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"Digital Transformation in Pharmaceutical Operations: A Business-Oriented Assessment of Efficiency Gains and Implementation Barriers"

"Sotiria Asimakopoulou"

Supervisor: "Ioannis Theotokas"

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“Sotiria Asimakopoulou”

Supervising Committee

Supervisor:
“Dr Ioannis Theotokas”
“University of Piraeus”

Co-Supervisor:
“Dr Ioannis N. Lagoudis”
“University of the Aegean”

Patras, Greece, June, 2026

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"I would like to thank my family and friends for their encouragement throughout this journey"

Abstract

This dissertation examines how digital transformation affects operational efficiency in the pharmaceutical sector, with a business-oriented focus on measurable efficiency gains and key implementation barriers. Digital transformation has become a strategic priority for pharmaceutical companies operating in highly regulated environments. Organizations increasingly adopt digital tools, however, despite substantial investments, improvements in operational efficiency are not always consistent.

Using a structured secondary research approach, the study analyses academic literature, regulatory documents and industry reports to compare traditional and digitally enabled processes across three operational domains: clinical operations, regulatory documentation and supply chain management.

The findings indicate that digital technologies alone do not automatically lead to performance improvements. Efficiency gains are more likely when digital systems are integrated into governance structures, decision-making processes and cross-functional coordination mechanisms. For instance, in clinical operations, risk-based monitoring supports better resource allocation. In regulatory processes, electronic platforms improve traceability and submission coordination. In supply chain management, predictive analytics enhances visibility and risk prevention when supported by proper system integration.

Overall, the study concludes that digital transformation in pharmaceutical operations is not merely a technological upgrade but a managerial and organisational change process. The dissertation provides practical recommendations for aligning digital initiatives with governance structures and compliance requirements in regulated settings.

Keywords

Digital Transformation, Pharmaceutical Operations, Operational Efficiency, Organisational Change, Implementation Barriers, Clinical Trial Management

Περίληψη

Η παρούσα διπλωματική εργασία εξετάζει πώς ο ψηφιακός μετασχηματισμός επηρεάζει την επιχειρησιακή αποτελεσματικότητα στον φαρμακευτικό τομέα, με έμφαση στις επιχειρήσεις, σε μετρήσιμα κέρδη αποδοτικότητας και βασικά εμπόδια εφαρμογής. Ο ψηφιακός μετασχηματισμός έχει γίνει στρατηγική προτεραιότητα για τις φαρμακευτικές εταιρείες που λειτουργούν σε περιβάλλοντα με αυστηρή ρύθμιση. Οι οργανισμοί υιοθετούν ολοένα και περισσότερο ψηφιακά εργαλεία, ωστόσο, παρά τις σημαντικές επενδύσεις, οι βελτιώσεις στην επιχειρησιακή αποτελεσματικότητα δεν είναι πάντα συνεπείς.

Χρησιμοποιώντας μια δομημένη δευτερογενή ερευνητική προσέγγιση, η μελέτη αναλύει την ακαδημαϊκή βιβλιογραφία, τα κανονιστικά έγγραφα και τις εκθέσεις του κλάδου για να συγκρίνει τις παραδοσιακές και τις ψηφιακά ενεργοποιημένες διαδικασίες σε τρεις επιχειρησιακούς τομείς: κλινικές λειτουργίες, κανονιστική τεκμηρίωση και διαχείριση αλυσίδας εφοδιασμού.

Τα ευρήματα δείχνουν ότι οι ψηφιακές τεχνολογίες από μόνες τους δεν οδηγούν αυτόματα σε βελτιώσεις στην απόδοση. Τα κέρδη αποδοτικότητας είναι πιο πιθανά όταν τα ψηφιακά συστήματα ενσωματώνονται σε δομές διακυβέρνησης, διαδικασίες λήψης αποφάσεων και μηχανισμούς διαλειτουργικού συντονισμού. Για παράδειγμα, στις κλινικές λειτουργίες, η παρακολούθηση βάσει κινδύνου υποστηρίζει την καλύτερη κατανομή πόρων. Στις κανονιστικές διαδικασίες, οι ηλεκτρονικές πλατφόρμες βελτιώνουν την ιχνηλασιμότητα και τον συντονισμό των υποβολών. Στη διαχείριση της αλυσίδας εφοδιασμού, η προγνωστική ανάλυση ενισχύει την ορατότητα και την πρόληψη των κινδύνων όταν υποστηρίζεται από την κατάλληλη ενσωμάτωση συστημάτων.

Συνολικά, η μελέτη καταλήγει στο συμπέρασμα ότι ο ψηφιακός μετασχηματισμός στις φαρμακευτικές δραστηριότητες δεν είναι απλώς μια τεχνολογική αναβάθμιση, αλλά μια διαδικασία διαχειριστικής και οργανωτικής αλλαγής. Η διατριβή παρέχει πρακτικές συστάσεις για την ευθυγράμμιση των ψηφιακών πρωτοβουλιών με τις δομές διακυβέρνησης και τις απαιτήσεις συμμόρφωσης σε ρυθμιζόμενα περιβάλλοντα.

Λέξεις – Κλειδιά

Ψηφιακός Μετασχηματισμός, Φαρμακευτικές Δραστηριότητες, Λειτουργική Αποτελεσματικότητα, Οργανωτική Αλλαγή, Εμπόδια Εφαρμογής, Διαχείριση Κλινικών Δοκιμών.

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List of Abbreviations & Acronyms

ACRO	Association of Clinical Research Organizations
AI	Artificial Intelligence
CAPA	Corrective and Preventive Actions
CRO	Contract Research Organization
CTMS	Clinical Trial Management System
DCT	Decentralized Clinical Trial
eConsent	Electronic Consent
EDC	Electronic Data Capture
EHR	Electronic Health Record
EHR-to-EDC	Electronic Health Record to Electronic Data Capture
ePRO	Electronic Patient-Reported Outcomes
eSource	Electronic Source
eTMF	Electronic Trial Master File
FMEA	Failure Modes and Effects Analysis
FPI	First Patient In
GCP	Good Clinical Practice
HTA	Health Technology Assessment
IoT	Internet of Things
IT	Information Technology
KPI	Key Performance Indicator
KRI	Key Risk Indicator
LPLV	Last Patient Last Visit
ML	Machine Learning
QTLs	Quality Tolerance Limits
RBM	Risk-Based Monitoring
RBQM	Risk-Based Quality Management
SDR	Source Data Review
SDV	Source Data Verification
TOE	Technology–Organization–Environment

1. Introduction

1.1 Background

It is becoming evident that clinical operations in the pharmaceutical industry become more and more complex as the pharmaceutical industry has become more regulated, including having stricter quality standards. Specifically, clinical trials have become harder to manage as they are more demanding and complicated. Moreover, there is more pressure to develop therapies and drugs as well as there is now utilization of worldwide processes such as supply chains (Wong et al., 2023).

Since the pandemic of COVID-19, clinical research has transitioned to decentralized and partially remote. Remote and digitally clinical trial processes have increase which resulted in complicated practicalities and coordination processes within a variety of stakeholders (Hanley et al., 2023; Kijewski et al., 2026). Furthermore over the last two decades, clinical trials have larger in size and more demanding protocols. Some of the operational requirements include biomarker-based patient groups, adaptable protocol designs, remote patient participation and rigorous standards of data collection (Pfeffer et al., 2025).

In addition, in order to ease and assist the decision making process, an increase in the use of electronic systems was noted. Thus, this increase of digital systems usage, the decentralised monitoring of clinical trials, electronic documentation and the importance of the maintenance of data integrity have resulted in stricter and more heavily regulatory guidelines that continue to evolve within the pharmaceutical sector. Good Clinical Practice (GCP) guidelines are constantly getting expanded and updated to include detailed regulations about audit trails and audit readiness, risk-based quality management and regulatory expectations across different countries (Adams et al., 2023; Stansbury et al., 2025). As a result, digital transformation is not only seen as a improvement initiative however, it has become an essential necessity for proper pharmaceutical operations.

Within the pharmaceutical companies, digital technology is profoundly used within different functions such as clinical, regulatory and supply chain. Some of the processes of digital technologies used in clinical trials is the Artificial Intelligence (AI) embroilment to assist in identifying possible risks as well as to assist in the recruitment process (Lu et al., 2023; Teodoro

et al., 2025), the risk-based monitoring systems as well as centralised monitoring (Adams et al., 2023; Stansbury et al., 2025) and remote visits and decentralised digital tools usage enhance activities to happen close to the participant instead of only the study site (Hanley et al., 2023; Kijewski et al., 2026).

There are several processes in clinical trials that have be proven to be more effective by the use of digital technology. For instance, collecting large amounts of data and relying on manual data entry can increase the workload for study sites, slow down reporting and sometimes affect data quality. Data management can be improved by using digital tools that can enhance the connection of data from the electronic health records (eHR) directly to trial databases. Therefore, there is minimization of delays and errors that exist in manual data entry (Pfeffer et al., 2025). Moreover, systems that use blockchain-based designs such as clinical trial management systems (CTMS), can advance transparency and data tracking via secure logging (Zhuang et al., 2022). Furthermore, during participant enrolment, its has been shown that electronic consent (eConsent) has better participant's understanding of the study and increased their engagement. On the other hand, it has also created implementation workflow challenges (Cohen et al., 2023; Appelbe et al., 2026; De Sutter et al., 2024).

Due to the heavily regulated environment in pharmaceuticals, any technological tool should comply with the regulatory guidelines as far as it concerns data integrity, traceability and documentation. Specifically digital transformation in pharmaceutical operations, involves adjustment in coordination management, changes in oversight mechanisms and managerial responsibilities (Vial, 2019). Therefore, digital transformation is not solely a technological and software addition on top of existing routines but adjustments of governance structures and workflow redesign that can profoundly improve organizations efficiency (Kane et al., 2015; Verhoef et al., 2021).

Many organisations invest heavily on digital transformation, however not all the companies accomplish efficiency gains. This is explained by many studies as the gap between technological adoption and the actual efficiency improvement. Specifically, infrastructure within the organisations, fragmented systems, restricted staff capabilities and resistance to change, are some of the factors impacting this gap especially within multilayer and extensive regulated organisations (Hanelt et al., 2021).

Summing up, it is imperative to examine and understand how digital transformation in pharmaceutical operations achieves efficiency gains not solely from a technological perspective but also from an organisational and managerial point of view.

1.2 Problem Statement

The pharmaceutical industry is continuously adopting technological tools that are widely available, however operational issues still remain as operational efficiency and managerial performance are not always stable and predictable. Even while many firms invest in digital tools, it is evident that the expected gains in cost minimization and in performance are not always the case (Hanelt et al., 2021).

It is prominent that scholars mostly emphasize on the the technological advances such as compliance and traceability systems, remote online trial platforms, AI-supported patient recruitment (Cohen et al., 2023; Teodoro et al., 2025) rather than organisational structures, cross-functional collaboration and managerial coordination that can influence measurable operational improvements (Vial, 2029).

Digital tools can help in making things more visible, automating workflows and, the flow of documents and easing decision making. However, this digital solutions could make things more complicated if governance procedures doesn't change, personnel aren't properly trained and departments work in silos (Hanelt et al., 2021). For example, while eConsent can improve participant's engagement as well as their understanding of the clinical trial study, it can also increase the time and the resources used and it can also add extra workflows (Cohen et al., 2023; Appelbe et al., 2026). In addition, as per Wang at al., 2023 and Maes at al., 2025, introducing electronic source systems require multidisciplinary and multifunctional collaboration in order to avoid facing technological, regulatory and operational problems (Wang et al., 2023; Maes et al., 2025). Consequantly this implies that the utilization of new technology as well as changes in infrastructure and the ability of organizations to use it are both equally important (Vial, 2019).

The core issue explored in this dissertation lies at the intersection of digital technology and business management.

Thus, the the central research question is:

How does digital transformation contribute to operational efficiency in pharmaceutical operations and what factors limit its successful implementation in regulated environments?

This question reflects a broader concern which is the gap between adopting digital systems and achieving actual organisational improvements.

As per Warner & Wäger (2019) and Bharadwaj et al. (2013), management and leadership coordination, organisational capabilities and the strategic integration of information Technology (IT) are some of the factors that positively influence performance results (Warner & Wäger, 2019; Bharadwaj et al., 2013). While Adams et al. (2023) focuses on the importance of workflow restructuring, redesign of processes in clinical operations and risk-based prioritization (Adams et al., 2023). It is also suggested by Chen at al., 2025 that regulated industries with strict oversight can impact implementation success (Chen et al., 2025).

While clinical functions, regulatory documentation and supply chain management are interrelated, yet they are often studied separately.

This dissertation attempts to address this gap by comparatively analyzing digital transformation across these three operational domains, with a focus on managerial implications and implementation barriers.

1.3 Research Aim and Objectives

The main aim of this dissertation is to examine digital transformation in pharmaceutical operations from a managerial and business perspective. This study focus on how digital initiatives influence operational efficiency and examines to identify the organisational, governance and regulatory factors that affect implementation results.

Rather than treating digital transformation only as a technological advancement, this research approaches it as a broader organisational change process that takes place within strict compliance regulations (Kraus et al., 2022).

To achieve this aim, the dissertation pursues the following objectives:

1. To examine how digital transformation initiatives are implemented in three key operational domains: clinical operations, regulatory documentation and supply chain management.
2. To evaluate whether and to what extent these initiatives contribute to improvements in operational efficiency.
3. To identify organisational, managerial, infrastructural and regulatory barriers that may limit and delay expected efficiency gains.
4. To analyse the role of leadership alignment, governance structures, workforce readiness and proces redesign in shaping digital transformation results.
5. To develop an analytical framework that connects digital capabilities with governance mechanisms and implementation challenges in regulated pharmaceutical environment.
6. To provide practical managerial recommendations for improving the effectiveness of digital transformation initiatives.

1.4 Research Questions

Based on the study's aim and objectives, this leads to the subsequent research questions that will be addressed below.

These are the four primary research questions that guide this study:

1. How are digital transformation initiatives currently being implemented acros different areas of pharmaceutical operations?
2. To what extent does digital transformation contribute to improvements in operational efficiency in clinical, regulatory and supply chain functions?
3. What organisational, managerial, infrastructural and regulatory barriers makes the implementation of digital transformation more difficult?

4. How do governance structures, leadership alignment, employee readines and institutional conditions influence the relationship between digital transformation and operational efficiency?

This research questions are connected to the conceptual discussion that will be presented in Chapter 2 and they guide the comparative analysis developed in Chapters 3 and 4. The intention is to examine digital transformation not only as a technological process, but as a managerial and organisational phenomenon that operates within regulatory conditions.

1.5 Overview of Methodology

This study aims to contribute to the discussion around digital transformation by examining operational efficiency from a managerial perspective. Rather than assuming that digital technologies automatically improve performance, the analysis focuses on how governance structures, decision-making processes and coordination mechanisms influence whether efficiency gains is actually achieved in regulated pharmaceutical environments (Kane et al., 2015; Vial, 2019).

This dissertation uses a comparative study approach based on secondary data. Instead of collecting primary data, the study is based on the systematic review and synthesis of existing sources. This include peer-reviewed academic articles, regulatory documents, industry reports and documented implementation cases.

The analysis focus on digital transformation across three main operational domains:

1. Clinical operations
2. Regulatory documentation processes
3. Supply chain and logistics management

The study examines two central dimensions. Firstly, it explore whether digital transformation initiatives are associated with improvements in operational efficiency. And secondly, it investigates the barriers that may limit these improvements.

Traditional workflows are compared with digitally supported processes in order to understand how structural and managerial changes impact performance under regulatory constraints. The objective is not to evaluate specific software systems in technical detail, but to analyse broader organisational patterns and governance implications.

In particular, no primary empirical data was collected for this research. Instead, the dissertation brings together theoretical and literature applied insights on digital transformation, strategic management, healthcare operations and regulatory governance.

A more detailed description of the research design, data selection criteria and analytical procedure is provided in Chapter 3.

1.6 Structure of the Dissertation

This dissertation is organized into six chapters and are analysed below:

Chapter 1 introduces the research context and explains the background of the study. It present the problem statement, research aim, objectives, research questions and a brief overview of the methodology.

Chapter 2 reviews relevant literature and develops the conceptual framework which guides the analysis. It discusses digital transformation theory, operational efficiency concepts, governance mechanisms and common implementation challenges.

Chapter 3 describes the research methodology in more detail, including the data sources used, selection criteria and the comparative analytical approach.

Chapter 4 presents the findings of the comparative analysis across clinical operations, regulatory documentation and supply chain management. The results discussed in relation to the conceptual framework introduced earlier.

Chapter 5 further interprets the findings and examines their managerial implications. It also discusses practical considerations and broader organisational consequences.

Chapter 6 concludes the dissertation by summarizing the main findings, outlining limitations of the study and suggesting directions for future research.

2. Literature Review

This chapter seeks to analyse the academic and industry literature regarding digital transformation in the pharmaceutical sector. The main focus is on operational efficiency and implementation challenges within regulated environments. Rather than treating digital transformation as a purely technological topic, the review approaches it as a managerial and organisational issue. The literature reviewed comes from several topics, including digital transformation theory, governance research, dynamic capabilities, healthcare management and studies of regulated industries. These different topics are combined and analysed and therefore give the theoretical base that justifies the need for the study.

Current research illustrates mixed results on digital transformation and performance results. Kraus et al. (2022), have analysed small and medium enterprises and have shown that even the fact that firms heavily invest in digital advancements that does not automatically correlate with improvements in performance. And this is because major changes have to occur to infrastructure, business culture, organisational roles and perceptions about risk, in order to achieve digital implementation. These changes to structure and behaviour comes with costs, challenges with coordination and short-term inefficiencies that can delay or make it harder to accomplish productivity improvements (Kraus et al. 2022). Similarly, De Sutter et al. (2024) argue that digital initiatives may initially reduce efficiency due to adaptation costs, validation requirements and learning curves before long-term gains are realized. This points to that digital transformation must be examined not solely as a technological process, but as a gradual organisational adaptation with swift difficulties and ongoing structural implications (De Sutter et al. 2024).

Summing up, it is evident that we need to understand that digital transformation requires combining strategy theory, governance research, operational management and institutional analysis due to the increased implementation complexity in pharmaceutical environments.

2.1 Conceptual Foundations of Digital Transformation

Digital transformation has become one of the most discussed topics in management research over the last decade and while some points of view stress new technologies and digital tools, others stress bigger changes at the organization, such as strategic reorientation and structure redesign. In highly regulated businesses like pharmaceuticals, digital transformation include things like institutional legitimacy, compliance procedures and governance systems (Vial, 2019; Hanelt et al., 2021).

The conceptual problem involves differentiating digitization, digitalization and digital transformation, as well as comprehending the degree to which technology change, modifies organisational logics and decision-making processes. Bulding on this, digital change cannot be regarded as a solely technical occurrence. Instead, it is an ongoing, systemic process that interacts with strategy, leadership, institutional regulations and professional norms (Hanelt et al., 2021).

This part examines the strategic and organisational aspects of digital transformation. It reviews theories on governance adaptation, dynamic capacities and leadership alignment and it then reviews at how institutional limitations, competing logics and compliance requirements affect how healthcare and pharmaceutical operations changes over time. This part brings together different perspectives and builds the foundation for exploring digital transformation as a conditional process in which the results of efficiency depend on how well managers and organizations work together, and as mentioned before, not only on how well technology is used (Warner & Wäger, 2019).

2.1.1 Strategic and organisational Perspectives

Verhoef et al. (2021) differentiate digitization which is the conversion of analogue information into digital format, digitalization which is the application of digital technologies to enhance current processes and digital transformation, which encompasses extensive modifications in business models, organisational frameworks and value creation strategie. This distinction is significant as it exemplifies that the simple implementation of digital and technological systems

does not constitute an organisational transformation. Verhoef et al. (2021) argues that digital transformation imposes certain requirements on companies' digital resources, organisational structure, growth plans and performance indicators and should not be regarded as a final objective due to the considerable organisational changes and associated challenges (Verhoef et al. 2021). Thus it is illustrated that digital transformation requires structural and managerial adaptation beyond technological deployment.

Vial (2019) describes digital transformation as a process in which digital technologies can cause changes in organisational structures, business models and value creation mechanisms. According to this perspective, digital transformation involves IT systems implementation but also involves adjustments in governance arrangements and managerial processes. According to Vial (2019), digital initiatives break old ways of creating value and force changes especially on how decisions are made, how responsibilities are allocated and how departments coordinate their activities. Moreover, it is shown that effective change occurs and is connected to dynamic skills, which are the company's ability to see technological changes, take advantage of them through coordinated strategic decisions and change the way it uses its resources and structures to fit the new situation. Companies are forced to rethink and restructure their strategy in regards to digital technologies. This transformation completely change a great majority of processes, working as well relationship arrangements leading to both tangible and intangible changes. This re-establishment of their business model can have a positive impact in value creation (Vial 2029).

Within the pharmaceutical sector and especially at clinical trials, there are many regulations and strict guidelines and consequently this can lead to additional procedures in both digitally and manually on paperwork such as thorough source data verification and document version control. Plekhanov et al. (2023) claim that digital transformation often means that companies have to deal with both old and new systems at the same time. An example can be technological tools that are used more nowadays such as centralized dashboards and automated monitoring platforms that improve transparency and coordination. This can be seen as a kind of layering, to where new technologies are added to old ones instead of replacing them. Many organizations are forced to continuously prepare and set up to the ongoing changes leading to uncertainty and reluctancy to completely get rid of the older traditional processes due to high concerns about compliance risk. As a result it can lead to a coexistence between the old and new procedures

that may increase demands. Thus, digitization does not necessarily make thing easier and lessen the workload. Instead, advances in efficiency depend on whether old processes are really reformed instead of just adding new technology to them (Plekhanov et al., 2023).

Bharadwaj et al. (2013) suggest that digital strategy should not be regarded as a conventional IT strategy that merely supports organisational functions. It is stressed that the combination of business strategy and IT implementation can transform industry competition. According to Bharadwaj et al. (2013), digital environments make it harder to distinguish one industry apart from another, make platforms and ecosystems more significant, modifying the meaning of t scale, scope and speed. Additionally, as technological resources increase quickly so is the time between new ideas that becomes shorter and shorter. To stay ahead of the competition and avoid slow digital response especially in strict hierarchical models, the company's business strategy and management processes must include digital capabilities and changes that might need to be incorporated within organisational structures and coordination mechanisms (Bharadwaj et al., 2013).

Kane et al. (2015), based on a large MIT Sloan study involving more than 4,000 executives acros industries further reinforce this argument. According to their findings, digitally mature organizations differ from less mature organizations in the technological implementation and especially in leadership management. The MIT Sloan Global Digital Business Study shows that only 15% of early-stage companies state that it has a clear and consistent digital strategy, as opposed to 81% of companies that are digitally matured. Approximately 80% of new businesses want to improve efficiency and customer experience, while only approximately 52% want to make changes in the firm itself. On the other hand, almost 90% of digitaly mature companies employ digital technologies on purpose to change their business models to increase innovation and improve decision-making. It is also indicated by their findings that over 75% of mature companies are confident in their ability to develop digital capabilities, in contrast to only 19% of low-mature ones. Additionally, it is noted that mature enterprises tend to create cultures that encourage taking risks and working together. On the other hand the less mature companies are still more cautious about taking risks. These results, indicate that, from a managerial standpoint, digital transformation necessitates strategic alignment, leadership dedication, competence enhancement as well as cultural transformation. Therefore, digital

adoption alone is insufficient unless accompanied by deeper organisational and cultural alignment (Kane et al., 2015).

Warner and Wäger (2019) link digital transformation with the development of dynamic capabilities. Based on their empirical case studies, it suggest that companies must cultivate particular dynamic characteristics for digital technologies to generate actual value. According to Warner and Wäger (2019), these skills are divided into three groups which are sensing, seizing and transforming. In more detail, sensing encompasses digital inspection and scenario preparation. Seizing encompasses strategic agility and prototype development. And lastly, transforming includes digital maturity and internal infrastructure changes. Therefore, it is illustrated that the most major role in digital transformation is the adjustment of how businesses work together, how they do business and even their culture.

Theotokas et al. (2024) point out that two of the biggest problems that companies have as they move to more digital settings is their cultural and workforce environment. Lack of knowledge on how new digital systems and processes work, lack of digital capabilities and resistance to change are some of the people related issues that can negatively affect digital implementation and thereafter performance. Additionally, attitudes, routines and work practices significantly influence the eficacy of new technology utilization. It is therefore indicated that digital transformation is not solely a technological process, but also a social and organisational phenomenon (Theotokas et al., 2024). Research on digital transformation highlight the role of organisational culture in determining whether new technologies are effectively embedded into the everyday operations. Culture influences how employees respond to new systems and procedures, how managers support change and how existing routines are adapted to accommodate digital tools. This means that it is considered a key factor in successful technology assimilation (Theotokas et al., 2024). That implies that digital initiatives are more likely to improve operational performance when organizations create an environment that supports behavioural adjustment and flexibility, collaboration and alignment between the new digital technologies and existing working practices.

Solely access to technology and utilisation as an IT project can negatively impact the company's success. However however, according to Warner & Wäger (2019), the ability of management to adapt their decision making and restructure their governing frameworks can enhance digital integration more smoothly (Warner & Wäger, 2019).

Hanelt et al. (2021), in their evaluation of 279 studies, argue that digital transformation modifies organisational design and boundary circumstances. It is shown that digital transformation forces businesses to become more flexible so that they can work in larger digital ecosystems. Digital transformation is differrent from the traditional IT implementation because it uses generative technologies that change over time and work with other systems. According to Hanelt et al. (2021), it is pointed out that a swift in power can be noticeable inside a company, since people with digital capabilities may have more power that people with traditional management skills. In organizations where there are strong professional norms, this shift of power may cause resistance and slow down the process of adapting. Thus, digital change has not only operational but also political and structural aspects.

Anthony and Stanhaus (2026) demonstrate that the significance and validity of health data are influenced by institutional regulations and governance structures. More speciffically just because data is available and technically correct doesn't mean it has value. Accountability, professionalism and regulation interpretation play a significant role in the data usage. For example, in pharmaceutical trials, health data that might be technically accurate, still need approval by regulatory authorities as valid evidence in order to be usable in practice. Thus, digital tools have limits set by regulatory authorities and may either help or harm their effectiveness.

Roth (2025) elaborate on this concept by examining conflicting institutional ideas. Healthcare systems, especially pharmaceutical operations, are affected by managerial logic (efficiency and performance), professional logic (expert autonomy), market logic and regulatory logic. Pharmaceutical bussinesses are under a lot of pressure to speed up trials and minimize costs, but they also need to have their systems approved, to meet regulatory requirements for documentation and be audit prepared. Which means that digital transformation, then, happens in the midle of structural tensions. For instance, digital initiatives typically need governance processes that set up ways to hold people accountable while maintaining oversight mechanisms. If governance structures remain unchanged, digital monitoring tools may generate more reports without necessarily improving oversight quality (Roth, 2025).

Kraus et al. (2021), in a systematic review of 27 high quality journal articles, outlined several principal themes in healthcare digital transformation research, encompassing operational efficiency, patient-centred innovation, organisational and managerial factors, workforce

practices and socio-economic implications. He also indicated that 67% ofthe papers that were examined were published after 2017, which shows that the subject is still new and growing. Many studies link digital transformation to better efficiency, but the research shows that these advantages depend more on redesigning the organization, coordinating stakeholders and adapting the structure additionally to putting new technology in place (Kraus et al., 2021).

Kraus et al. (2022) examines 217 peer-reviewed articles in business and management journals and discover that 81% of them were published in 2019 and 2020. This sharp increase reflects heightened expectations regarding digital transformation. On the other hand though, it is also stated that many transformation initiatives face implementation barriers and that is important because digital transformation is not a minor adjustment but a large-scale organisational change process. It is also highlighted that digital transformation needs to be in line with the organization's culture, goals, governance structures and leadership practices. Without such alignment, digital investments risk remaining fragmented and underutilized (Kraus et al., 2022).

Empirical research from Mauro et al. (2024) also reinforces this claim. In their Delphi study including 11 healthcare specialists, they analyse the influence of various digital technologies on managerial support procedures. The results show that people thought Internet of Things (IoT) and AI had the most impact in making management and administration better, whereas blockchain was thought to be the least important. Theirs findings also show that how well an organization is ready and how skilled its employees are are more important for effective adoption than the technologies themselves. Therefore, the most significant factor influencing effective adoption was not the technology per se, but rather employee competencies and organisational preparedness. The study utilizes the Technology–Organization–Environment (TOE) framework to illustrate that regulatory demands, infrastructure capabilities and internal competences substantially influence digital results (Mauro et al., 2024).

In general, the literature considers that efficiency gains in digital transformation occur as a holistic structurally and strategic bussiness response rather than only a new technology implementation. Even when advanced systems such as electronic data capture systems (EDC), risk-based monitoring tools, electronic Trial Master File (eTMF) platforms, electronic health record to electronic data capture (EHR-to-EDC) integration, predictive analytics, Artificial Intelligence (AI) recruitment tools and digital tracking systems are introduced, improvements

are not actually guaranteed. They seem to depended on whether governance structures are adapted, whether leadership provides direction and whether employees are able to work with new digital processes in practice (Vial, 2019). In addition and from a management perspective, organisational effectiveness depends on the alignment between people, structures and managerial processes. According to Mihiotis (2005), performance results are influenced not only by the resources available to an organization but by the way these resources are coordinated and directed towards common objectives. In this sense, digital technologies can be viewed as organisational resources whose impact depends on managerial alignment rather than on their technical capabilities alone.

These is much more complicated in industries that are heavily regulated, like the pharmaceutical companies. These companies have to follow tight criteria for compliance, audits and professional accountability, which means that technology initiatives therefore cannot operate outside these structures. If they are just added to current procedures without changing how decisions are made, how people work together and how problems are reported, they could make reporting and documentation more complicated instead of lessening inefficiencies (Plekhanov et al., 2023).

Overall, three broad conclusions can be drawn from the literature. First, digital transformation involves not only technological modernization but more so, strategic and organisational renewal (Vial, 2019; Verhoef et al., 2021). Second, capability development and governance adaptation are necessary for digital tools to create sustained value (Warner & Wäger, 2019; Hanelt et al., 2021). Third, empirical research shows that leadership alignment and institutional context influence whether digital investments translate into performance gains (Kane et al., 2015; Kraus et al., 2022; Mauro et al., 2024).

Therefore, digital transformation should be translated as a conditional process. Efficiency gains do not emerge automatically from technology adoption, but from the interaction between digital tools and organisational alignment. This viewpoint offers the theoretical framework for analysing digital transformation in pharmaceutical operations with a focus on managerial and governance perspective.

2.1.2 Digital Transformation and Operational Efficiency

Building on the theoretical perspectives discussed above, this section focus more specifically on how digital transformation affects operational efficiency within complex systems. The focus here is how digital transformation actually affects everyday performance in pharmaceutical operations.

In more detail, clinical operations, regulatory documentation, pharmacovigilance, quality and supply management are closely linked. That means that if something slows down in one area, the effect can appear somewhere else later in the process. For example, delayed query resolution in clinical data management may postpone database lock, which then affects submission timelines. Therefore, efficiency is not only about speed but also includes stability, reliability and reduction of repeated work. In regulated environments, documentation integrity, traceability and inspection readiness are intercorrelated with efficiency. A system that processes documents faster but increases inspection findings cannot be considered greatly efficient. Because of this, operational efficiency needs to be evaluated across the whole lifecycle rather than at isolated steps. Porter and Lee (2013) argue that performance should be assessed across full delivery cycles instead of fragmented departments.

As per Rubio (2013), lifecycle efficiency in clinical trials typically is measured by operational parameters such as:

1. Timeframe from first patient first treatment (FPFT) to last patient last visit (LPLV)
2. Duration from LPLV to database lock
3. Timeframe from database lock to regulatory submission
4. Frequency of the protocol deviations
5. Volume and duration of corrective and preventive action (CAPA) processes
6. Number of major and critical audit findings
7. Average time to close data queries

Porter and Lee (2013) connect efficiency to cost-per-cycle logic rather than cost-per-task. A digital system that reduce the cost of document routing by 10% but doesn't lower the overall cost of preparing for inspections, monitoring and the length of the submission cycle does not make the complete cycle more efficient. Therefore, operational Key Performance Indicators (KPIs) need to show the total lifetime costs, like the cost of each completed trial phase, the cost of every authorized submission and the cost per treated patient over the development cycle. Enhancing one stage without improving subsequent implications can simply redistribute the workload and that targeted improvement can't lead to systemic efficiency (Porter & Lee, 2013).

Additionally Adams et al. (2023) report that by 2021, 88% of trials used at least one Risk-Based Quality Management (RBQM) component. Stansbury et al. (2022) demonstrate that more fundamental components, including centralized monitoring and a significant decrease in 100% Source Data Verification (SDV), have been implemented with less consistency.

According to Rubio (2013), expected RBQM efficiency indicators inlcude:

1. Monitoring hours per enrolled patient
2. Cost per monitoring visit
3. Reduction in on-site visit frequency
4. Increased proportion of remote monitoring
5. Earlier detection of high-risk sites
6. Faster resolution of critical findings

Centralized dashboards may be put in place, but SDV can still continue as before an as a result, the overall monitoring workload may not really decrease. Staff may see more data, however , workload intensity may stay the same (Stansbury et al., 2022).

Verhoef et al. (2021) explain that there is a difference between small digital improvements and broader transformation. In practice, small digital changes could make reporting faster, but they do not always reduce rework and extra checks.

Vial (2019) also notes that digital technologies can change how value is created in organizations. This means that steps such as repeated review steps, extra document quality

checks and unclear approval processes need to be simplified. Otherwise, digital tools may be added alongside old controls instead of replacing them.

Verhoef et al. (2021) also states that digital transformation impacts how we measure performance. Management will need to stop counting things like how many reports employees make and start focusing on things like fewer recurrent mistakes and more reliable timetables. That means that digital tools may add extra reporting without really making it more efficient if outdated KPIs are still in place.

Vial (2019) also points out that digital transformation can make performance more unpredictable at first. During transition periods, workload may temporarily increase and overlapping processes may appear also costs may also fluctuate when old systems are kept alongside new digital platforms. As a result, short-term performance may get worse before long-term efficiency improvements are visible.

Digital transformation can also change how the work is coordinated. Plekhanov et al. (2023) explains that digital tools affect different parts of an organization at the same time. That means that greater transparency may help with managing risks, but it can also increase the need for coordination. In practice, this may lead to increased number of escalation events and points, longer time to review dashboards, longer decision approval processes and higher number of cross-departmental meetings.

More data does not automatically mean shorter cycle time and in some cases, reporting intensity increases before workload decreases.

In supply chain contexts and as per Wong et al. (2023), using fuzzy FMEA and Data Envelopment Analysis in a pharmaceutical case, identifys demand volatility and supplier dependency as critical performance risks.

Digital analytics are expected to improve forecast accuracy, inventory turnover, lead time variability, stockout frequency and finally fill rate consistency.

The findings suggest that predictive tools improved performance only when linked to predefined mitigation rules, such as automatic safety stock thresholds which means that simply having better visibility did not reduce disruption risk on its own (Wong et al., 2023).

Coordination between a variety of different organizations can also make efficiency harder to achieve. Hanelt et al. (2021) explain that digital transformation often takes place across wider ecosystems rather than within a single company. And specifically in pharmaceutical operations, this includes sponsors, Contract Research Organisations (CROs), clinical sites, regulatory authorities and logistics providers working through connected systems.

Because of this, efficiency may be influenced by factors such as data transfer errors and time that is needed to combine safety information, the increased need for manual data checks and delays in batch release prosesses.

Konopik & Blunck (2023) emphasize that digital maturity must be coordinated across ecosystem partners and that if systems do not work well together, manual work is still needed. In these cases, digital investment within one organization may not lead to efficiency gains across the wider network.

Capability alignment also plays a significant role. Warner and Wäger (2019) describe digital transformation as a cycle of sensing, seizing and transforming. In operational terms, sensing can reduce deviation detection time, seizing can redirect monitoring resources toward higher-risk areas and transforming can embed automation into routine workflows. As a result, digital systems could remain peripheral rather than central to performance improvement, if these adjustments donot occur.

In addition, Kraus et al. (2021) claim that research on digital transformation in healthcare generally emphasizes making things more efficient, but they also point out that the results depend alot on the decisions made by managers and employees. Kraus et al. (2022) also state that simply acquiring digital technologies doesn't mean higher performance, because how well companies are ready to use them affects the results.

Mauro et al. (2024) further stresses that effective implementation is closely tied to how ready the organization is and how skilled the employees are. In reality when employees are not completely educated, technological advances can initially cause extra coordination work and additional data activities (Mauro et al., 2024).

Acros clinical, regulatory and supply domains, digital tools can increase transparency and standardize information flows. However, measurable operational efficiency such as reduced

monitoring cost per patient, shorter cycle times, lower deviation rates, improved forecast accuracy, fewer shortages and reduced inspection preparation time emerges only when workload structures and coordination mechanisms adjust accordingly. These perspectives suggest that operational efficiency should be evaluated not only by immediate cost reductions but by structural changes in full-cycle cost composition, variance stability and workload intensity over time.

Summing up, in regulated pharmaceutical settings, operational efficiency is not automatically proportional to digital investment but it alsot depends on how deeply digital systems alter verification intensity, escalation design, interoperability and capability alignment. Digitalization modifies the informational environment, but performance metrics improve only when workload structures and verification intensity are reconfigured.

2.1.3 Digital Transformation in Regulated and Pharmaceutical Environments

Digital transformation in regulated industries differ from transformation in less regulated sectors because digital projects must operate within legally defined compliance frameworks and formal accountability structures. In pharmaceutical and healthcare environments, regulation shapes data governance, documentation accuracy, auditability and risk management practices. For this reason, digital transformation in pharmaceuticals is not simply a technology shift and it actually requires changes in governance processes so that new digital solutions fit within approved and compliant ways of working (Vial, 2019; Verhoef et al., 2021).

In recent years, clinical trial operations have started to change quite a lot because of digital tools that are now being used in everyday processes. For example, newer systems such as e-recruitment platforms, electronic consent (eConsent) and patient matching tools are increasingly used to support how participants are identified and enrolled into studies. A recent review of digital recruitment platforms showed that these tools can improve patient engagement and help speed up parts of the recruitment process, especially after COVID-19 pandemic where remote interaction became more necessary (Bikou et al., 2024).

In addition, decentralized clinical trials (DCTs), where some activities takes place at the patient's home instead of the hospital, are becoming more common. These models allow participants to avoid travel and make participation easier, which in some cases improves recruitment reach (Lagerwaard et al., 2025). This suggests that digital transformation is already influencing how clinical operations are carried out in practice, not just at a strategic level but also in the day-to-day execution of trials.

And, evidence from decentralized clinical trials (DCTs) illustrates how regulation affects not only compliance workload but also the definition of acceptable evidence. De Jong et al. (2023), based on interviews with 25 European HTA representatives, reports limited familiarity with decentralized trial methodologies. Assessors expressed concerns about the reliability of remotely collected data and the absence of standardized validation protocols (de Jong et al., 2024). Similarly, Chen et al. (2025) describes the growth of DCT implementation across different regions but highlight governance, trust, infrastructure and sustainability challenges. These findings suggest that digital transformation in pharmaceuticals depends not only on internal readiness but also on external institutional legitimacy (De Jong et al., 2023; Chen et al., 2025). And this indicates that even if decentralized technologies improve patient access and recruitment speed, institutional legitimacy remains a constraining factor.

Research in healthcare also shows that digital transformation affects not only the clinical practice but also the managerial and administrative functions (Chen et al., 2025). Mauro et al. (2024), using Porter's value chain and the Technology–Organization–Environment framework in a Delphi study, identify IoT, AI/ML and analytics as key technologies influencing managerial support activities. Importantly, he emphasize workforce skills as a critical success factor. This shows that having access to technology is rarely the fundamental problem but though developing skills and designing governance determine whether digital systems become a part of everyday work or stay as pilot projects (Mauro et al., 2024; Kraus et al., 2021). Furthermore, Mauro et al. (2024), using the Technology–Organization–Environment framework combined with Delphi methodology, identifies workforce competencies as the most influential factor in healthcare digital transformation. It is notable that technology availability ranked lower than managerial alignment and training readiness and these reinforces the idea that digital tools are necessary but insufficient for digital transformation.

Kraus et al. (2021), in their systematic review, identify organisational characteristics and workforce practices as central themes in healthcare digital transformation research. They show that performance improvements tend to occur when initiatives are supported by stakeholder integration and managerial coordination. In pharmaceutical operations, where clinical management, safety reporting and supply coordination are closely interconnected, digital systems improves transparency and standardization mainly when governance and workforce adaptation support cross-functional alignment (Kraus et al., 2021)

Governance become even more complex in ecosystem environments. Konopik & Blunck (2023) argue that digital transformation reshapes internal proceeses but even more importantly stakeholder interdependencies. In pharmaceutical operations, sponsors, CROs, sites, regulatory authorities, vendors and internal quality units must coordinate documentation standards and evidence integrity. When digital tools are introduced without cross-boundary governance alignment, then fragmentation and duplication can increase (Konopik & Blunck, 2023; Hanelt et al., 2021).

Batool et al. (2025) emphasize essential aspects like accountability, transparency and risk management in the governance of AI. AI technologies may be utilized in the pharmaceutical industry for things like recruitment, monitoring and risk assessment. Because of this, auditability and accountability become essential for safe and reliable operations. More broadly, governance mechanisms are closely linked to inspection readiness and patient safety in regulated environments (Batool et al., 2025; Roth, 2025). Moreover, validation and quality control are important factors withing regulated settings. Modifications to a process must keep audit trails, version control and generally system stability. Consequently, new systems need to remain traceable and compliant. (Verhoef et al., 2021). In reality, organizations must balance efficiency improvements with compliance requirements.

Digital transformation in regards to documentation involves not only new technology but also institutional alignment. Maes et al. (2025) examined the use of eSource and EHR-to-EDC integration. They describe a multi-stakeholder European initiative aiming to to improve automated data transfer between systems. Their findings show that the main challenge is not only technical but also involves coordination across organizations and agreement on common standards (Maes et al., 2025; Anthony & Stanhaus, 2026). Although the technology exists, regulatory alignment and shared governance remain key barriers. Pfeffer et al. (2025) report

similar findings in their pilot study, where data duplication was reduced, but wider implementation required coordination among multiple stakeholders. Furthermore, Aiyegbusi et al. (2023) examines the use of electronic patient-reported outcomes(ePRO). He identifies advantages such as reduced paperwork and real-time data capture, supporting remote participation. However, he also discusses access limitations and digital inequality issues which indicates that efficiency results depend on inclusive operational design and not simply on technology deployment (Aiyegbusi et al., 2023) At the same time, these digital tools do not automatically make operations more efficient. Evidence from studies on electronic consent systems shows that although they can improve documentation quality and reduce paper-based workload, they often require extra setup, training and workflow adjustments before they actually bring benefits (Appelbe et al., 2026). For example, eConsent platforms may improve patient understanding of trial information, but they can also increase the time needed to complete the consent process because patients interact more deeply with multimedia content (Cohen et al., 2023). Similarly, remote recruitment strategies in decentralized trials reduce logistical barriers like travel, but they may create additional workload at the pre-screening stage because many interested participants still do not meet eligibility criteria (Lagerwaard et al., 2025).

Overall, this suggests that digital transformation within pharmaceutical operations is not a simple way to improve efficiency. The literature also indicates that in regulated pharmaceutical environments, efficiency gains are more likely when digital systems are supported by compliant governance structures, aligned management practices and workforce capability development (Kraus et al., 2021).

2.1.4 Implementation Barriers in Digital Transformation

Although research highlights the potential benefits of digital transformation, empirical studies repeatedly show that organizations struggle during implementation. These barriers are rarely purely technical and they usually reflect interconnected managerial, organisational, infrastructural and regulatory challenges (Vial, 2019).

organisational resistance and workforce preparedness remains one of the most persistent implementation barriers. Borges do Nascimento et al. (2023), in a large review of digital health implementation studies, identify psychological resistance, workload concerns and infrastructure constraints as common challenges. Digital systems may be perceived as additional administrative burden, especially if workflows remain unchanged and responsibilities are unclear (Borges do Nascimento et al., 2023).

Nebie et al. (2023), obtained interviews with stakeholders in sub-Saharan Africa and Switzerland and indicate that infrastructural challenges and inequality in digital literacy may influence trial implementation. His results indicated that worker preparedness encompasses not just training but also workload and practical functionality. This can mean that if digital systems add more duties instead of replacing ones that aren't working well, performance may suffer. Nebie et al. (2023) demonstrate that infrastructure preparedness significantly influences the effective implementation of digital trials by comparing Switzerland with sub-Saharan Africa. The fact that people in different places have different access to devices, connection and training shows that digital transformation challenges vary across regions. Also, Hanke et al. (2025) identify device heterogeneity and site-level variability as practical constraints in decentralized trial deployment and even when sponsors adopt advanced digital platforms, local execution capacity determines actual performance (Hanke et al., 2025).

In pharmaceutical environments, where compliance tasks are already demanding, the introduction of centralized dashboards and AI-supported recruitment tools may initially increase cognitive load. Mauro et al. (2024) emphasize that workforce competencies are strongly associated with implementation success and structured change management becomes necessary (Mauro et al., 2024).

Moreover, another important barrier relates to strategic capability and leadership constraints. Warner and Wäger (2019) describe digital transformation as requiring dynamic capabilities such as sensing, seizing and transforming as without these, digital projects could remain fragmented. Kane et al. (2015) similarly argue that leadership alignment influences transformation results more than technological adoption. In addition, Zhang et al. (2025), using survey data from 620 organizations, demonstrate that digital transformation capability influences performance through digital leadership and strategic intuition. In pharmaceutical contexts, weak executive coordination may result in local improvements that do not translate

into system-wide efficiency therefore the challenge is aligning governance and operating models acros domains (Zhang et al., 2025).

Moreover, infrastructure and integration complexity can create another challenge and as indicated by Plekhanov et al. (2023), digital transformation impacts many organisational levels at the same time, hence increasing coordination complexity. In pharmaceutical operations, interoperability across sponsor systems, CRO platforms, site technology and regulatory systems becomes apparent as a key performance factor. Hanke et al. (2025) also address practical issues that might come up when decentralized trials are set up, such as differences across devices and problems with infrastructure at the site level. Zhuang et al. (2022) also report fragmented data collecting in CTMS systems, which make things less clear and less transparent. Thus, this findings suggest that legacy systems often require structural redesign rather than basic technological changes.

Furthermore, Chen et al. (2025) shows that differences in jurisdictional rules complicate standardization of DCT components and hence governance constraints and regulatory heterogeneity can actually add another layer of difficulty. Therefore, different privacy needs and validation standards can delay harmonization across borders (Chen et al., 2025; Roth, 2025).

Hanley et al. (2023) also observes that decentralized technologies are often implemented gradually rather than through a comprehensive redesign of operations. Kijewski et al. (2026) also note that alot of decentralized experiments are still in the pilot stage and haven't become part of normal operations yet which means that digital transformation is typically just partial and not systemic. Roth (2025) notes that organizations operate under different pressures such as professional autonomy, accountability and efficiency and these need to be balanced, otherwise older systems may continue to exist alongside new digital ones.

Batool et al. (2025) emphasize that AI governance requires regulatory coherence, organisational supervision and technological protections. AI technologies used in the pharmaceutical industry for activities like recruitment and analysing data must pass inspections and follow ethical guidelines (Batool et al., 2025). Batool et al. (2025), in a large systematic review of AI governance incidents, identify over 3,000 documented cases of algorithmic risk, bias and misuse across industries. These systems need to be regularly checked. He emphasizes fairness, accountability and transparency as core governance pillars. Also, if these adjustments

do not occur, some AI techniques are already being utilized in the pharmaceutical industry for things like prioritizing job candidates and analysing clinical documents (Lu et al., 2024; Teodoro et al., 2025). Thus, if AI is not integrated within proper governance structures, it may expose organizations to regulatory and reputational risks.

The literature highlights four main types of barriers to digital transformation:

1. Gaps in workforce skills and resistance
2. Limitations in leadership and capability
3. Infrastructure fragmentation
4. Governance and regulatory complexity

To sum up, workforce readiness influences capability deployment, leadership shapes integration, regulatory diversity affects governance design and infrastructure fragmentation increases uncertainty. This explains why digital adoption may not result in transformation level efficiency results.

2.1.5 Conceptual Model: Conditional Efficiency in Regulated Digital Transformation

Based on the literature reviewed above, this dissertation proposes that operational efficiency in pharmaceutical digital transformation is conditional rather than automatic. The relationship between digital technology and performance results is mediated and moderated by several structural dimensions identified across the literature.

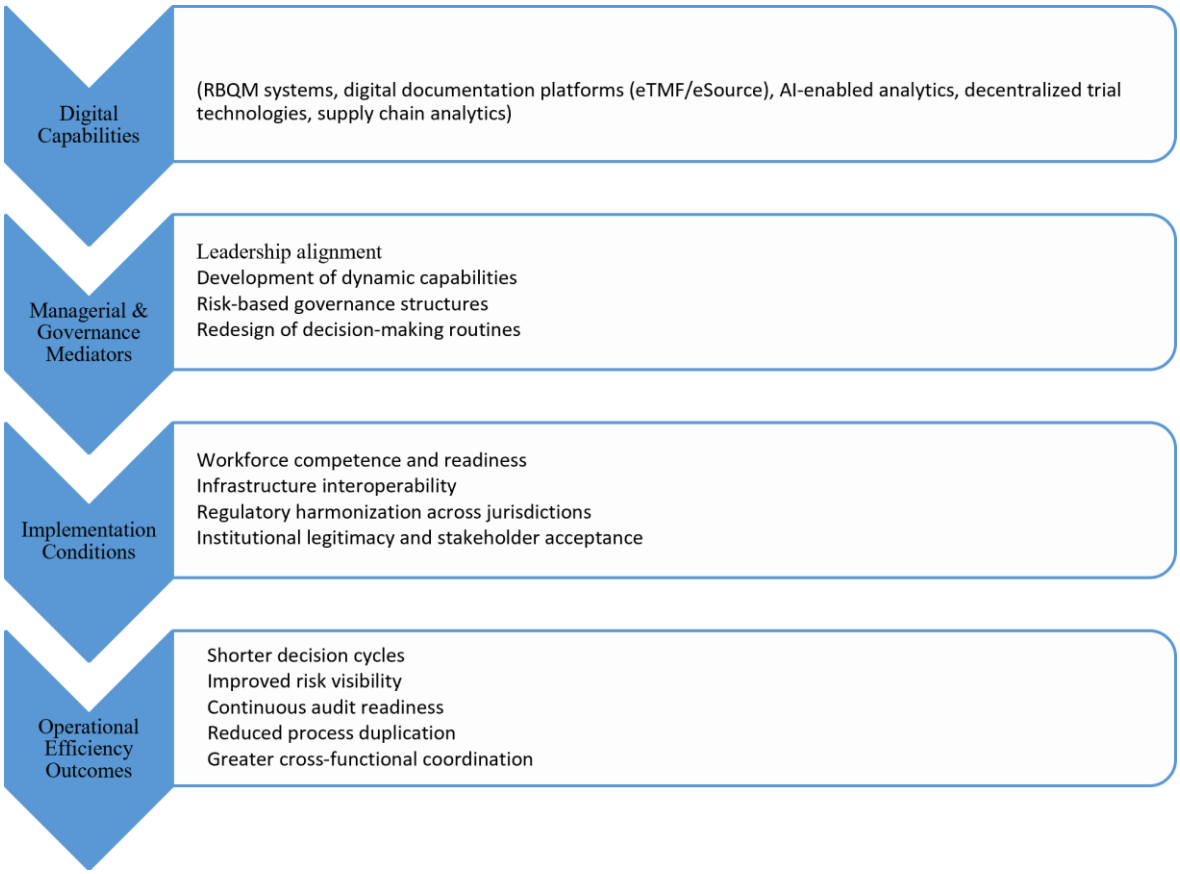

Figure 1: Conceptual Framework of Digital Transformation in Pharmaceutical Operations

This model suggest that digital initiatives do not directly improve operational efficiency. Rather than producing direct effects, digital capabilities operate through managerial mediators such as governance redesign and the development of dynamic capabilities. In addition, implementation conditions shape whether these changes translate in to measurable performance improvements. Efficiency therefore depends on alignment and not on technology adoption alone.

If any dimension is weak (for example, infrastructure fragmentation and regulatory divergence), efficiency gains may be partial and unstable. This supports findings by Adams et al. (2023) and Stansbury et al. (2022), who report high RBQM adoption but uneven structural integration. It also aligns with Plekhanov et al. (2023), who argues that digital transformation across organisational layers can increase coordination costs if complementary adjustments are absent.

The model therefore treats efficiency as something that depends on multiple factors rather than being achieved through simple additions.

3. Methodology

3.1 Research Approach

This dissertation is based on secondary research. No primary data (such as interviews or surveys) were performed and collected. Instead, the study examines existing academic articles, regulatory publications and industry reports aiming to investigate how digital transformation affects operational efficiency in pharmaceutical operations.

There is already a substantial body of research on digital transformation in healthcare and pharmaceutical environments, particularly in areas such as risk-based monitoring, decentralized trials, AI systems and digital supply chains. For this reason, the objective of this dissertation is not to generate new empirical findings, but to analyse and combine existing knowledge from a managerial and business perspective.

A secondary research approach was adopted to systematically review and synthesize existing published evidence in order to identify recuring patterns and relationships across studies.

3.2 Research Design

The research design combines critical literature review with comparative analysis. Digital transformation is examined not simply as the adoption of new technologies, but as a process that affects workflows, coordination mechanisms and governance structures.

The analysis follows the logical sequence:

1. Identification of digital initiatives
2. Examination of workflow and governance changes
3. Assessment of reported operational efficiency results
4. Evaluation of implementation bariers

Digital transformation theory suggests that performance improvements depend on how well technology is integrated into organisational structures (Vial, 2019; Verhoef et al., 2021).

Similarly, dynamic capabilities theory highlights the importance of organisational adjustment in achieving performance results (Warner & Wäger, 2019).

Empirical studies also shows that adoption alone does not guarantee consistent efficiency improvements, as implementation depth and organisational alignment often vary (Adams et al., 2023; Stansbury et al., 2022). Therefore, this study considers both results and the conditions under which they occur.

The study applies a structured thematic comparison acros different operational areas.

3.3 Data Sources

The study relies primarily on peer-reviewed academic literature in the fields of management, healthcare operations, information systems and regulatory science. The selected studies mainly cover the period from 2013 to 2026, with greater emphasis on more recent research reflecting the acceleration of digital transformation initiatives after 2019. Priority were given to empirical studies, systematic reviews and research examining governance, institutional and operational performance dimensions.

In addition to academic literature, regulatory publications and structured industry reports where included in order to capture practical implementation dynamics and institutional constraints (Chen et al., 2025; Roth, 2025). Where industry sources reported efficiency improvements, findings were interpreted cautiously and compared with peer-reviewed research.

Documented implementation cases, such as RBQM adoption, decentralized clinical trials, AI-supported recruitment systems and digital supply chain initiatives, were incorporated when they clearly described workflow changes and performance implications. These cases were used comparatively across domains rather than analysed as standalone case studies.

3.4 Comparative Analysis

The main analytical tool of this dissertation is comparative analysis. This approach makes it possible to compare how digital tools are used across different operational areas and to explore

how they interact with existing management and governance practices. In this way, the study does not simply describe the technologies themselves but examines their role within everyday coordination and decision-making processes.

The study contrasts traditional workflows with digitally enabled workflows across three operational domains: clinical operations, regulatory documentation and supply chain/logistics management.

Traditional workflows typically involve manual documentation, sequential approvals, fragmented data systems and predominantly on-site monitoring. In contrast, digitally enabled workflows include automated processes, integrated platforms, centralized, hybrid monitoring models and real-time data visibility.

Efficiency-related indicators examined include cycle time reduction (Adams et al., 2023), monitoring allocation practices (Stansbury et al., 2025), traceability (Chen et al., 2025) and compliance reliability (Roth, 2025).

Implementation barriers are also compared across domains, including workforce readiness (Mavro et al., 2024), infrastructure and integration complexity (Plekhanov et al., 2023) and regulatory heterogeneity (Chen et al., 2025).

3.5 Operational Efficiency

In this dissertation, operational efficiency is viewed as a multi-dimensional concept. It includes faster processes, better coordination, improved use of resources, earlier risk detection and consistent regulatory compliance (Vial, 2019; Verhoef et al., 2021).

In pharmaceutical settings, efficiency improvements must also preserve documentation integrity and auditability. For this reason, strong governance is treated as part of operational efficiency rather than something separate from it (Warner & Wäger, 2019; Roth, 2025).

3.6 Limitations

This study relies entirely on secondary data, which may introduces publication bias, as successful digital initiatives are more likely to be reported.

And, operational performance results are based on documented findings rather than direct organisational measurement. Regulatory environments also differ across jurisdictions, which may limit generalizability (Chen et al., 2025).

Finally, because no primary data were collected, causal relationships cannot be empirically tested. The conclusions are based on structured comparison and synthesis.

3.7 Methodology Summary

Overall, this dissertation applies a literature-based comparative methodology. Academic research, regulatory publications and documented implementation evidence were synthesised acrross three pharmaceutical operational domains.

Digital transformation is examined as a governance-related organisational change process. Efficiency results and implementation barriers are analysed comparatively in order to identify recurring structural patterns.

4. Findings and Discussion

4.1 Overview of the Findings

This chapter presents the findings from the structured comparative analysis of digital transformation initiatives in pharmaceutical operations. Rather than approaching digital transformation as a technological trend, the analysis examines how digital systems reshape governance, coordination mechanisms &operational performance across three interdependent domains: clinical operations, regulatory documentation and supply chain management. Digital transformation does not necessarily mean simplification of operations but can guarantee visibility boost. For instance organizations can see more data, more dashboards and more indicators. De Sutter et al. (2024) explain that digital projects often create temporary inefficiencies because people need time to adapt as well as systems must be validated. Within the pharmaceutical environment this effect is more noticeable as digital implementation run in parallel with other processes such as audit preparation and documentation verification (De Sutter et al., 2024). Summing up, it is illustrated that digital transformation often progreses in stages and many firms operate between these stages rather than being fully digitally transformed. Those stages is data visibility, adaption of governance structures and organization alignment. These results are interpreted using the conceptual framework developed in Chapter 2, where digital technologies act as enablers and leadership shape results and implementation barriers influence how operational efficiency is achieved (Vial, 2019; Verhoef et al., 2021; Hanelt et al., 2021).

Hanelt et al. (2021) also points out that digital transformation involves broader organisational changes triggered by digital technologies rather than simple IT adoption.

And, according to Stansbury et al. (2022), digital tools such as RBQM adoption may not be fully transformed in practice and this is because many organizations focus mostly on meeting compliance standards rather changing their routine work activities. The Association of Clinical Research Organizations (ACRO) RBQM surveys show increasing levels of formal implementation, but some components remain unevenly embeded across organizations (Adams et al., 2023; Stansbury et al., 2022). For instance, according to Stansbury et al. (2022),

centralized monitoring in combination with reduced source data review and verification strategy, can enhance patient safety oversight, data integrity as well as improved operational efficiency. However, this efficiency does depend on the proper implementation into the routine practice.

4.2 Digital Transformation in Clinical Operations

Traditionally in clinical trial oversight, monitoring intensity such as frequent site monitoring visits and extensive source data verification, was a major indicator of quality. But this approach required significant resources, had higher costs and did not always lead to better critical risk detection.

According to Stansbury et al. (2022), only a limitted number of trials included risk-based monitoring components before the year of 2020 (Stansbury et al., 2022). The clinical trial oversight depended heavily on physical site presence and although data was available, real-time aggregation and analysis were limited, resulting in fragmented visibility. According to Adams et al. around 88% of clinical trials had adopted at least one RBQM element by the year of 2021. Risk-Based Quality Management (RBQM) introduced an important shift in how clinical trials are monitored and the focus moved towards identifying and prioritizing critical risks and key data. RBQM combines initial and ongoing risk assessments, quality tolerance limits (QTLs), key risk indicators (KRIs), centralized monitoring and reduced reliance on full source data verification (SDV) (Adams et al., 2023). On the other hand deeper operational changes, such as a good reduction in SDV, have not been implemented consistently (Stansbury et al., 2025). Thus, it can be shown that many organizations adapt RBQM in principle but may continue traditional monitoring practices in reality.

As per Warner & Wäger (2019), organizations may improve their ability to detect risks earlier ("sensing"), but redesigning core processes ("transforming") tends to progress more slowly. Subsequently, effficiency gains are often gradual rather than transformational.

It is worth mentioning that organisational barriers have to be addresed and roles and responsibilities have to be clear in order to simplify processes and improve decision-making. For example, when KRIs exceed thresholds in centralised monitoring, the responsible person

have to act on it, otherwise dashboards may generate more reports without improving decision-making (Vial, 2019).

Similarly, according to the paper of Chen et al. (2025), during the COVID-19 pandemic, many sponsors introduced decentralized clinical trials (DCTs). However, full transition to decentralized models remained limited as most of the organizations adopted hybrid approaches rather than fully redesigning oversight systems (Chen et al., 2025). Research from European HTA stakeholders show ongoing concerns about the reliability of remotely collected data (De Jong et al., 2023). This indicates that institutional acceptance plays an important role in determining whether digital flexibility translates into broader adoption (De Jong et al., 2024).

Artificial intelligence adds another layer to this complexity. While AI tools may support recruitment, anomaly detection and monitoring prioritization, their use requires clear governance structures. Batool et al. (2025) highlight the importance of explainability, accountability and oversight in AI-enabled systems, particularly in regulated environments.

Overall, improvements in clinical efficiency appear to depend on more than just technology. Centralized monitoring &risk-based approaches may enable earlier detection and better allocation of resources (Adams et al., 2023). But, successful implementation is strongly influenced by workforce capability. Mauro et al. (2024) identify staff readiness as a key factor in digital adoption. Without sufficient training and adaptation, digital tools may increase workload instead of reduce it.

Taken together, these findings suggest that clinical efficiency improves when governance structures, workforce readiness, technological systems and institutional acceptance evolve together. When alignment remains partial, efficiency gains tend to be limited.

4.3 Digital Transformation in Regulatory Documentation

Regulatory documentation has traditionally relied on manual version tracking, email exchanges and documents stored across separate platforms and systems. In many cases, audit readiness depended on reviewing and reconciling records after the fact. As a result, this often increased duplication and slowed ethiks and regulatory submission timelines.

On the other hand, digital documentation platforms such as electronic Trial Master File (eTMF) systems aim to build traceability directly into everyday workflows. Features like automated routing and centralized audit trails reduce reliance on manual coordination. Zhuang et al. (2022) suggest that distributed ledger approaches may further strengthen documentation integrity by improving data immutability acros fragmented systems. Similarly, Wang et al. (2023) show that electronic source (eSource) capture can improve transcription accuracy and reduce repeated data entry.

Pfeffer et al. (2025) report that EHR-to-EDC integration can reduce duplication and delays, but successful implementation requires coordination between vendors, sites and regulatory expectations. Maes et al. (2025) also notes that interoperability is not only a technical issue but it depends on shared governance standards across participating organizations.

Chen et al. (2025) highlights, acceptance of decentralized processes varies between countries. Kijewski et al. (2026) similarly observe that many decentralized documentation approaches are still being tested in pilot settings rather than fully integrated into routine practice. Thus, regulatory differences across jurisdictions can actually add further complexity.

Roth (2025) explains these challenges through the presence of competing institutional priorities, such as professional autonomy and accountability. In practice, digital systems may operate alongside existing documentation methods instead of replacing them which means it can result in parallel processes rather than simplification.

Overall, regulatory efficiency appears to improve when digital traceability tools are supported by stable governance structures.

4.4 Digital Transformation in Supply Chain Operations

Pharmaceutical supply chains have traditionally operated with limited real-time visibility and fragmented data sharing. As a result, disruptions and shortages often occur because information is not shared quickly across different parts of the system.

Digital tools such as predictive analytics and integrated platforms aim to improve transparency. Wong et al. (2023), using fuzzy Failure Mode and Effects Analysis (FMEA) together with Data Envelopment Analysis, identify high-risk points in pharmaceutical supply chains and show how data-driven approaches can support better risk prioritization and traceability.

Konopik & Blunck (2023) explain that digital transformation changes how stakeholders interact with each other. This means supply chain efficiency improvments depend on coordination across the wider network, not just on changes within a single company.

Plekhanov et al. (2023) also highlight that digital transformation affects several organisational layers at the the same time. Specifically, coordination can become greatly complex when core operations, support functions and external partnerships are digitized together. As a result, if organisational structures are not adjusted, digital systems could increase communication demands.

Overall, digitally supported supply chains may improve risk awareness and response speed. However, system compatibility and trust between partners remain an important challenge. Therefore, efficiency tends to improve when digital tools are aligned with governance practices across sourcing, distribution and delivery processes.

4.5 Discussion

The findings suggest that digital transformation in pharmaceutical operations is not just about introducing new technologies but, it involves broader structural changes which often require adjustments in governance and working practices.

Tools such as RBQM systems, decentralized trial elements, AI-based analytics, eTMF platforms and digital supply tracking can improve coordination and performance. However these improvements usualy happen only when new technologies are supported by changes in governance processes and when staff are able to use them effectively.

According to Warner & Wäger (2019), organizations need to identify risks, take advantage of digital opportunities and redesign how work is organized in order to benefit from digital change (Warner & Wäger, 2019). In addition, institutional acceptance can influence how scalable digital approaches are, especially in areas such as decentralized clinical evidence (de Jong et al., 2024; Chen et al., 2025). As noted by Mihiotis (2005), human resource practices also play a significant role as employee skills and behaviour are important in supporting organisational goals. This means that digital transformation depends not only on technology but also on how well the workforce adapts to new ways of working (Mihiotis 2005).

To sum up, the adoption of digital tools should be accompanied with institutional alignment, leadership direction and adjustment of governance processes in order to see positive impacts on operational efficiencies. Thus, digital initiatives should be assessed not only based on their technical featurres but also on how they improve coordination, decision-making and compliance. In practice, the value of digital transformation appears to depend on how well organizations adjust their governance structures alongside the adoption of new technologies.

5. Discussion and Implications

5.1 Discussion of the Findings

This chapter explains the findings from Chapter 4 which described what is happening across clinical operations, regulatory documentation and supply chain management. It focus on interpreting these patterns and linking them to the main research questions.

The main argument of this dissertation is that digital transformation in pharmaceutical operations is not only about introducing new systems but that it also requires changes in governance structures and operating models, particularly in regulated environments.

The study addressed three key questions:

1. How does digital transformation influences operational efficiency across pharmaceutical functions?
2. What organisational and managerial factors help translate digital adoption into efficiency gains?
3. What barriers limit efficiency improvements in highly regulated settings?

The findings suggest that digital systems tend to improve visibility, traceability, coordination and risk detection, insisting that the introduction of a digital tool alone does not necessarily improve efficiency.

Efficiency gains seemto depend on several organisational conditions, including leadership alignment, governance integration , workforce capability,infrastructure interoperability and institutional legitimacy.

Summing up, these findings indicate that digital transformation is most effective when these conditions are present at the same time, while when one of these elements is missing, it will also limit performance improvements.

5.2 Theoretical Implications

5.2.1 Digital Transformation and Dynamic Capabilities

The findings of this study are broadly consistent with the dynamic capability framework proposed by Warner &Wäger (2019). Their model suggests that digital transformation depends on three main capabilities: sensing, seizing &transforming.

In clinical operations, tools such as centralized monitoring and key risk indicators (KRIs) support sensing by enabling earlier detection of potential risks (Adams et al., 2023; Stansbury et al., 2022). Seizing takes place when monitoring resources are allocated based on risk levels rather than applying the same SDV intensity across all sites. Transforming occurs when oversight processes are redesigned and reliance on manual verification is reduced.

Although 88% of trials reported using at least one RBQM component in 2021 (Adams et al., 2023), more advanced practices such as meaningful SDV/SDR reduction and fully centralized monitoring were still not consistently applied (Stansbury et al., 2025). This suggests that organizations may improve risk visibility without fully redesigning their operational routines and therefore implementation depth remains uneven.

Similarly, Zhang et al. (2025) shows that digital transformation capability improves performance when supported by digital leadership and strategic direction. More specifically, digital dashboards and AI tools appear to enhance efficiency only when managers actively integrate them into decision-making processes.

Overall, the results suggest that dynamic capabilities are important, but not sufficient on their own and their impact depends on how effectively they are embedded into everyday governance practices.

5.2.2 Institutional Legitimacy and Efficiency

This dissertation also highlights the importance of institutional factors in shaping digital transformation.

Anthony and Stanhaus (2026) argue that data only become useful when institutions recognize them as legitimate. For example, de Jong et al. (2023) report that European HTA representatives expressed concerns about the reliability of data generated through decentralized trials. Similarly, Chen et al. (2025) show that regulatory expectations for decentralized components differ across countries, while Kijewski et al. (2026) describes the regulatory landscape for DCTs as still developing and uneven.

Even technically effective solutions, such as EHR-to-EDC integration (Maes et al., 2025; Pfeffer et al., 2025), they only appear to improve efficiency only when regulators accept the resulting data as valid. Furthermore, Roth (2025) further explains that tensions between professional autonomy and accountability can lead organizations to maintain parrallel systems instead of replacing older processes.

To conclude, this suggests that digital efficiency in regulated environments depends heavily on the regulatory acceptance and that institutional constraints often shape how far digital tools can improve performance.

5.2.3 Digital Transformation Across Ecosystems

Konopik and Blunck (2023) suggested that digital transformation changes how different stakeholders interact especially in pharmaceutical operations, which are inter-organisational. Clinical trials typically involve multiple stakeholders such as sponsors, CROs, study sites, regulators and technology vendors, while supply chains depend on coordination between manufacturing, logistics and distribution partners.

Hanke et al. (2025) show that differences in local infrastructure can complicate the implementation of decentralized trials. Similarly, Wang et al. (2023) highlight interoperability

challenges when scaling eSource solutions and Wong et al. (2023) demonstrates which reducing supply chain risk often depends on integrating data across multiple nodes. Likewise, Plekhanov et al. (2023) note that digital transformation affects several organisational layers simultaneously, which can increase coordination complexity.

Concluding, these findings suggest that digital transformation in pharmaceutical settings extends beyond internal process digitization and often involves adjustments in how organizations coordinate across multiple broader networks.

5.3 Study Contributions

Fourr contributions emerge from this dissertation the first of which is that efficiency gains are not guaranteed. What that means is that digital tools do not automatically lead to better performance as well as the partial digital adoption can have a more limted impact. Instead, efficiency tends to improve when digital capability, governance integration, workforce readiness, infrastructure alignment and institutional acceptance are present together. For instance, RBQM adoption without full integration of centralized monitoring may improve visibility but it will not always deliver strong efficiency gains (Stansbury et al., 2022; Adams et al., 2023).

Secondly, the study brings together insights from dynamic capability theory and institutional perspectives. Dynamic capabilities help explain how organizations adapt to digital change (Warner & Wäger, 2019), while institutional theory helps explain why transformation is constrained by regulatory expectations and established practices (Anthony & Stanhaus, 2026; Roth, 2025).

Third, the the dissertation compares digital transformation across clinical, regulatory and supply chain domains. This comparison highlights recurring patterns, such as improved visibility, increased governance demands, reliance on interoperability and efficiency results that depend on organisational alignment.

Fourth, the findings indicate that digital transformation in pharmaceutical operations often have a strong governance dimension. Examples from RBQM frameworks (Adams et al., 2023), AI

governance requirements (Batool et al., 2025), interoperability initiatives (Maes et al., 2025) and regulatory diversity across jursdictions (Chen et al., 2025) that all suggest which changes in governance practices plays an important role alongside technological adoption.

5.4 Managerial Implications

Managers may need to view digital transformation as a redesign of operating models rather than only a technology investment. Bharadwaj et al. (2013) describe digital strategy as the integration of technology together withbusiness strategy and taking into consideration compliance regulations.

In addition workforce capability appears to be an important influencing factor. Mauro et al. (2024) identify staff competencies as a key influence on digital transformation results, while Borges do Nascimento et al. (2023) reports which resistance is often linked to workload concerns. This suggests that training and role adjustments will be needed to accompany and improve system - mplementation.

And another important factor is that AI-based tools require the appropriate governance. Batool et al. (2025) emphasize the importance of accountability and transparency in AIuse. For example, applications such as recruitment support and risk management in pharmaceutical contexts (Lu et al., 2024; Teodoro et al., 2025) will need to remain auditable and compliant.

Lastly, another important consideration is interoperability across organizations. Wong et al. (2023) and Hanke et al. (2025) suggest that isolated digital investments may not lead to sustained efficiency improvements, however shared standards and coordinated governance approaches may therefore play a big role in enabling long-term benefits.

5.5 Policy Implications

Regulatory divergence across jurisdictions can limit the integration of digital solutions in pharmaceutical operations (Chen et al., 2025). From a policy perspective, this highlight the

importance of developing more harmonized regulatory frameworks for decentralized trials and the acceptance of digital evidence.

In addition interoperability initiatives such as EHR-to-EDC integration (Maes et al., 2025; Pfeffer et al., 2025) depends on clearly defined validation standards. Policymakers may therefore play an important role in establishing consistent requirements that support safe implementation while maintaining data reliability and regulatory trust.

5.6 Final Remarks

Digital transformation can improve operational performance in pharmaceutical settings when digital systems are supported by appropriate governancechanges, workforce capabilities, interoperable infrastructure and institutional acceptance.

In addition in regulated environments, digital transformation is not only about introducing new technologies, but also about adapting organisational structures within existing compliance requirements.

As a result, efficiency improvements appear to depend on these broader conditions and are shaped by institutional factors.

6. Conclusions and Recommendations

6.1 Conclusions

This dissertation examined how digital transformation influences operational efficiency in pharmaceutical operations. The analysis focused on three key domains which is theclinical operations, the regulatory documentation and supply chain and logistics management. The objective were to explore whether digital initiatives genuinely improve performance especially in regulated environments &under what conditions these improvements actually occur.

The findings indicated that digital transformation can enhance operational processes and that is beacause across all three domains, digital systems were associated with increased visibility, improved traceability, earlier risk detection and faster coordination. More specifically, clinical monitoring became more data-driven rather than fully dependent on the site visits. As well as, documentation processes became more structured and auditable, while supply chains showed improved transparency and responsiveness to disruptions.

However, a consistent pattern emerged that showed that efficiency gains were not automatic and that the introduction of digital tools alone did not always result in better performance. This aligns with the broader digital transformation literature, which emphasises that transformation involves more than technology adoption (Vial, 2019; Verhoef et al., 2021).

The findings support the dynamic capability perspective which is that organizations that achieved performance improvements where those which not only identified digital opportunities but also redesigned workflows and governance structures. On the other side, when systems where implemented without adjustments to accountability and decision-making processes, it resulted in additional complexity (Warner & Wäger, 2019).

Digital evidence, decentralized data collection and AI-supported processes contributed to efficiency only when they were accepted by regulators and HTA bodies. Therefore, it is obvious that institutional legitimacy plays a very important role in the higly regulated pharmaceutical settings (Anthony & Stanhaus, 2026; Roth, 2025).

Overall, the study suggests that digital transformation is more likely to improve operational efficiency when digital systems are aligned with governance changes, workforce capabilities, infrastructure integration and regulatory acceptance. It is therefore important for alignment to be complete in order to reduce inefficiencies, otherwise digital initiatives may increase workload andresult in parallel systems.

6.2 Recommendations

Based on the findings, we have several practical recommendations that can be suggested.

Firstly digital transformation may be more effective when it is approached as an operating model redesign rather than only as an IT upgrade. This suggests that alongside the implementation of new digital tools there are further systems that need to be evolved such as governance structures, monitoring approaches and accountability systems. Otherwise, digital dashboards may improve visibility without necessarily improving decision-making.

Secondly, workforce capability appears to be an important factor as digital systems often require analytical skills, risk interpretation and cross-functional understanding. As highlighted in healthcare digital transformation studies (Mauro et al., 2024), stuff competencies can influence implementation results. This therefore suggests that training and role adaptation may need to accompany system deployment.

Thirdly, interoperability is really important and should ideally be considered early in the process asfragmented platforms limit end-to-end coordination. ystem integration can support smoother collaboration across stakeholders, especially in pharmaceutical ecosystems that involve several parties such as sponsors, CROs, sites, regulators and vendors

Fourth, compliance by design may help guide digital implementation especially in regulated environments where auditability and validation are closely linked to operational efficiency. This tells us that early engagement with regulators as well as the design of inspection-ready systems may reduce friction during later stages of scaling.

Overall, managers benefit from viewing digital transformation as a broader organisational change process rather than purely a technological upgrade. Organisations may be more likely to experience efficiency improvements when digital systems are integrated into governance

and coordination structures. Likewise, industry stakeholders &policy bodies may consider supporting initiatives that align digital innovation with organisational practices.

6.3 Limitations and Future Research

This dissertation relied on structured secondary research andwhile the, cross-domain comparison provided useful analytical insight, the the study did not include primary quantitative data.. Thus future studies could therefore examine performance indicators more directly and test the proposed framework using empirical methods.

Moreover, highly regulatory environments evolve continuously and some areas such as AI governance, decentralized trial frameworks and interoperability standards are still developing, which means that efficiency results change over the time.

On that basis future research could examine the impact of RBQM in the long term. Future research can measure if if companies that adopts RBQM see operational efficiency over the time. Further research is needed in how firms can build structures or processes around the AI systems in order to be able to pass any inspection especially in clinical trials that it's highly regulated. Additionally more research is needed in how organizations and different regulators such as EMA, FDA operate practically different rules and possible institutional tensions within multiple countries. And lastly, how the developement of workforce capability can be utilised as a mediator for transformation success.

To sum up given this those suggested research could contribute to a deeper understanding of how efficiency gains are shaped within regulated digital transformation contexts.

6.4 Final Reflection

Arguably digital transformation in pharmaceutical operations is a broader structural shift and must take into consideration strict regulatory boundaries.

The findings of this dissertation suggest that efficiency gains depend strongly on alignment &digital capabilities. More specifically, changes in governance, leadership coordination, infrastructure integration and institutional acceptance may need to develop together.

In highly regulated environments, sustainable digital transformation seems to require careful management across technological, organisational and institutional levels.

For pharmaceutical organizations, digital transformation may therefore be viewed not only as an innovation challenge, but also as an issue of governance and responsible implementation.

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Appendix A: Conceptual Framework of Digital Transformation in Pharmaceutical Operations

This appendix presents the conceptual framework used in the dissertation to explain how digital transformation influences operational efficiency in pharmaceutical operations.

The framework asumes that digital technologies alone do not automatically produce efficiency gains but depend on how these technologies are embedded within organisational structures and supported by governance, leadership alignment, workforce capability and process redesign.

Digital transformation initiatives introduces new technological capabilities into pharmaceutical operations. Examples include:

- Electronic data capture systems (EDC)
- Risk-based quality management platforms (RBQM)
- Electronic Trial Master File systems (eTMF)
- Predictive analytics tools
- Digital supply chain monitoring technologies

These initiatives create potential for improved coordination, transparency and decision-making. However, this potential translates into operational efficiency only when supported by organisational mechanisms such as:

- Leadership commitment
- Governance structures
- Workflow redesign
- Workforce readiness and skills

Operational efficiency in this study is understood as reliable performance under compliance conditions and include:

- Improved process consistency
- Faster decision-making

- Better resource allocation
- Stronger traceability and audit readiness

At the same time, implementation barriers influence results. Common barriers include:

- Organisational resistance
- Legacy system constraints
- Skill gaps
- Regulatory diversity across jursdictions

The framework therefore proposes that operational efficiency emerges when digital initiatives are supported by organisational alignment and when implementation barriers are managed.

Appendix B: Comparative Overview of Traditional and Digitally Enabled Workflows

Table 1: Clinical Operations Comparison

Component	Traditional Workflow	Digitally Enabled Workflow	Efficiency Impact
Data Collection	Manual transcription and fragmented capture	Electronic Data Capture (EDC) systems	Improved data accuracy & reduced errors
Monitoring	On-site, SDV-heavy monitoring	Risk-based & centralized monitoring	Reduced monitoring cost & targeted oversight
Communication	Email-based coordination	Integratted digital trial platforms	Faster escalation & decision-making
Data Oversight	Fragmented site-level visibility	Centralized dashboards & KPI tracking	Earlier risk detection & improved transparency

Table 2: Regulatory Documentation Comparison

Component	Traditional Workflow	Digitally Enabled Workflow	Efficiency Impact
Document Submission	Paper based & manual compilation	Electronic submission platforms	Reduced submission cycle time
Version Control	Manual tracking	Automated document	Improved traceability & fewer conflicts

		management systems	
Approval Workflows	Sequential manual approvals	Automated routing systems	Faster processing & clearer accountability
Regulatory Communication	Decentralized communication	Centralized databases	Improved coordination & visibility

Table 3: Supply Chain Operations Comparison

Component	**Traditional Workflow**	**Digitally Enabled Workflow**	**Efficiency Impact**
Inventory Management	Historical forecasting	Predictive analytics	Improved stock optimization
Distribution Monitoring	Limited visibility	Real-time digital tracking	Increased transparency
Demand Forecasting	Manual estimation	AI-supported forecasting	Greater forecasting precision
Logistics Coordination	Manual stakeholder communication	Integrated coordination platforms	Faster response time

Appendix C: Summary of Secondary Data Sources

This dissertation is based on arange of secondary research using academic and industry literature.

Key categories of sources include:

Digital Transformation Theory and Organisational Change
Examples: Vial (2019); Verhoef et al. (2021); Hanelt et al. (2021); Plekhanov et al. (2023); Kraus et al. (2022)
Used to frame digital transformation as an organisational and strategic process rather than purely a technological shift.

Dynamic Capabilities and Strategic Renewal
Example: Warner & Wäger (2019)
Used to support the role of managerial sensing, seizing and transformation in enabling performance results.

Clinical Trial Operations and Digital Enablement
Examples: Adams et al. (2023); Stansbury et al. (2022, 2025); Aiyegbusi et al. (2023); Hanley et al. (2023); Hanke et al. (2025); Lagerwaard et al. (2025); Teodoro et al. (2025)
Used to examine the operational implications of digital monitoring, decentralized trials and risk-based quality approaches.

Decentralized Trials, eConsent and Participant Engagement
Examples: Cohen et al. (2023); Appelbe et al. (2026); Bikou et al. (2024); Nebie et al. (2023); Kijewski et al. (2026); Lu et al. (2024)
Used to explore implementation realities and participant-facing digital adoption.

Governance, Institutional Context and Data Infrastructure
Examples: Anthony & Stanhaus (2026); Batool et al. (2025); Roth (2025); Konopik & Blunck (2023)
Used to analyze how governance structures influence digital performance results.

Healthcare Digital Transformation and Managerial Processes

Examples: Mauro et al. (2024); Kraus et al. (2021); Borges do Nascimento et al. (2023)

Used to assess organisational readiness and workforce implications.

Supply Chain Digitalization

Examples: Wong et al. (2023); Pfeffer et al. (2025)

Used to examine digital coordination and risk visibility in pharmaceutical supply networks.

Digital Infrastructure and System Integration

Examples: Zhuang et al. (2022); Wang et al. (2023); Maes et al. (2025)

Used to explore the role of system interoperability and structured data environments.

Artificial Intelligence and Recruitment Optimization

Examples: Chen et al. (2025); Lu et al. (2024); Teodoro et al. (2025)

Used to examine emerging AI-enabled trial optimization.

This categorization reflects the multidisciplinary nature of the literature supportiing the dissertation's business-oriented assessment of digital transformation in pharmaceutical operations.

Appendix D: Literature Search Strategy and Study Selection Criteria

The literature search was conducted through academic databases and publisher platforms.

Core Academic Databases:

- ProQuest One Academic (via Hellenic Open University Library)
- Scopus
- PubMed
- ScienceDirect
- Google Scholar

Publisher Platforms and Journal Collections:

- BMJ Journals
- SPRINGER Nature Link
- JMIR Publications
- MDPI
- Harvard Business Review
- Cambridge University Press
- Oxford Academic JAMIA
- PLOS Digital Health
- Wiley Online Library
- Sage pub Journals
- Frontiers Org Journals

Relevant articles were also identified through:

- Npj digital medicine
- International Journal of Integrated Care
- Scientific Reports
- ESMO Journals
- ASCPT Journals

- Hellenic Open University (HOU) MBA Programme Study Materials

Indicative search keywords included:

- digital transformation pharmaceutical operations
- risk-based monitoring clinical trials
- regulatory digital governance healthcare
- pharmaceutical supply chain digitalization
- operational efficiency regulated industries

Inclusion criteria:

- Peer-reviewed publications published between 2013 and 2026
- Empirical studies and theory-based contributions
- Research with organisational, managerial, governance, or operational focus
- Studies relevant to regulated healthcare or pharmaceutical environments
- Recent publications were prioritized whre they provided updated evidence on digital transformation implementation

Exclusion criteria:

- Purely technical engineering studies
- Studies unrelated to regulated industries
- Opinion-based publications without analytical evidence

Appendix E: Summary of Identified Efficiency Benefits and Implementation Barriers

The following themes emerged consistently across the literature reviewed for the study and grouped here for reference:

Efficiency benefits include:

- Data transparency acros departments was notably improved
- Process fragmentation has been reduced
- Risk visibility has been improved
- Faster decision cycles

Managerial enablers include:

- Governance integration
- Leadership alignment
- Workforce capability development

Implementation barriers include:

- organisational resistance
- Legacy system constraints
- Skill gaps
- regulatory diversity across jursdictions

Structural constraints include:

- Interoperability limitations between existing and new systems
- Uneven adoption depth acros departments within the same organisation
- Partial system integration, which in some cases created new inefficiencies rather than resolving existing ones

It was noted that barriers and enablers have overlapped across the studies reviewed which has made the categorization more difficult in practice.

Author's Statement:

I hereby declare that, in accordance with article 8 of Law 1599/1986 and article 2.4.6 par. 3 of Law 1256/1982, this thesis/dissertation is solely a product of personal work and does not infringe any intellectual property rights of third parties and is not the product of a partial or total plagiarism and the sources used are strictly limited to the bibliographic references.