cloud-based solutions in a pharmaceutical context. The identified benefits, challenges, and correlations offer practical guidance for pharmaceutical companies considering or undergoing similar technological transitions.

The integration of literature, quantitative analysis, and qualitative exploration allowed for a comprehensive exploration of the multifaceted implications of adopting Veeva Vault RIM. The findings resonate with the broader discourse on cloud-based solutions, offering practical considerations for both practitioners and researchers.

6.3 Limitations and Areas for Future Research

While this study offers valuable insights, it is not without limitations. The sample size, though representative of Eli Lilly and Company, may not fully capture the diversity of experiences across the entire pharmaceutical industry. Additionally, the cross-sectional nature of the analysis limits the exploration of long-term trends and evolving user perceptions.

Future research endeavors could delve into longitudinal studies, comparing different cloud solutions, and exploring the evolving impact of technology adoption over time. Further investigation into user experience, industry-wide collaboration, and regulatory implications would enhance our understanding of the dynamic interplay between technology and pharmaceutical processes.

6.4 Closing Reflection

In conclusion, the adoption of Veeva Vault RIM at Eli Lilly and Company stands as a testament to the industry's responsiveness to technological advancements. The positive perceptions underscore the potential benefits of cloud-based solutions, while the challenges highlight the need for meticulous planning and ongoing support.

This study encourages a continuous dialogue within the pharmaceutical community, fostering collaboration, and knowledge sharing. As the industry navigates a landscape shaped by digital transformations, the lessons learned from this study contribute to informed decision-making, ultimately steering the pharmaceutical sector towards enhanced efficiency, collaboration, and innovation in drug registration processes.

Table 3: Consistency table: research questions, propositions, data collection and data analysis

RQ #		State Research Question or Objective	Prop/hypo #	State Proposition or Hypothesis	Data collection detail	Data analysis method
1	Does cloud computing help the drug registration process.	To determine the level of efficiencies attained with the implementation of Veeva Vault RIM at Eli Lilly and Company	1	The implementation of Veeva Vault RIM at Eli Lilly and Company has significantly enhanced the efficiency of the drug registration process by improving data visibility, streamlining processes, and enabling faster response to changing regulatory requirements.	Interview guide	Thematic analysis
2	Does cloud computing technology influence the tasks of the regulatory personnel	To assess the impact of the implementation on various functions involved in producing a submission dossier for registration	2	User perceptions influence the extent of use and level of efficiencies attained with cloud computing in drug registration processes	Questionnaire Likert statement	Descriptive statistics Inferential statistics Regression analysis
3	What significance does cloud computing implementation have on the pharmaceutical company.	To evaluate the improvement of drug registration processes following the implementation of cloud computing technology.	3	Cloud-based features and the selection of vendor, as well as internal organizational and technical factors can contribute to the benefits and challenges of successful implementation of cloud technology in drug registration processes.	Interview guide	Thematic analysis

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APPENDIX A – Research Instruments

1. Survey questions

1. In which geographical region of the organization are you located?
- Asia/Pacific
- Latin America
- North America
- Middle East
- Africa
- Europe
- CIS and Balkans

2. Which functional area of the drug registration process are you involved in?
- CMC
- Affiliate
- Management

3. How long have you been using cloud computing (Veeva Vault RIM) for drug registration activities?
- Less than 1 year
- 1-3 years
- 3-5 years
- More than 5 years
- Not applicable (I do not use Veeva Vault RIM)

4. How frequently do you use Veeva Vault RIM to execute your work?
- Not at all
- Once a week
- Twice a week
- Four times a week
- Daily

5. How would you rate the overall effectiveness of using Veeva Vault RIM in improving the efficiency of your work in drug registration?
- Very ineffective
- Ineffective
- Neutral
- Effective
- Very effective

6. What the main benefits you have experienced from using Veeva Vault RIM in your executing your work?
- Faster processing times
- Improved decision-making processes.
- Increased productivity

- Improved collaboration

7. Please rate the level of challenges experienced with the adoption of Veeva Vault in executing your tasks for drug registration processes.
- Not a challenge
- Minor challenge
- Moderate challenge
- Significant challenge
- Major challenge

8. On a scale of 1 to 5, how satisfied are you with the overall performance of Veeva Vault RIM to execute your work?
- 1: Very dissatisfied
- 2: Dissatisfied
- 3: Neutral
- 4: Satisfied
- 5: Very satisfied

9. Veeva Vault RIM has positively impacted your productivity compared to the traditional process?
- Strongly disagree.
- Disagree
- Neutral
- Agree
- Strongly agree.

10. To what extent has cloud computing improved collaboration and communication among team members involved in drug registration?
- No improvement
- Minimal improvement
- Some improvement
- Significant improvement
- Substantial improvement

11. Please rate the extent to which cloud computing has enhanced the accuracy and quality of your work in drug registration:
- Not at all
- To a small extent
- Moderately
- To a great extent
- Completely

12. How would you rate the overall impact of cloud computing on the timeliness of completing drug registration tasks?
- Very negative
- Negative
- Neutral
- Positive

- Very positive

2. Interview guide:

1. What were the main factors or considerations that influenced your decision to adopt Veeva Vault RIM for drug registration processes?

2. Have you encountered any challenges or obstacles during the implementation and utilization of Veeva Vault RIM? How did you address or overcome these challenges?

3. What specific benefits or advantages have you observed as a result of implementing Veeva Vault RIM for drug registration processes? How have these benefits impacted the overall performance and outcomes?

4. In your opinion, what are the key success factors for a successful implementation and utilization of cloud computing in the drug registration process? Are there any critical lessons learned that you would like to share?

5. How have employees responded to the adoption of Veeva Vault RIM for drug registration? Have there been any noticeable changes in their perception, productivity, or satisfaction levels?

6. What are your future plans or considerations regarding the continued use of cloud computing in the drug registration process? Are there any areas for potential expansion or improvement?

APPENDIX B – Ethics Documentation

Graduate School of Business Administration
University of the Witwatersrand, Johannesburg

Wits Business School

Wits Business School Ethics Committee
Constituted under the University Human Research Ethics Committee (Non-Medical)

Ethics Clearance Certificate

Ethics protocol number: WBS/BA9401007Y/421
This certificate is only valid with a legitimate ethics protocol number and signed by the Researcher (below)

This certificate is only valid if accompanied by formal permission from the relevant stakeholder(s).

Project title	Assessment of the implementation of a cloud-based software solution for drug registration at a pharmaceutical company
Investigator / Researcher	Ms Kogilam Moodley
Nature of Project	MBA (Research Article)
Decision of the Committee	Approved, provided stakeholders and participants are guaranteed confidentialty.
Issue Date of Certificate	2023/11/03
Expiry date	Date of submission of the project / research report
Chairperson	Dr Pius Oba ☎ +27 11 717 3976 +27 82 733 6587 pius.oba@wits.ac.za

Declaration by Researcher

One copy must be signed by the Researcher and returned to the Chairperson of the Wits Business School Ethics Committee.

I fully understand the conditions under which I am authorized to carry out the abovementioned research and I guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I undertake to resubmit the protocol to the Committee.

Angeline Moodley
Signature

06 November 2023
Date: