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Digital Transformation of Pharmaceutical Industry

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Introduction to the Thesis Work

Digital transformation (DT) in the Pharmaceutical Industry (PI) is a topic of increasing scholarly importance but remains underexplored within management studies. This thesis, comprising five scientific articles, addresses various aspects of DT in PI, offering significant contributions to existing literature and proposing new research perspectives, in particular:

1. To analyze the key technologies driving DT in PI.
2. To develop practical frameworks for implementing DT.
3. To integrate interdisciplinary and stakeholder-oriented perspectives.
4. To investigate the impact of DT on sustainability dimensions.

The main research objectives are specifically addressed in the five articles, each focusing on a particular aspect of PI-DT:

- **Paper 1:** Establish a theoretical foundation and identify literature gaps in the existing literature on PI-DT.
- **Paper 2:** Develop a practical framework for implementing DT by integrating people, processes, and technology.
- **Paper 3:** Explore the alignment between AI-driven and Stakeholders engagement
- **Paper 4:** Investigate the relationship between strategic and cognitive readiness, AI Social Engagement, and the improvement of SDGs and economic performance.
- **Paper 5:** Analyze opportunities and challenges for PI-DT deployment in practice

The five articles included in this thesis are connected by a common thread that explores how DT can transform various aspects of the Pharmaceutical Industry (PI), and how these transformations can be integrated into a broader framework of sustainability and digital innovation.

The first paper, through a systematic literature review, initially covering 404 articles and narrowing down to 35 relevant papers, proposes a future research agenda to be pursued in the next years of studies. This agenda focuses on key technologies driving DT in PI and addresses significant gaps in the current literature of Operations Management, Strategic Management, Organization's Theory, and Stakeholder's Theory. This review offers a theoretical foundation for further scholarly inquiry and knowledge development of the overall thesis.

The second study highlights the transformation of organizational business structures and processes through DT, emphasizing the need for an interdisciplinary approach and cross-level perspectives. Using Action Design Research (ADR), a practical "Digital by Design" (DbD) framework is developed, emphasizing the interconnected dimensions of People, Process, And Technology dimensions. This framework provides practical guidance for designing and implementing DT into business processes, recognizing the significance of diverse organizational needs, individual uniqueness, technology integration, and cross-level empirical perspectives.

The third study addresses the lack of research aligning AI and stakeholder Theory with industry and technology-oriented, interdisciplinary perspectives, utilizing different empirical lenses. Based on 16 interviews with Italian and Indian PI experts, 14 relevant themes were identified, leading to the development of an AI-driven Stakeholder Engagement Strategies. This model integrates organizational structure, culture, and means, enhancing stakeholder engagement and providing theoretical insights for effective AI deployment.

The fourth paper emphasizes the relationship between strategic and cognitive readiness for digital innovation, AI Social Engagement, and their role in enhancing Sustainable Development Goals (SDGs) and economic performance. Using a Structural Equation Model based on a sample of 511

respondents in the PI, the study identifies that strategic and cognitive readiness improves SDG performance through AI Social Engagement. It also highlights the positive and significant relationship between AI user acceptance and improved economic performance through enhanced SDGs commitment.

The fifth paper, an analysis of the evolving landscape of DT in the PI, based on a systematic literature review and topic modelling, identifies the opportunities and challenges of future PI-DT deployment. This study explores the transformative impact of integrating digital technologies, emphasizing the potential of the metaverse to revolutionize collaboration, patient care, simulation, precision, and safety within the industry. It provides a foundation for further exploration and discourse in this rapidly evolving field.

Overall, this thesis significantly contributes to the understanding of DT in the PI by offering a comprehensive exploration of both theoretical and practical frameworks. Each article not only proposes innovative models and frameworks but also demonstrates their practical applications, thus bridging the gap between theory and practice. The insights gained from this research are instrumental in shaping the future of DT in PI and guiding the development of sustainable and innovative strategies. These strategies are crucial for enhancing operational efficiencies, fostering stakeholder engagement, and achieving long-term sustainability goals within the PI landscape. Through this work, new pathways are opened for academic inquiry and practical implementation, ensuring that the PI can effectively navigate and leverage the opportunities presented by digital transformation.

Paper 1: Digital transformation of the Pharmaceutical Industry: A future research agenda for management studies

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Abstract

Despite the widespread attention given to Digital Transformation (DT), there is a notable lack of comprehensive knowledge concerning its implications within the Pharmaceutical Industry (PI), particularly from a Management Studies perspective. This research employs a Systematic Literature Review approach, utilizing an initial review of 404 articles (which resulted in the identification of 35 relevant papers) to propose a comprehensive Future Research Agenda focusing on key technologies driving PI-DT and addressing the major gaps in current literature. Specifically, four primary research directions are delineated in the areas of (I) Operations Management, (II) Strategic Management, (III) Organization's Theory, and (IV) Stakeholder's Theory. In conclusion, the Literature Review addresses the underdeveloped field of PI-DT in Management Studies, offering the theoretical foundation for further scholarly inquiry and knowledge development in this field.

Keywords: Digital Transformation, Pharmaceutical Industry, Management Studies, Organization Theory, Stakeholder Theory, Operations Management

1. Introduction

Over the past decade, digital transformation (DT) has emerged as a pivotal force, redefining the operational, strategic, and competitive landscapes across various industries (e.g., Song et al. 2024; Appio et al. 2021; Gastaldi et al. 2018; Llopis-Albert, Rubio, and Valero 2021; Leão and da Silva 2021 to mention a few). This phenomenon, driven by the rapid convergence (Appio et al., 2023) of the internet, emerging technologies, and automation, has acquired extensive attention from scholars and practitioners alike (Hausberg et al., 2019; Vial, 2019). Yet, in the Pharmaceutical Industry (PI), a sector where innovation is both a constant demand and a critical challenge (Achilladelis & Antonakis, 2001; Malerba & Orsenigo, 2015), DT's journey is still unfolding. The exploration of DT within PI, particularly through a management studies lens, is sparse, indicating a significant gap between the potential of DT and its current scholarly examination.

The PI stands at a crucial juncture, with DT offering unprecedented opportunities to enhance drug Value Chain Phases (VCP) — from Drug Discovery (DD) and Clinical Trials (CT) to Manufacturing (MK), Supply Chain (SC), and Market Access (MA). Technologies such as the Internet of Things (IoT), Augmented Reality (AR), Artificial Intelligence (AI), Blockchain, Cybersecurity, Cloud Computing, 3D Printing, Digital Twins, Virtual Reality (VR), Robotics, and Big Data are poised to drive transformative changes (e.g., Silva et al., 2020; Kulkov, 2021; Sharma et al., 2022; Reinhardt, Oliveira, & Ring, 2021). However, the academic dialogue around these technological integrations in PI, especially from a management perspective, remains in its nascent stages. The discourse is often limited to practice-oriented phenomena, with substantial insights buried in practitioner's journals or generalized within the broader healthcare context, thus overlooking the nuanced implications for management studies (e.g., Hariry, Barenji, and Paradkar 2022; Kraus et al. 2021). Acknowledging the profound need to supplement the theoretical aspects of DT in PI and to unravel the complex interplay

between emerging technologies and management practices, a systematic literature review (SLR) was performed following the methodology outlined by Tranfield, Denyer, and Smart (2003). This rigorous review of 404 articles, employing stringent selection criteria, distilled down to 35 papers that resonate with the research objectives of this study.

The analytical journey through these selected works uncovered four pivotal research domains: Operations Management Research, Strategic Management Research, Organization's Theory Research, and Stakeholder's Theory Research. Each domain offers a unique vantage point to dissect and understand the multifaceted impacts of DT within PI, underscoring the urgency for a robust theoretical framework that can guide both scholarly inquiry and practical applications.

This paper endeavors to synthesize the fragmented landscape of DT research in PI, offering a coherent picture of its current state and carving out a structured research agenda that lays the groundwork for future inquiries. The objective of this study is twofold: first, to synthesize the extant research into a cohesive overview that elucidates the current contours of DT within PI, particularly emphasizing management implications, and highlighting the critical role of management studies in deciphering the multifaceted impacts of DT on PI; second, to identify and articulate the critical research gaps and potential directions, thus catalyzing a robust academic inquiry into DT's role in reimagining the pharmaceutical landscape, advocating for a theoretical enrichment that matches the practical advancements in the field.

Overall, this paper is not just a call to arms for bridging the theoretical voids in PI-DT; it is an invitation to the academic community to engage with, debate, and advance the discourse on digital transformation in the pharmaceutical industry. Through a structured presentation of the research gap and a clear articulation of the research aims, this study aims to enrich the ongoing conversation around

DT, offering a scaffold for both theoretical advancement and empirical exploration, ensuring that the transformative potential of DT is fully realized in advancing healthcare outcomes.

The paper first unveils the research gaps identified, employing a structured approach for clarity. Following this, it describes the investigation methodology, navigating through the selected articles to distill key themes and insights. A detailed discussion on the future research agenda, derived from the analysis, aims to spark scholarly dialogue and exploration. Lastly, a reflection on the theoretical and practical implications of the findings is offered, setting the stage for a concluding synthesis that highlights the main research limitations and articulates the core takeaways.

2. Research Gap

This study is situated in the Pharmaceutical Industry (PI). The PI comprises multiple companies that collaborate and compete to research, develop, manufacture, and distribute drugs for diagnosing, curing, mitigating, treating, and preventing diseases (Tinkle et al., 2014). This industry involves a complex set of stakeholders interacting in various Value Chain Phases (VCP), including *Drug Discovery* (DD), *Clinical Trials* (CT), *Manufacturing* (MK), *Supply Chain* (SC), and *Market Access* (MA). Before the Covid Pandemic, there was worrying evidence of PI's poor digital deployment. According to a Deloitte survey,[1] most of the companies were either in the early Phases of Digital adoption (25%) or developing their capabilities (55%); and only 20% reported themselves to be digitally mature. Nevertheless, the Covid Pandemic consistently empowered PI-DT, such that a pandemic era survey[2] showed that companies had become keener to invest in and take risks with DT across different VCP. This promising trend is also reflected by the growing attention PI-DT has

[1] https://www2.deloitte.com/content/dam/insights/us/articles/4797_CHS-MIT-survey/DI_CHS-MIT-survey.pdf

[2] https://www2.deloitte.com/content/dam/Deloitte/it/Documents/life-sciences-health-care/DI_Life_sciences_digital_innovation.pdf

gained in practitioners' literature. However, despite the volume of works discussing PI-DT, only a few have been conducted under a Management lens (S. M. Lee & Lee, 2021; Nambisan et al., 2017, 2019; Vial, 2019; Walsh et al., 2020). This demonstrates a substantial limitation in the literature; thus, more comprehensive studies are required to expand academic debates in DT. The first significant problem addressed by this study is that most of the current literature on PI-DT has been debated under a Scientific Perspective or through a practical lens of application without projecting the phenomenon as a long-term inquiry to be investigated under a Management perspective. For instance, Polykovskiy et al. (2018) studied AI applications to address rare diseases; Lusci, Pollastri, and Baldi (2013) adopted deep learning architectures to predict aqueous solubility for drug-like molecules; Moreno-Benito et al. (2022) examined Digital Twins in the context of continuous manufacturing and the digital design of drugs, while Algahtani and Ahmad (2022) discussed 3D printing adoption to develop a self-nano-emulsifying drug delivery system.

Despite the great relevancy of these topics within the management debate, the above works are more concerned with advancing the scientific or practical knowledge within the field rather than opening new research questions to future researchers. This creates an interesting opportunity to establish consistent foundations in the Management PI-DT Literature, and this paper will address this latent problem.

Another reason is that the most relevant PI-DT works are situated within the broader Healthcare setting (Dal Mas et al., 2023; Kraus et al., 2021). Although PI falls under the *Healthcare* umbrella, these articles include other sector's implications, such as those of the *Hospital Industry* or *Pharmacies*. For instance, J. Liu et al. (2021) discussed the implementation of a Cloud-Based pre-prescription system for pharmacies and clinicians to minimize the prescription of inappropriate medications; Kohl et al. (2019) investigated the use of Big Data techniques in Hospitals; while Ho et

al. (2023) conducted research on the acceptance of emotional AI for aiding the elderly or individuals with physical disabilities. Thus, to fill the gap in the PI-DT Management studies area, this more comprehensive and focused research has been engaged.

Although some research has been conducted within the PI-DT Management field, it has been limited to addressing only a single drug's VCP or individual Technologies. Although these works support the creation of PI-DT as a stream of research in Management Studies, they are restrictive as they only represent distinct or narrow issues within DT. For instance, the article from Zulfiqar et al. (2022) discusses adoption of Blockchain technology to fight counterfeited drugs; Coito et al. (2022) evaluates the impact of digital twin for quality control in drug laboratories; and Solfa (2022) examines the impact of cybersecurity and Supply Chain risk management on digital operations. As a result, the subsequently proposed research agendas are often bounded by the prior research constraints. Thus, this study intends to provide a solid, comprehensive foundation within literature by engaging in a broad examination of PI-DT.

There have, however, been some attempts at addressing the broader PI-DT phenomenon. In 2020, Reinhardt et al. surveyed the current DT developments of the Irish Pharma Sector to provide a base of information for developing strategies and future directions. The same year, Silva et al. conducted fieldwork in Portuguese BioPharma Manufacturing based on ten interviews to represent the applications and impacts of Industry 4.0 technologies. These articles have four main common limitations: (1) they describe only general benefits and barriers to PI-DT without discussing in detail different technology patterns across the different drug's VCP; (2) these articles base their contribution primarily on their sample responses, which are often too small to provide diversified perspectives on technology and VCP, without mentioning relevant Literature as theoretical background; (3) these works were conducted before Covid; therefore, they did not consider the recent disruptive

developments brought by the pandemic to PI; (4) these articles do not represent future research agendas to be pursued in the Literature of Management PI-DT. This paper aims to address these limitations and provide a more comprehensive understanding of PI-DT through this study.

3. Review Methodology

In support of this research, the *Systematic Literature Review* (SLR) methodology (Tranfield, Denyer, and Smart, 2003) has been used. SLR is a rational, transparent, and replicable research methodology for analyzing the body of knowledge about a specific construct or technology (Sivarajah et al., 2017) exploring, and dedicating available evidence related to a specific research question to replicate it (Kitchenham & Charters, 2007; Nassif et al., 2019; Xiao & Watson, 2019). There are various motivations for conducting an SLR, such as proposing the current state of the art about a specific construct or providing a reference structure identifying current research gaps and potential future study themes (Sivarajah et al., 2017). The review framework carried out in this study follows a *Three-Phase* approach (Tranfield et al. 2003) as illustrated in the following outline**:**

- ***Phase I - Planning the review****, (a) describe the research question, research aims, and (b) develop a review protocol (Subsection 3.1);*
- ***Phase II - Conducting the review****, describe the material selection criteria for the research purposes, and divide them into three stages (Subsection 3.2);*
- ***Phase III - Reporting and dissemination****, (a) conduct a descriptive analysis of the review framework, (b) research contributions, (c) research limitations, and (d) conclusions (Section 4).*

The articles selected for this comprehensive examination were collected and extracted in *Rayyan Software*[3] to enforce the exclusion criteria and quality control over the review framework. Afterward, the review framework was examined several times to establish clusters; accordingly, recurrent patterns emerged. By strictly controlling the review process, this method resulted in the analysis of 35 articles, uncovering relations not previously identified in the Management Literature (Compagnucci & Spigarelli, 2020; David & Han, 2004; Delbufalo, 2012; Mahmud et al., 2022; Singh et al., 2020; Sivarajah et al., 2017; Tranfield et al., 2003), Figure 1 summarizes the review methodology.

FIGURE 1

3.1 Phase I – Planning the review

(a) Description of Research Question and Research Aims

Using the guiding principles from Tranfield et al. (2003) and Kitchenham and Charters' (2007) publications, the following research questions, objectives, and protocols to disclose data selection and criteria analysis were developed. To begin, the study originates from the claim made by many practitioners that DT helps renovate business models, establish more agile organizational structures, improve patient care levels, adapt more effectively to competitor's moves or regulatory guidelines, and improve other aspects of a drug's Value Chain Phases (VCP). However, these assertations have been completely disregarded in the Management Literature discussion, lacking a solid research agenda projecting the Pharmaceutical Industry Digital Transformation (PI-DT) phenomenon as a

[3] https://rayyan.ai/

field of study. Accordingly, this research aims to enrich the body of knowledge, focusing on the following research question:

RQ: What is the future Research Agenda in the PI-DT Management Literature?

(b) Development of a Review Protocol

Below, the design of the relevant material collection of the SLR is described. In particular, the following primary requirements were applied:

- ***Requirement I*** – The review was conducted from September 2022 until February 2024 by searching the Scopus, Science Direct, and Google Scholar databases. These databases were selected because they are the most well-recognized academic search engines. Accordingly, they include most international peer-reviewed journals worldwide and are likely to offer significant contributions to the area of interest.
- ***Requirement II*** – To collect only relevant perspectives, all the chosen articles included pertinent keywords and were reviewed with particular attention given to those section(s) that referred explicitly to research objectives.
- ***Requirement III*** – Only peer-reviewed articles written in English published after 2010 were considered within the review framework. Year 2010 as selected as a cut-off as works preceding this were not likely to yield relevant DT perspectives.
- ***Requirement IV*** – Because of the varying nature of the research question, various kinds of studies were included, such as qualitative, quantitative, surveys, mixed methods, or literature reviews. Based on the research scope, only those papers that deal with PI-DT under a *Management Studies* perspective were selected.

- ***Requirement V*** – The final quality control assurance method involved a full-text reading analysis to support researchers in providing relevant contributions.

These requirements were observed rigidly to guarantee an effective and reproducible database searching process (Compagnucci & Spigarelli, 2020; David & Han, 2004; Delbufalo, 2012; Mahmud et al., 2022; Singh et al., 2020; Sivarajah et al., 2017; Tranfield et al., 2003) which will be discussed in the following sub-section.

3.2 Phase II—Conducting the review

The database searching process was conducted in three stages. The following discussion details how these stages were structured.

Stage I - Identification

In the first stage, following Requirement I, the following relevant keywords were used for the database search:

"#Technology AND Pharma OR Pharmaceutical Industry AND Digital Transformation OR Industry 4.0 AND Literature Review OR #ValueChainPhase"

As a result, 404 publications were identified.

Stage II – Screening and Exclusion Criteria

In this second stage, an exploratory title, abstract, and keyword analysis have been conducted to exclude certain studies from the research domain. As a first step, duplicate papers (n=27) were eliminated. By keeping in mind that the research objective was to provide PI-DT Management Studies

with a cognitive roadmap for future research, non-PI papers (n=9), PI papers not dealing with DT (n=75), and Healthcare Papers (n=65) that failed to mention any PI implications (Requirement II) were excluded. Moreover, Outdated Papers (n=12) and un-peer-reviewed articles such as Book Chapters, Consulting Reports, and Industry Reports (n=27), and not yet published materials such as Conference Papers, Proceedings Papers, and Recommendations (n=34) (Requirement III) were also excluded. Among the selected peer-reviewed articles, Science-related papers dealing with DT (n= 50) and PI-DT practitioner's articles (n=70) were omitted because Science-related papers are too specialized, focusing on topics such as Biology or Chemistry, and practitioner's studies lack Management foundational input, which is required to build a future Research Agenda (Requirement IV).

Stage III – Inclusion

As a result, the study focused on articles including discussions on PI-DT ranging from subject journal from Business and Management Sciences, Computer Sciences, Industrial Engineering Sciences, Sustainability and Environmental Sciences, and Social Sciences. At the end of the screening and exclusion stage, 35 relevant articles were included in the analysis and were then read and analyzed by the authors of this study (Requirement V).

3.3 Phase III - Reporting and dissemination of results

The primary purpose of this study is to create a future research agenda for management scholars. The motivation for conducting this investigation comes from the limited amount of research on this topic. To gain insight into the Literature, articles related to PI-DT were thoroughly reviewed, starting with a preliminary group of 404 papers and narrowing it down to a final review framework comprised of

35 relevant articles within the management Literature. Table 1 provides an overview of the review framework belonging journals, while Figure 2 provides a descriptive statistics considering Years of Publication, Methodology, Technology, and Value Chain Phases (VCP).

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TABLE 1 AND FIGURE 2

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There has been a significant rise in the number of articles delving into Pharmaceutical Industry Digital Transformation (PI-DT) since 2018. No relevant works before 2018 were found, confirming the topic's novelty in the Management Literature context. Indeed, PI-DT has consistently gained attention over the years, particularly after the Covid Pandemic, with a notable increase in publications during 2020 and 2022, where more than half of the review framework was published. These findings indicate that the subject is becoming increasingly attractive for scholars, and this research will support future research. According to Figure 2, researchers are employing a wide range of methodologies to investigate PI-DT. It is worth highlighting that a substantial portion of management studies utilize qualitative methods, accounting for 40% of the total review framework. These qualitative approaches encompass various techniques, such as single case studies, multiple case studies, exploratory research, and a considerable number of semi-structured interviews conducted with field experts. This notable emphasis on qualitative methodologies underscores a strong commitment to comprehending the experiences, attitudes, and perceptions of individuals actively engaged in PI-DT. The review framework further reveals that Literature Reviews constitute the second most used methodology, accounting for 23% of the total aggregate. The Literature review approach is valuable in identifying

gaps and opportunities for further investigations. However, the few articles addressing insights from such studies only partially address the PI-DT, as they tend to be confined to isolated boxes, eighter to single VCP or digital technology, lacking a comprehensive insight of the phenomenon. In conclusion, Quantitative methods, Mixed Methods, Surveys and Bibliometric Analysis are underutilized (17%, 9%, 3%, 3%), indicating less emphasis on these methodologies.

Based on the review framework, PI-DT is being researched across the whole VCP. The two most cited VCP are *SC* and *MK*, consisting respectively in 66% and 46% of the reviewed papers. These two VCP are cited together in 42% of the review framework, evidencing an interesting association of these VCP for researchers. Additionally, 40% of the papers concentrate on the MA phase, implying that researchers are increasingly interested in this topic. Finally, 20% of the papers are focused on the CT phase and 17% on the DD phase. This suggests a growing interest in DT, but more studies are needed to thoroughly address the enabled digital technology's positive and negative effects on these phases.

The review framework presents the prevalence of various digital technologies contributing to PI-DT. IoT and AI appear to be highly significant, mentioned in 54% and 51% of the articles. This indicates a substantial focus on interconnected devices and data analytics, improving operational efficiencies within PI VCP, possibly for monitoring, data collection, or process optimization (Patel and Shah 2022; D. K. Sharma, Bhargava, and Singhal 2020; Hariry, Barenji, and Paradkar 2022). Big Data follows closely behind at 46%, indicating a considerable emphasis on handling and deriving insights from vast volumes of data in pharmaceutical research, development, and decision-making processes (Banner et al., 2021). Furthermore, Cloud technology (37%) and Blockchain (37%) both show a considerable presence. Cloud computing likely plays a role in data storage, accessibility, and collaboration (Reinhardt et al., 2020), while Blockchain might be utilized for enhancing transparency,

security, and traceability in the pharmaceutical supply chain or clinical trials (Omar et al., 2021). In addition, 3D technology (29%), AR (Augmented Reality) (20%), and VR (Virtual Reality) (20%) seem to be moderately represented. These technologies might be used in drug modeling, training simulations, or even patient education and engagement (Awad et al., 2018; Trenfield et al., 2022). Last, Cybersecurity (11%) and Digital Twin (9%) appear less frequently, suggesting potentially less emphasis on ensuring robust cybersecurity measures and implementing Digital Twin technologies within the pharmaceutical sector (Y. Chen et al., 2020b), at least in the context of the articles reviewed. Overall, this data indicates a widespread integration of various digital technologies in the pharmaceutical industry, with IoT, AI, Big Data, Cloud, and Blockchain being particularly prominent. This integration reflects a concerted effort to innovate, improve processes, and advance research and development within the pharmaceutical landscape.

4. Review Framework

Table 2 provides a comprehensive overview of the review framework, addressing Research Objectives and Findings, Methodology, Value Chain Phase, Technology included and Limitations and Future research for PI-DT Management research.

TABLE 2

5. Future Research Agenda

After conducting an in-depth analysis of the review framework, four crucial research areas that hold significant relevance to the PI-DT context were identified. These areas include (I) *Operations Management Research, (II) Strategic Management Research, (III) Organization's Theory Research,* and *(IV) Stakeholder Management Research*. These research areas have a strong connection with all the DT technologies, and profound influence on critical aspects of drug's value chain phases. In the next paragraphs, a new research agenda, technologies involved, VCP, relevant literature, and viable research questions is presented.

5.1 Operations Management Research

The first research area that emerged from the review framework is (I) *Operations Management Research*, which involves the design, planning, and control of processes and systems to deliver drugs effectively and efficiently to stakeholders (Slack et al., 2010). The research agenda of this study encompasses a series of related topics to be advanced in the upcoming years of research, considering the following Macro-areas: *(a) Maintenance and Monitoring of Equipment, (b) Productive Process Reengineering, (c) Supply Chain Management, (d) Tracking, Transparency and Trust*, which have not been comprehensively detailed so far, specifically focusing on leveraging digital technologies for: (a.1) Predictive Maintenance, (a.2) Process Visualization and Simulation, (a.3) Product Quality Control, (a.4) Real-Time Monitoring; (b.1) Business Process Management, (b.2) Flexible and Agile Production Lines, (b.3) Manual Work Reduction, (b.4) Production Lead Time, (b.5) Reduced Bureaucracy (b.6); Centralized and Decentralized Supply Chain, (c.1) Inventory Management, (c.2)

Logistics Management, (c.3) Supply Chain Resilience, (d.1) Track of Products and Material's Procurement, (d.2) Cold Chain Control Monitoring, (d.3) Lack of Transparency, and (d.4) Lack of Trust. Overall, the research agenda outlined aligns with *Operations Management Research* principles by seeking to optimize processes, improve quality, and enhance supply chain coordination through the integration of new technologies. Future research should therefore address the unique challenges faced by the PI and related new streams of research in the literature, as indicated in Table 3.

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TABLE 3

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5.2 Strategic Management Research

The second area that emerged from is *Strategic Management Research*, which involves the formulation and implementation of strategies to achieve organizational goals competitive advantage and superior performance (Durand et al., 2017). To this account, the rapidly evolving pharmaceutical landscape, by integrating digital technologies offers significant opportunities for organizations. The research agenda of this study encompasses a series of related topics to be advanced in the upcoming years of research, considering the following Macro-areas: (a) *Business Model Innovation (b) Data Governance and Analytics,* and *(c) Scalability*, which have not been comprehensively detailed so far, specifically focusing on leveraging digital technologies for: (a.1) New Marketing Channels, (a.2) New Value Creation, (a.3) Need of New Business Models, (a.4) Smart Contracts; (b.1)Patient Retention, (b.2) Data Accessibility, Governance, Transparency, Mining and Demand, (b.3) Forecasting production to Demand, Sales and Profits (b.4) Risk management; (c.1) Venture

Capitalism, Startup financing and acquisition, (c.2) Lack of Strategic Guidance over digital innovation. Overall, the review framework emphasized the need for more comprehensive studies in the PI-DT Strategic Management Research field, that future researchers shall pursue, as indicated in Table 4.

TABLE 4

5.3 Organization's Theory Research

The third area is related to *Organization Theory Research*, which seeks to understand and analyze how organizations function, evolve, and adapt to changes in their external environment (Wilden et al., 2019). The identified research agenda aligns with the field of Organization Theory, examining the impact of digital technologies on (a) *Decision Making and Support*, (b) *HR Management*, and (c) *Organizational Communication and Learning*, which has not been comprehensively detailed. More specifically, the examination focuses on leveraging digital technologies for: (a.1) Agile Decision Making, (a.2) Project Lifecycle monitoring; (b.1) the Need for new Multidisciplinary Figures and Digital trainings, (b2) Workforce Turnover and Recruitment; c.1) Cultural Change and Technology Acceptance, (c.2) Interoperability, Obsolescent IT Infrastructures, and inefficient Information sharing across Functions, (c.3) Managerial Awareness and Leadership, (c.4) Organizational Readiness for innovation. Overall, the research agenda aligns with the principles of Organization Theory by focusing on the impact of digital transformation on various aspects of organizational functioning and

addressing key challenges and opportunities in adapting to the digital landscape within the pharmaceutical industry. Future research shall therefore pursue these research streams, as indicated in Table 5.

TABLE 5

5.4 Stakeholder's Theory Research

The fourth area is Stakeholder's Research, identifying PI organizations as responsible agents for a wide range of stakeholders and focusing on the integration of digital technologies for triggering different impacts (Matten & Moon, 2004) on: (a) the *Environment*, (b) *Patients*, (c) *Regulatory Institutions*, (d) *Governance,* (e) *Society* which have not been comprehensively examined. More specifically, the framework highlights: (a.1) the environmental footprint, (a.2) sustainability certifications, (b.1) Customization, Personalization, and Precision Medicine, (b.2) Ensuring Drug Safety, Counterfeit Drug Prevention, and Higher Accessibility to Drugs, (c.1) Data Transparency for Regulatory Validation, (c.2) Enhanced adherence to Regulatory standards, (c.3) Need for standardized data sharing protocols and Updated Regulatory Frameworks, (d.1) Eliminating Discrimination in recruitment, (d.2) Patient-Data Security and Privacy, and (e.1) University Education Gap. Accordingly, future research should pursue these research streams, as indicated in Table 6.

TABLE 6

6. Implications for theory and practice

This systematic literature review on the digital transformation (DT) of the pharmaceutical industry (PI) from a management studies perspective enriches theoretical frameworks in several ways.

The literature review underscores a critical gap in the comprehensive understanding of DT's implications within the PI, particularly from a management studies viewpoint. This gap highlights the nascent stage of PI-DT in academic discourse, echoing the call for a more robust theoretical foundation in this domain. Vial (2019) acknowledges this need by emphasizing the transformative potential of DT across industries but points out the scarcity of research specifically within PI. The review, by proposing a future research agenda across key areas (Operations Management, Strategic Management, Organization's Theory and Stakeholder's Theory), sets a foundational base for theoretical exploration and scholarly inquiry. This approach aligns with the views of Fichman, Dos Santos, and Zheng (2014) who argue for the necessity of interdisciplinary research agendas to fully understand DT's impacts.

The review's inclusion of diverse digital technologies (e.g., IoT, AI, Blockchain) within PI's value chain phases (Drug Discovery, Clinical Trials, Manufacturing) represents a significant integration of technology and management theory. Such integration is crucial for developing a comprehensive understanding of how DT reshapes industry practices and management strategies. Tidd and Bessant (2020) discuss the importance of this integration for innovation management, suggesting that understanding the role of technology in organizational change is vital for strategic innovation.

Similarly, Westerman, Bonnet, and McAfee (2014) highlight how digital technologies are redefining competitive landscapes, necessitating a reevaluation of management theories to incorporate these technological advancements.

Identifying research gaps in literature also serves as a directive for future scholarly efforts, encouraging the development of new theoretical frameworks to address these gaps. The provided research agenda serves this aim. This approach is in line with the work of Benner and Tushman (2003) who emphasize the value of research diversity for the advancement of management studies. The systematic review calls for a deeper investigation into the comprehensive impact of DT across the entire pharmaceutical value chain, echoing the sentiments of scholars like (Yoo et al., 2010a), who argue for a more nuanced understanding of digital innovation's role in organizational transformation. By outlining the future research agenda, this literature review advocates for a multidisciplinary approach to studying PI-DT. This suggestion is supported by the work of (Autio et al., 2018) who argue that the complexities of digital ecosystems can only be fully understood through a multidisciplinary lens. Such research is crucial for developing a holistic understanding of DT's implications, integrating insights from operations management, strategic management, organizational theory, and stakeholder theory to foster a comprehensive theoretical framework.

The review not only identifies the need for theoretical advancements in the context of PI-DT but also sets the stage for future research to explore these areas. This aligns with the argument presented by Nambisan et al. (2019) regarding the evolving nature of innovation in the digital age and the consequent need for management theory to adapt. By focusing on the integration of digital technologies within PI and their multifaceted impacts, the review contributes to the broader discourse on digital transformation and its theoretical implications.

Overall, the systematic literature review on DT in the pharmaceutical industry not only highlights the existing gaps in the literature but also proposes a structured agenda for future research. This endeavor not only advances theoretical understanding within the field of management studies but also encourages the integration of technological and management theories to address the complex dynamics of digital transformation in the pharmaceutical industry.

For practitioners in the pharmaceutical industry, the systematic literature review offers several actionable insights.

The review provides a comprehensive overview of the key technologies driving DT in PI and their applications across different value chain phases. This serves as a guide for pharmaceutical companies to prioritize their DT initiatives, focusing on technologies and areas with the highest potential impact on their operations and strategic goals. The outlined future research agenda and identified research gaps offer insights into emerging trends and challenges in PI-DT. Practitioners can use this information to inform their strategic planning and investment decisions, ensuring they are aligned with the future direction of technology and management practices in the industry. By highlighting the importance of integrating digital technologies into pharmaceutical management practices, the review underscores the potential for these technologies to enhance competitive advantage. Companies that effectively leverage DT can improve their operational efficiency, agility, and stakeholder engagement, positioning themselves favorably in a rapidly evolving industry landscape. The focus on Stakeholder's Theory research underscores the importance of considering the diverse interests and impacts of DT on various stakeholders, including patients, regulatory bodies, and the environment. Practitioners are encouraged to adopt a more stakeholder-centric approach to DT, which can lead to more sustainable and socially responsible business practices. The review points to the need for standardized data sharing protocols and updated regulatory frameworks to support DT in PI. Practitioners can leverage

these insights to advocate for regulatory changes that facilitate innovation while ensuring patient safety and data security.

To sum up, the systematic literature review on the DT of the Pharmaceutical Industry not only advances theoretical understanding but also offers practical guidance for navigating the challenges and opportunities of digital transformation in a highly regulated and competitive sector.

7. Research Limitations

It is necessary to recognize the limitations of this work. First, the restrictions due to limited source availability. Despite the utmost efforts to access relevant research studies, certain articles were inaccessible. This could potentially introduce bias and limit the inclusiveness of this review. Second, despite the attempts to include a wide range of studies, some pertinent articles may have been excluded due to selection criteria and search terms. Third, the quality and rigor of the included studies varied, which may have impacted the strength of the evidence hereby synthesized. Fourth, given the rapidly progressing nature of PI-DT, it is conceivable that some recent advancements were not captured in the Literature available until the date of this review.

8. Conclusions

In conclusion, this literature review addressed the current knowledge gap in the field of PI-DT, which has been relatively underdeveloped in Management Studies despite the increasing attention given to DT by practitioners. Indeed, while practical applications of PI-DT have been explored extensively in the practitioner's literature, Management studies was still limited by, e.g., being too practitioner-focused, neglecting recent PI-DT developments arising from the Covid-19 pandemic, and, most

importantly, lacking a comprehensive research agenda in the context of Management studies to boost this subject as field of debate. By reviewing a framework of 35 relevant articles, this SLR contributed to the existing literature by presenting a well-structured research agenda for PI-DT Management studies. Researchers can explore strategies and technologies that improve *operational activities,* investigate the role of PI-DT in gaining a superior *competitive advantage*, examine the *changes to organization's* processes associated with DT initiatives, and investigate the source PI-DT *Impacts on various Stakeholders*. These research directions offer a solid foundation for additional scholarly inquiry and contribute to the development of knowledge in the field of PI-DT management studies.

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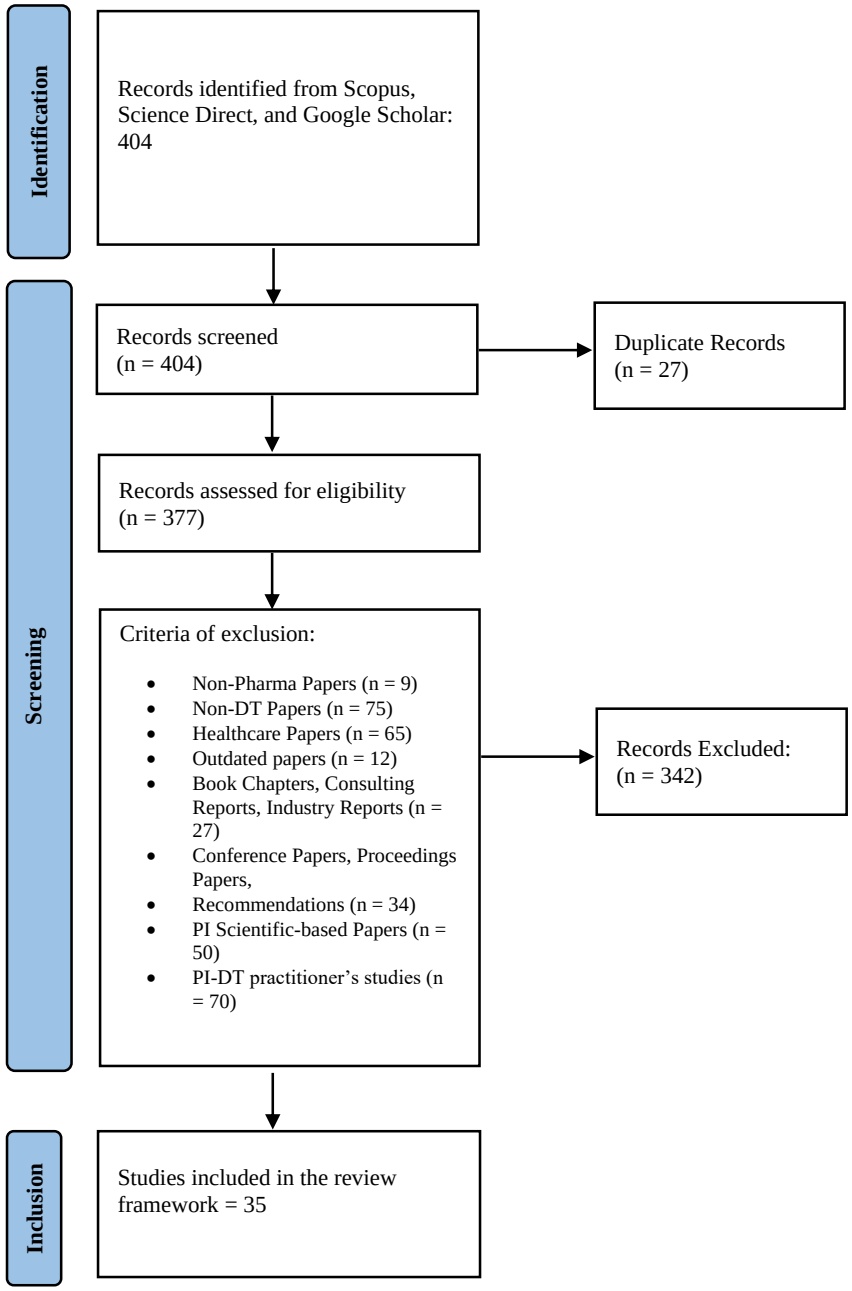
FIGURES AND TABLES

Figure 1. Review Methodology (Adopted from PRISMA[4])



[4] http://prisma-statement.org/prismastatement/flowdiagram

Figure 2. Descriptive statistics (Abbreviations: Artificial Intelligence (AI), Augmented Reality (AR), Virtual Reality (VR), Internet of Things (IoT))

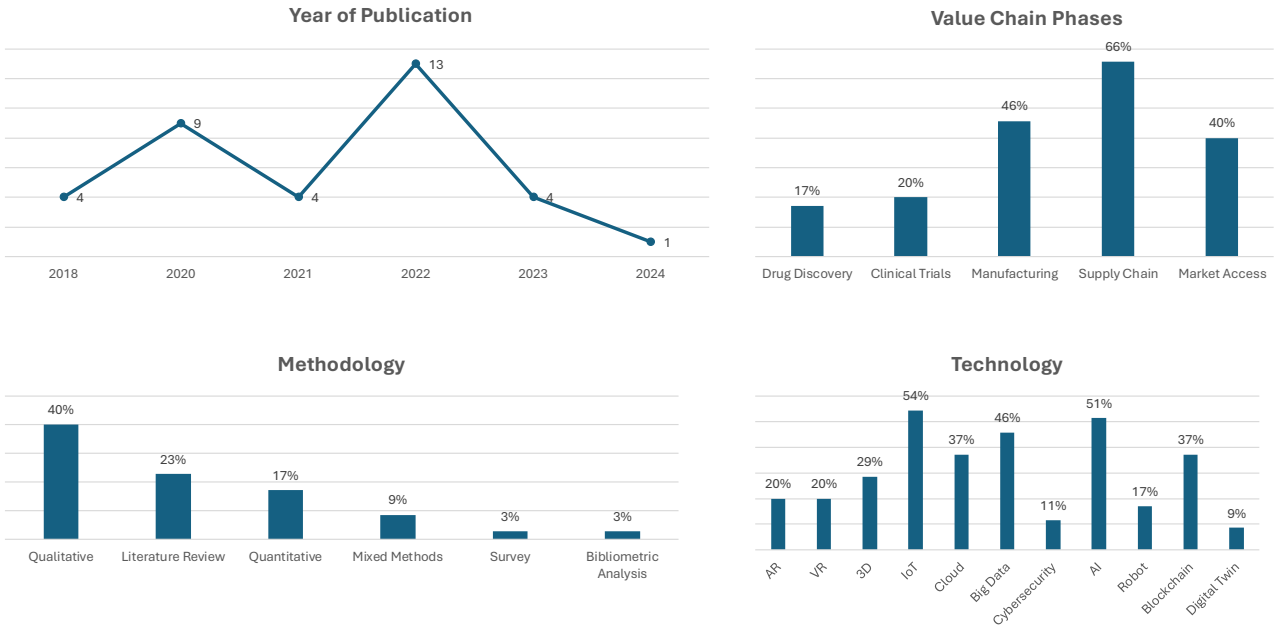


Table 1. Overview of the selected journals, number of papers, and related research topics

Journal	Papers	Research Topics
Technological Forecasting and Social Change	6	Applied Psychology; Business and International Management; Management of Technology and Innovation
IEEE Transactions on Engineering Management	3	Electrical and Electronic Engineering; Strategy and Management
Journal of Business Research	2	Marketing
International Journal of Production Research	2	Industrial and Manufacturing Engineering; Management Science and Operations Research; Strategy and Management

Annals of Operations Research	1	Decision Sciences (miscellaneous), Management Science and Operations Research
Journal of Industrial Information Integration	1	Industrial and Manufacturing Engineering; Information Systems and Management
Journal of Manufacturing Systems	1	Control and Systems Engineering; Hardware and Architecture; Industrial and Manufacturing Engineering; Software
Journal of Cleaner Production	1	Environmental Science; Industrial and Manufacturing Engineering; Renewable Energy, Sustainability and the Environment; Strategy and Management
Technology in Society	1	Business and International Management; Education; Human Factors and Ergonomics; Sociology and Political Science
Process Safety and Environmental Protection	1	Chemical Engineering; Environmental Chemistry; Environmental Engineering; Safety, Risk, Reliability and Quality
Journal of Open Innovation: Technology, Market, and Complexity	1	Development; Economics, Econometrics and Finance; Sociology and Political Science
Business Process Management Journal	1	Business and International Management, Business and International Management
Heliyon	1	Multidisciplinary
Current Research in Environmental Sustainability	1	Environmental Science
PeerJ Computer Science	1	Computer Science
SN Computer Science	1	Computational Theory and Mathematics; Computer Graphics and Computer-Aided Design; Computer Networks and Communications; Computer Science Applications; Computer Science; Artificial Intelligence
Processes	1	Chemical Engineering; Process Chemistry and Technology; Bioengineering
Futures	1	Business and International Management; Development; Sociology and Political Science
Journal of Industrial Engineering and Management (JIEM)	1	Industrial and Manufacturing Engineering; Strategy and Management
Asian Journal of Business Research	1	Political Science and International Relations; Sociology and Political Science; Business and International Management; Marketing; Strategy and Management
Journal of Commercial Biotechnology	1	Biotechnology; Economics and Econometrics; Management of Technology and Innovation
International Journal of Technology, Innovation and Management (IJTIM)	1	Management of Technology and Innovation
JISR management and social sciences & economics	1	Management Science, Social Sciences and Economics
Journal of Supply Chain and Customer Relationship Management	1	Business, Management and Accounting
Management and Economics Review	1	Business, Management and Accounting
Transportes	1	Business, Management and Accounting

Table 2. Overview of the review framework

Paper	Research Objectives and findings	Topics	Methodology	Value Chain Phase	Technology included in the study	Limitations and Future Research for PI-DT Management
Silva et al. 2020	To represent current PI-DT Trends, Barriers, and Challenges.	Predictive Maintenance; Quality control and product design; HR Management; Patient Engagement and Monitoring.	Qualitative, Semi structured Interviews with Field Experts	MK, SC, MA	AR,VR,3D,IoT,Cloud,Big Data, AI	• More research to address Human Performance with Robots in MK; • Understanding Data Integration for the SC through the adoption of DT technologies; • More research deepening the organizational culture shift is needed to address DT Technologies.
Shahzeb Zulfiqar et al. 2022	The paper discusses the potential of Blockchain technology to address current challenges for PI-SC management in Pakistan. It sheds light on various aspects such as the counterfeit medicine market, existing systems, lack of Blockchain expertise, and the need to clarify the role of Blockchain.	Cultural Change; Technology Acceptance; Training; Managerial Awareness and Leadership; Traceability; Product Quality Control; Logistics; Procurement; Track of Products; Need for standardized data sharing protocols; Waste Management	Qualitative, Semi structured Interviews with Field Experts	SC	Blockchain, IoT	• More field research linking procurement of raw materials, Counterfeited drugs, and SC Trust • More research for improving the regulatory framework on tracking counterfeited drugs; • Conduct similar study in other countries in order to uncover cultural biases.
Alharthi, Cerotti, and Far 2020	The objectives of this research were: (1) to explore blockchain opportunities and address related problems in the PI-SC; (2) To identify barriers and challenges related to the adoption and implementation of blockchain; (3) To develop guidelines for successful implementation of blockchain technology in the context of Saudi Arabia; (4) To investigate professionals' perceptions regarding the impact of blockchain adoption in the PI-SC.	Maintenance and Monitoring; Productive Process Reengineering; Scalability; Decision Making and Support; HR Management; Organizational Communication and Learning; Regulatory Compliance.	Qualitative, Semi structured Interviews with Field Experts	SC	Blockchain, Cloud	• Extend this research framework to non-developing countries; • To operationalize and validate the developed theoretical framework through quantitative analysis.
Satwekar et al. 2022	To design a Framework for Digital Innovation Management Orchestration.	Process and Organizational Change; Agile and Flexible Decision-making; Business Model transformation; Technology Lifecycle monitoring.	Qualitative, Action Design Research	MK	AI	• Application of the developed Framework with other technologies in the context of healthcare organizations.
Coito et al. 2022	To establish a method to evaluate the introduction of automation QC laboratories, through a simulation model.	Resource management; Manual Work Reduction; Equipment Maintenance; Job Allocation; Resource efficiency.	Quantitative	MK	Digital Twins	• Adopt the established methodology with more advanced heuristics and dynamic scheduling.
Festa et al. 2018	Creation of a theoretical Framework that addresses the impact of Big Data on Process efficiency and Efficacy.	Business Process Management; Data Standardization; Information Systems Management.	Qualitative, Multiple Case study	DD, CT, MK, SC, MA	Big Data, IoT	• Quantitative Analysis testing the influence among knowledge process standardization (dependent variable) and big data (independent variable) in ambidextrous organizations; • Demonstrating the effectiveness of the developed theoretical Framework through empirical analysis or multiple case studies.
Ghadge et al. 2022	This research aims to link Blockchain to PI-SC building a conceptual framework for implementation and a future research agenda.	Maintenance and Monitoring; Productive Process Reengineering; SC Management; Business Model Innovation; Data Governance and Analytics; Scalability; Decision Making and Support; HR	Literature Review	CT, SC	Blockchain, IoT, Big Data, Cybersecurity	• To address how Blockchain can enhance sustainability and Circular economy in PI-SC; • To understand how Blockchain can improve Drug Recall Management;

		Management; Organizational Communication and Learning; Environmental; Impact on Patient; Regulatory Compliance; Social/Governance.				• To address how to align and standardize Blockchain practices for data collection on a large scale; • More research addressing the transition process from pilot projects to permanent systems; • More studies addressing the scalability for a solid transaction mechanism across different organizations through smart contracts; • Improving the interoperability and compatibility of Blockchain within a wider Industry 4.0 digital technology's ecosystem; • Building performance measurement for Blockchain.
Zakari et al. 2022	Represent the use of Blockchain in PI	Quality control and product design; SC Transparency and Trust; Logistics; Cold Chain; Data Governance; Technology Acceptance; Workforce Turnover; Regulatory Protocols.	Literature Review	SC, MA	Blockchain	• To address how enhanced Data governance through Cloud Computing can prevent counterfeit drugs circulation; • Investigating the interaction between 5G and Blockchain to enhance Cold Chain Control • Barriers to Blockchain adoption: Trust, transparency, Scalability, Integration and Cost; • Development of universal guidelines and rules to drive Blockchain adoption.
Hosseini Bamakan et al. 2021	To represent through Case Studies Blockchain applications in PI.	Data Serialization and Traceability; Data Integrity, Security, Privacy and Transparency; and Waste Management.	Qualitative, Multiple Case study	SC, MA	Blockchain, IoT	• To study Cold Chain Management addressing the Creation, Deployment, Execution and Completion of Smart contracts: • How different Blockchain-based PI Cold Chains can cooperate and interact with each other.
Al-Shura et al. 2018	Through Technology–Organization–Environment (TOE) framework, this article investigates the influence of cloud computing adoption in Jordan PI MK companies. This article addresses 8 critical success factors: *Complexity, compatibility, Relative advantage, top management support, firm size, technical readiness, competitive pressure, and trading partner pressure*.	Business Model Transformation; Cultural Change; Technology Acceptance.	Quantitative	MK	Cloud	• Estimate through real case scenarios whether Cloud Services are compatible with the current settings; • Apply the provided model including more Small sized PI firms; • Apply the provided model making cross-country comparisons.
Reinhardt, Oliveira, and Ring 2021	To represent current PI-DT Level of adoption, Planned Pathway, Future technology advancements.	Flexible and Agile Decision Making; Quality control and product design; Process Transparency; Workforce turnover; Cold Chain; Real-Time Monitoring.	Survey	MK	AR,VR,3D, IoT, Cloud, Big Data, Cybersecurity	• Investigate Process Automation performance through DT technologies, avoiding siloed Technology/Process research; • Investigate through Technology Acceptance and Organizational Culture Literature the social and Individual's barriers to DT.
Nguyen et al. 2022	To represent the state of art, opportunities and challenges of Big Data Analytics in PI SC.	Shortage avoidance; Visibility and coordination improvement; SC Management; Inventory Management; Product Quality assurance; Sustainability.	Literature Review	SC, MA	Big Data, AI, Cloud	• Need for standardized data sharing protocols; • Address drug shortages and inventory management through forecasting demand models; • Use of Data Analytics to foster SC resilience; • Investigate how to foster data sharing while ensuring regulatory compliance and data privacy; • To conduct Case Studies in the context of PI-SC to understand the main managerial and technological barriers for I4.0 tech adoption; • Shed light on how to match regulatory compliance with data usage.

Shamsuzzoha, Ndzibah, and Kettunen 2020	This study found that implementing a centralized logistics system can have positive impacts on both the environment and the inbound processes.	SC Management; Enhanced Visibility.	Mixed Methods	SC	Big Data, Cloud	• To conduct comprehensive analysis of the inbound shipments and communication with other PI-SC partners.
R. Liu et al. 2021	This study explores the current status of DT of sales in Japanese PI and identifies nine 9 initiatives: *"Creating Quality Patient Touch Points and Communication," "Responding to Changing Patient Demands," "Using Data and Information under Governance," "Analyzing Patient Data with AI," "Cross-functional Data Sharing," "Utilizing the Data Platform," "Cultivating Human Talent," "Changing Employees' Mindsets," "Exploring New Value Creation."*	Productive Process Reengineering; SC Management; Tracking, Transparency and Trust; Data Governance and Analytics; Scalability; Decision Making and Support; HR Management; Organizational Communication and Learning; Environmental; Impact on Patient; Regulatory Compliance; Social/Governance.	Qualitative, Semi structured Interviews with Field Experts	MA	AI, Big Data	• More research analyzing DT of PI sales is needed, possibly, by extending this research with a more diversified sample, ranging from early to experienced DT adopters; • To build a digital maturity model based on these research findings to assess PI companies' capacity to engage the DT of sales.
Chen et al. 2020	This study aims to provide a detailed overview of Digital Twin's state of art and horizons in Pharma and Biopharma MK.	Real Time Monitoring; Agile and Flexible Decision Making; Business Model Transformation.	Literature Review	MK	Digital Twin, Cloud	• More investigations aiming at advanced data aggregation, mining, storage, and visualization methods; • Demonstrate the value of Real-Time monitoring for enhancing the PI regulatory approval process.
Wu and He 2020	This study proposes and applies a framework to investigate the transfer of innovative drug discoveries from biopharma DIY labs to established PI R&D networks, with the ultimate goal of transforming them into marketable products.	Productive Process Reengineering; SC Management; Tracking, Transparency and Trust; Business Model Innovation; Data Governance and Analytics; Scalability; Decision Making and Support; Organizational Communication and Learning; Regulatory Compliance.	Qualitative, Case Study - Semi structured Interviews with Field Experts	DD	3D	• To analyze various innovation ecosystems in order to produce a broader range of evidence on the makeup of bio-PI innovation systems; • Conduct research on the links between the obstacles/facilitators and the innovative input of do-it-yourself (DIY) laboratories and development (R&D) networks.
Aquino et al. 2018	Investigating the future potential avenues of using 3D printing for personalized medicine.	Personalized Medicine; Customization; Rapid Prototypting; Product Quality.	Qualitative, Semi structured Interviews with Field Experts	DD, CT, MK, SC, MA	3D, AI	• Understanding levels of acceptance by Pharmacists, Physicians and Patients in using 3D printed drugs; • Addressing the benefits for Pharma manufacturers of abandoning standardized production of drug; • How 3D printings interact with Distribution, Logistics, and Warehouse Management.
Burrichter, Chen, and Marco 2022	To investigate how DT technologies interacts with HRM companies in PI for sustainable development.	Productive Process Reengineering; Data Governance and Analytics; Scalability; HR Management.	Quantitative	MA		• More investigation understanding the Role of AI for recruitment process.
Solfa 2022	To evaluate the impact of cybersecurity and SC risk management on digital operations. This paper identifies that (1) cybersecurity increases digital operations efficiency; (2) adopting digital operations allows to efficient SC risk management; and (3) cybersecurity allows to efficient SC risk management.	Maintenance and Monitoring; Productive Process Reengineering; Decision Making and Support.	Quantitative	MK, SC	Cybersecurity	• To replicate the research model across different geographical areas.
A. Sharma, Kaur, and Singh 2020	To represent IoT applications in SC and MK phases of PI.	Cold Chain Control; Product Quality; Lack of Transparency; Minimizing failure Costs of the equipment; Real-	Qualitative, Semi structured Interviews with Field Experts	MK, SC	IoT, AR, VR	• To address how IoT enhances patient satisfaction value using Big Data Analytics; • The interaction of Manual Labor, IoT, AR and VR.

		Time Monitoring; Warehouse Management; Drug Safety Assurance				
M. Sharma et al. 2022	To investigate the barriers critical to PI 5.0 adoption and identify effective solution initiatives to overcome these barriers.	Productive Process Reengineering; Tracking, Transparency and Trust; Data Governance and Analytics; Scalability; Decision Making and Support; HR Management; Organizational Communication and Learning; Impact on Patient; Regulatory Compliance.	Mixed Methods	MK, SC, MA	IoT, Cloud, Big Data, Blockchain, Digital Twin, AI, Robot, AR, VR	• Further research may investigate, through quantitative analysis, the links between solution initiatives and the barriers identified in this paper; • This fieldwork was limited to German PI Experts, future research may extend the current framework to other countries.
Arief et al. 2022	This study aims to address the main competencies needed for PI-DT (critical thinking, bioinformatics, entrepreneurial thinking, digital skills, intrapreneurial skills, research skills, regulatory compliance, and data ethics) and digital levels (simplification, automatization, integrated system, digital transformation, disease prediction).	HR management, Technology Innovation Readiness; Regulatory compliance.	Mixed Methods	DD, CT, MK, SC, MA	IoT, Cloud, Big Data, Blockchain, AI, Robots, 3D, AR, VR	• Test research findings on a larger sample • Integrate research findings with HR practices; • To map PI-DT readiness on an international perspective.
Ding 2018	To investigate the main opportunities and barriers to implement Industry 4.0 technologies and sustainable practices within PI SC.	SC Management, Sustainability; Training and Development; Quality Control and Safety; Advanced Technology; Precision Medicine.	Literature Review	MK, SC	IoT, Cloud, Big Data, 3D	• To conduct a Life Cycle Assessment (LCA) to demonstrate enhanced Inventory management performance, adjustment of production and optimization of MK operations; • Urge new regulations to accept new Industry 4.0 practices in Pharma; • New standardization of data sharing systems • Focus research on Social Impacts of PI-SC, by using organization behavior theories or tools such as “Social Life Cycle Assessment”; • To investigate how to enhance responsiveness of drug recall SC through cross-company symbiosis to reduce defected/counterfeited drug circulation; • To examine how smart logistics can improve sustainable and agile delivery service; • Have cross-country investigations about Hospital procurement; • Design appropriate Environmental, Social, and Governance (ESG) indicators and assessment systems; • Review legal frameworks and regulations to integrate industry 4.0 technologies and sustainable practices.
Lima Jr et al. 2021	This study aims to identify the main challenges related to the PI-SC and its associated technological advances based on product characteristics, vehicle capabilities, and logistics service provider’s expertise.	Maintenance and Monitoring; Organizational Communication and Learning; Impact on Patient.	Literature Review	SC	IoT, Big Data, Blockchain	• More research about the maintenance and logistic support in the Latin America Cold Chain; • Understanding the integration between IoT and Blockchain for effective SCM; • Deepening new regulation strategies to create incentives in using Dt technologies.
Argiyantari, Simatupang, and Basri 2020	To address Literature relating to the Lean principle application within PI-SC.	Maintenance and Monitoring; Productive Process Reengineering; Scalability; Decision Making and Support; HR Management; Organizational Communication and Learning; Regulatory Compliance.	Literature Review	SC, MK	IoT	• To investigate how IoT influences lean practices, concerning inventory control or Product visibility. A potential solution might be to conduct Action Research, since the scarcity of deployment of this research methodology.
Denicolai and Previtali 2020	To understand key dimensions and discuss theoretical foundations of Business Model	Precision Medicine; Business Model Transformation; Patient Centered	Qualitative, multiple case study	DD, MA, CT, SC	3D,Big Data, AI, IoT, Cloud	• More case studies engaging diversified companies in terms of capabilities and healthcare niche; • Verify through quantitative studies the theoretical contributions of this paper.

	Transformation of PI companies because of Precision medicine.	approaches; SC Management; CT Efficiency; Regulatory Compliance.				
Kordestani, Oghazi, and Mostaghel 2023	Collecting Knowledge of PI blockchains, identifying (1) features of smart contracts in the PI-SC, (2) role of smart contracts to fight counterfeited drugs, (3) Future research agenda.	Productive Process Reengineering; SC Management; Scalability; HR Management; Organizational Communication and Learning; Environmental; Impact on Patient; Regulatory Compliance; Social/Governance.	Literature Review	SC, MA	Blockchain, IoT	• Further studies addressing the adoption of smart contract's potential against counterfeited drugs. • Need to design new protocols for safeguarding data safety and user's privacy; • To investigate how smart contracts create value for stakeholders such as patients, retailers, and manufacturers by removing intermediaries and enhancing visibility; • How smart contracts might reduce waste by enhancing visibility of SC.
Ramos et al. 2022	To establish 3D printing technology road mapping for the fields of DD and in vitro disease models. This research is of particular interest as it focuses on a startup company.	Bioprinting, Business Model Innovation; Crowdsourcing; Startup R&D	Qualitative, Case study	DD, CT	3D, IoT, AI, Robots	• Exploration of 3D printing R&D through crowdsourcing; • Multidisciplinary figures to integrate 3D printing in Drug and Discovery.
Saha et al. 2022	Adopting Emerging Technologies enhances Pharma SC Performance through the mediating effect of MK, distribution, and consumption processes.	Flexible and Agile Decision Making; Workforce turnover; Logistics and Procurement; Increasing Product Quality.	Quantitative	SC, MK	3D, IoT, Cloud, Blockchain, AI, Big Data	• To address AI deployment for Centralized or Decentralized SC; • Risk Identification across SC partners through AI; • To investigate how PI organizations can reach a Resilient Sustainability Performance (Integration with UN's SDGs Goals); • Engage studies in PI-organizations within developed countries.
Kulkov 2021	This study sheds the light on how AI influences and support for different business processes of PI companies.	Warehouse Management; Predictive Maintenance; Business Process Reengineering; HR; Patient Engagement.	Qualitative, Semi structured Interviews with Field Experts	DD, CT, MK, SC, MA	AR, VR, Robot, Big Data, AI	• Comparing AI application experience of other healthcare niches to assess opportunities for Business Model Transformation; • Need for more Case Studies dealing with AI and PI VCP; • How Venture Capitalism can influence AI based DD.
Kumar Detwal et al. 2023	To introduce a model for choosing vendor contract terms using machine learning specifically designed for direct drop-shipping within a worldwide omnichannel pharmaceutical supply chain.	Tracking, Transparency and Trust; Data Governance and Analytics; Real Time Monitoring; Agile and Flexible Decision Making; Business Model Transformation.	Quantitative	SC	AI, Big Data, Robot	• This model could be expanded upon to create a model for a supply chain network that manages order fulfillment via regional distribution centers. • This research was mainly focused on "Air Transportations"; future research could be further validated with Trucks, Rails, or waterways as other shipment modes.
M. Sharma et al. 2023	This article suggests a framework aiming to transition from I4.0 to Industry 4.0 + (I4.0+), highlighting the significance of collaboration between humans and machines. This collaboration is seen as pivotal in advancing towards sustainable supply chain management.	Predictive Maintenance; Quality control and product design; Maintenance and Monitoring; Productive Process Reengineering; Scalability; Decision Making and Support; Flexible and Agile Decision Making.	Qualitative, Semi structured Interviews with Field Experts	MK, SC	Big Data, Cloud, IoT, Blockchain, AI, Robots	• This article is based on expert opinions from India Practitioners, the generalizability of results should be tested across different countries. • Validate the developed Framework through cross-sectional and Longitudinal quantitative works.
Ertz, Centobelli, and Cerchione 2022	This article conducts a bibliometric and network analysis to explore how digital and sustainable technologies have influenced the cold chain sector.	Cold Chain Management; Logistics; Sustainability; Traceability; Energy Saving; Product Quality; Temperature Monitoring; IT infrastructure Renovation; Agile Decision Making; Decision Making and Support.	Bibliometric Analysis	SC	Blockchain, IoT, Big Data, Cybersecurity, AI, 3D	• This study is limited to Web of Science repository; future research should include other databases. • This investigation was focused mainly on Supply Chain and Logistics; future research should provide more comprehensive overview on the whole Pharmaceutical Value Chain.
Rathi, Majumdar, and Chatterjee 2024	This Paper discussed how the Covid Pandemic enhanced the use of AI for Pharmaceutical Innovation.	Decision Making and Support; Regulatory Compliance; Impact on Patient; Patent Protection.	Quantitative	DD	AI	• Future researchers can further expand on this analysis to delve into the specific advantages or disadvantages associated with the growing utilization of AI.

Junaid et al. 2023	This research aims to investigate the interconnections between supply chain dynamic capabilities, supply chain integration, supply chain resilience, sustainable competitive advantage, and sustainable supply chain performance.	Supply Chain Resilience; Sustainability; Environmental Performance; Decision Making and Support; Flexible and Agile Decision Making.	Quantitative	SC	AI, Big Data, IoT, Blockchain, Cloud	• This Paper's outcomes are limited on Pakistan's data; future research may conduct comparative analysis between Developed and Underdeveloped Countries' performance. • This study limits its focus on only three elements—sensing, learning, and coordinating—as part of the supply chain dynamic capability, which provides supply chain visibility. Future research could broaden this scope by incorporating additional factors, such as integration, into the pool of supply chain dynamic capabilities.

Abbreviations: Drug Development (DD), Clinical Trials (CT), Manufacturing (MK), Supply Chain (SC), Market Access (MA), Pharmaceutical Industry (PI), Digital Transformation (DT), Artificial Intelligence (AI), Augmented Reality (AR), Virtual Reality (VR), Internet of Things (IoT)

Table 3. Future research agenda for the Operations Management Research area

Research Topic	Aggregated Area	Possible Related Technologies	Value Chain	Literature	Research Questions
Predictive maintenance	Maintenance and Monitoring	AI, IoT	MK, SC	Kulkov 2021; Silva et al. 2020; Reinhardt, Oliveira, and Ring 2021; Bamakan, Moghaddam, and Manshadi 2021; A. Sharma, Kaur, and Singh 2020; Coito et al. 2022; Arief et al. 2022; Lima Jr et al. 2021; M. Sharma et al. 2023; Ding 2018	• How can AI and IoT-based predictive maintenance impact the reduction of downtime, maintenance costs, and equipment failure rates in pharmaceutical manufacturing operations? • How can AI and IoT-based predictive maintenance systems enable proactive identification of potential risks and deviations in supply chain operations to ensure product safety and integrity?
Process Visualization and simulation	Maintenance and Monitoring	Digital Twins, AR, VR, AI	MK	Chen et al. 2020; Coito et al. 2022; Kumar Detwal et al. 2023; M. Sharma et al. 2023; Ertz, Centobelli, and Cerchione 2022	• How can AR and VR technologies be utilized to improve training, process monitoring, and decision-making in pharmaceutical manufacturing? • How can process visualization and simulation, augmented by AI, AR, VR and Digital Twin technologies, support quality control, regulatory compliance, and risk management in pharmaceutical manufacturing?
Product Quality Control	Maintenance and Monitoring	AI, Digital Twins, Blockchain, IoT, 3D, Big Data	MK, SC	Kulkov 2021; Chen et al. 2020; Zakari et al. 2022; Saha et al. 2022; Silva et al. 2020; Hosseini Bamakan, Ghasemzadeh Moghaddam, and Dehghan Manshadi 2021; A. Sharma, Kaur, and Singh 2020; Aquino et al. 2018; Ding 2018; Coito et al. 2022; Arief et al. 2022; Shahzeb Zulfiqar et al. 2022; Lima Jr et al. 2021; Alharthi, Cerotti, and Far 2020; Argiyantari, Simatupang, and Basri 2020; M. Sharma et al. 2023; Ertz, Centobelli, and Cerchione 2022; Nguyen et al. 2022	• How can big data analytics and advanced statistical techniques be applied to large-scale quality control data sets in the pharmaceutical industry, leading to improved process optimization and defect detection?
Real-Time Monitoring	Maintenance and Monitoring	Blockchain, AI, IoT, Digital Twins	CT, MK, SC	Kulkov 2021; Chen et al. 2020; Silva et al. 2020; A. Sharma, Kaur, and Singh 2020; Ding 2018; Arief et al. 2022; M. Sharma et al. 2022; Lima Jr et al. 2021; Kordestani, Oghazi, and Mostaghel 2023; Del and Solfa 2022; Reinhardt, Oliveira, and Ring 2020; Kumar Detwal et al. 2023; M. Sharma et al. 2023; Ertz, Centobelli, and Cerchione 2022; Junaid et al. 2023	• How can real-time monitoring systems enhance the agility and responsiveness of the pharmaceutical supply chain, enabling faster decision-making, reduced lead times, and improved user's satisfaction? • Can IoT and AI deployment improve clinical trials efficiency through Blockchain based data protection?
Business Process Management	Productive Process Reengineering	Digital Twins, AI, Big Data, VR, AR, AI, Cloud, Digital Twins, 3D	DD, CT, MK, SC	Satwekar et al., 2022; Kulkov 2021; Festa et al. 2018; Burrichter, Chen, and Marco 2022; Ghadge et al. 2022; Argiyantari, Simatupang, and Basri 2020; Chen et al. 2020; Aquino et al. 2018; Wu and He 2020; Kumar Detwal et al. 2023; M. Sharma et al. 2023; Ertz, Centobelli, and Cerchione 2022; Junaid et al. 2023	• How can cloud computing adoption improve communication, coordination and efficiency of manufacturing activities?
Flexible and Agile production lines	Productive Process Reengineering	IoT, AI, VR, AR, 3D	MK, MA	Chen et al. 2020; Aquino et al. 2018; Ding 2018; M. Sharma et al. 2022; Kumar Detwal et al. 2023; Ertz, Centobelli, and Cerchione 2022; Junaid et al. 2023	• How do flexible and agile production systems impact supply chain coordination, responsiveness, and customer satisfaction, particularly in adjusting production to meet dynamic market demands?
Manual Work Reduction	Productive Process Reengineering	Robots, AI, AR, VR, IoT, Digital Twins	MK	Kulkov 2021; Silva et al. 2020; Sharma, Kaur, and Singh 2020; Coito et al. 2022; M. Sharma et al. 2023	• How to evaluate IoT effectiveness in reducing manual interventions, optimizing the utilization of equipment and resources in pharmaceutical production lines?
Production Lead Time	Productive Process Reengineering	AI, IoT, 3D	MK	Kulkov 2021; Silva et al. 2020; Sharma, Kaur, and Singh 2020; Aquino et al. 2018	• How can digital process automation and workflow optimization, utilizing AI and IoT technologies, contribute to the reduction of lead time and increase agility in pharmaceutical manufacturing?
Reduced Bureaucracy	Productive Process Reengineering	AI, Cloud, Blockchain	MK, MA	Kulkov 2021; Zakari et al. 2022; Silva et al. 2020; Alharthi, Cerotti, and Far 2020	• What are the key bureaucratic challenges and bottlenecks faced in the manufacturing phase of the pharmaceutical value chain, and how can digital technologies be leveraged to mitigate these challenges?

					• How can cloud-based solutions facilitate collaboration and information sharing among different stakeholders in the pharmaceutical value chain to reduce bureaucracy and enhance operational efficiency? • How can regulatory frameworks and policies be adapted to foster the digital transformation of pharmaceutical manufacturing and effectively address potential challenges related to reduced bureaucracy?
Centralized and Decentralized SC	Supply Chain Management	3D, IoT, Cloud, Blockchain, AI, Big Data	SC	Saha et al. 2022; Shamsuzzoha, Ndzibah, and Kettunen 2020; Kumar Detwal et al. 2023; M. Sharma et al. 2023; Junaid et al. 2023	• What are the key advantages and disadvantages of implementing a centralized supply chain model in the pharmaceutical industry, and how does it impact operational efficiency and cost-effectiveness in other phases? • What are the critical success factors for transitioning from a traditional decentralized supply chain model to a centralized model in the pharmaceutical industry, and how can organizations effectively manage this transition?
Inventory Maanagement	Supply Chain Management	VR, AI, AR, 3D, Big Data, Cloud, Robots, IoT	MK, SC	Kulkov 2021; Saha et al. 2022; Ding 2018; Nguyen et al. 2022; Lima Jr et al. 2021; Kordestani, Oghazi, and Mostaghel 2023; Argiyantari, Simatupang, and Basri 2020; Reinhardt, Oliveira, and Ring 2021; Sharma, Kaur, and Singh 2020; Aquino et al. 2018; Nguyen et al. 2022; Arief et al. 2022; Solfa 2022; Kumar Detwal et al. 2023; Ertz, Centobelli, and Cerchione 2022; Junaid et al. 2023	• How can cloud-based inventory management systems enhance data accessibility, collaboration, and decision-making efficiency across the pharmaceutical manufacturing and supply chain operations? • What are the critical success factors for implementing inventory visibility and synchronization initiatives across multiple stakeholders in the pharmaceutical supply chain? • How can inventory management practices be aligned with sustainability goals in the pharmaceutical industry, considering factors such as reducing waste, optimizing transportation, and minimizing environmental impact? • How can AR and VR technologies be utilized to optimize warehouse layout and design in the pharmaceutical industry, considering factors such as reduction of manual labor, space utilization, inventory management, and picking efficiency? • What are the environmental sustainability implications of digital warehouse management technologies in the pharmaceutical industry, and how can organizations measure and minimize their carbon footprint and waste generation?
Logistics Management	Supply Chain Management	AI, Blockchain, IoT	SC	Kulkov 2021; Zakari et al. 2022; Saha et al. 2022; Aquino et al. 2018; Ding 2018; Nguyen et al. 2022; Zulfiqar et al. 2022; Lima Jr et al. 2021; Argiyantari, Simatupang, and Basri 2020; M. Sharma et al. 2023; Ertz, Centobelli, and Cerchione 2022; Junaid et al. 2023	• How can AI algorithms and machine learning techniques be utilized to optimize route planning, transportation scheduling, and resource allocation in pharmaceutical logistics operations? • What are the implications of adopting autonomous vehicles, drones, and robotics technologies in last-mile delivery and distribution processes within the pharmaceutical logistics context? • What are the critical success factors for implementing green and sustainable practices in pharmaceutical logistics, including reducing carbon emissions, optimizing packaging materials, and minimizing waste generation?
Supply Chain Resilience	Supply Chain Management	Blockchain	SC	Saha et al. 2022; Solfa 2022; Kumar Detwal et al. 2023; Ertz, Centobelli, and Cerchione 2022; Junaid et al. 2023	• How can supply chain resilience be enhanced through the adoption of Blockchain? • What are the implications of adopting blockchain-based smart contracts and decentralized platforms for enhancing trust, transparency, and collaboration among supply chain partners in the pharmaceutical industry? • What are the key performance indicators and metrics for measuring and benchmarking supply chain resilience in the pharmaceutical industry, and how can organizations track and evaluate their progress towards achieving resilience goals?

Track of Products and Material's Procurement	Tracking, Transparency and Trust	AI, IoT, Blockchain, Cloud	SC, MK	Sharma, Kaur, and Singh 2020; Ding 2018; Arief et al. 2022; Zulfiqar et al. 2022; Lima Jr et al. 2021; Solfa 2022; Satwekar et al. 2022; Kulkov 2021; Chen et al. 2020; Saha et al. 2022; Shamsuzzoha, Ndzibah, and Kettunen 2020; Denicolai and Previtali 2020; M. Sharma et al. 2022; Zakari et al. 2022; Zulfiqar et al. 2022; Ghadge et al. 2022; Hosseini Bamakan et al. 2021; Nguyen et al. 2022; Ertz, Centobelli, and Cerchione 2022; Junaid et al. 2023	• What are the potential applications of blockchain technology in enhancing transparency, traceability, and security in material procurement and supplier's verification? • What are the key challenges and opportunities in utilizing predictive analytics models to optimize procurement decision-making, including strategic sourcing, order quantity determination, and lead time management in the pharmaceutical supply chain?
Cold Chain Control Monitoring	Tracking, Transparency and Trust	Blockchain, IoT	SC	(Zakari et al. 2022)(Hosseini Bamakan et al. 2021)(Sharma, Kaur, and Singh 2020)(Ding 2018)(Lima Jr et al. 2021)(Ghadge et al. 2022)(Argiyantari, Simatupang, and Basri 2020)(Solfa 2022)(Shamsuzzoha, Ndzibah, and Kettunen 2020)(Alharthi, Cerotti, and Far 2020)(Ghadge et al. 2022)(Kulkov 2021)(Saha et al. 2022) (M. Sharma et al., 2023) (Ertz et al., 2022)	• How can IoT devices and sensors be integrated into Cold Chain of biological systems to enable real-time tracking and monitoring of products, temperature-sensitive items, and inventory levels? • What are the critical success factors and best practices for implementing a robust cold chain control system that ensures compliance with regulatory requirements, reduces waste due to expired products, and maintains product quality and efficacy throughout the supply chain?
Lack of Transparency	Tracking, Transparency and Trust	Blockchain, IoT, Big Data	SC	Zakari et al. 2022; Sharma, Kaur, and Singh 2020; Ding 2018; Nguyen et al. 2022; Shamsuzzoha, Ndzibah, and Kettunen 2020; Kordestani, Oghazi, and Mostaghel 2023; Solfa 2022; Alharthi, Cerotti, and Far 2020; Ghadge et al. 2022	• How can IoT and sensor technologies be utilized to capture and collect real-time data in the pharmaceutical supply chain, enabling improved visibility, accountability, and transparency in the movement and storage of products? • How can collaborative platforms and information sharing systems be designed and implemented to facilitate transparency and trust among supply chain partners in the pharmaceutical industry, considering the sensitivity and confidentiality of health information?
Lack of Trust	Tracking, Transparency and Trust	Blockchain	SC	Zakari et al. 2022; M. Sharma et al. 2022; Ertz, Centobelli, and Cerchione 2022	• How can blockchain technology be utilized to enhance trust and security in the pharmaceutical supply chain, particularly in ensuring the integrity of product information, verifying the authenticity of drugs, and facilitating transparent transactions between supply chain partners? • How can smart contract technology be integrated into the pharmaceutical supply chain to automate trust-based processes, such as verification of product provenance, compliance with regulations, and execution of contractual agreements between stakeholders?

Abbreviations: Drug Development (DD), Clinical Trials (CT), Manufacturing (MK), Supply Chain (SC), Market Access (MA), Pharmaceutical Industry (PI), Digital Transformation (DT), Artificial Intelligence (AI), Augmented Reality (AR), Virtual Reality (VR), Internet of Things (IoT)

Table 4. Future research agenda for the Strategic Management Research area

Research Topic	Aggregated Area	Possible Related Technologies	Value Chain	Literature	Research Questions
New Marketing Channels	Business Model Innovation	AI, Big Data	MA	Kulkov 2021; Liu et al. 2021; Kumar Detwal et al. 2023; Junaid et al. 2023	• How can the integration of AI and big data analytics enable pharmaceutical companies to identify and target new customer segments through personalized marketing strategies? • What are the potential risks and challenges associated with adopting new marketing channels driven by AI and big data, and how can organizations mitigate these risks while maximizing the overall performance? • How do the regulatory and legal frameworks impact the adoption and implementation of AI-driven marketing channels in the pharmaceutical industry, and what strategies can organizations employ to navigate these complexities?
New Value Creation	Business Model Innovation	Digital Twins, AI, Big Data, VR, AR, AI, Cloud, Digital Twins, 3D	DD, CT, MK, SC, MA	Saha et al. 2022; Satwekar et al. 2022; Kulkov 2021; Silva et al. 2020; Denicolai and Previtali 2020; Ramos et al. 2022; Liu et al. 2021; Festa et al. 2018; Burrichter, Chen, and Marco 2022; Ghadge et al. 2022; Argiyantari, Simatupang, and Basri 2020; Chen et al. 2020; Aquino et al. 2018; Wu and He 2020; M. Sharma et al. 2023; Ertz, Centobelli, and Cerchione 2022; Rathi, Majumdar, and Chatterjee 2024	• What are the key challenges and opportunities associated with integrating AI, big data, and advanced analytics into clinical trial processes, and how can organizations leverage these technologies to enhance patient recruitment, trial design, and overall trial efficiency for a competitive edge? • How can the implementation of digital technologies such as AI, VR, and AR revolutionize manufacturing processes in the pharmaceutical industry, improving productivity, quality control, and supply chain integration to achieve superior performance? • What are the implications of business process transformation and the adoption of digital technologies on market access strategies, pricing models, and reimbursement negotiations in the pharmaceutical industry, and how can organizations align these processes to secure a competitive position in the market?
Need of New Business Model	Business Model Innovation	IoT, 3D, AI, Blockchain, Big Data, Digital Twins	MA, MK, SC, DD, CT	Denicolai and Previtali 2020; Al-Shura et al. 2018; Wu and He 2020; Liu et al. 2021; Ghadge et al. 2022; Kumar Detwal et al. 2023; Rathi, Majumdar, and Chatterjee 2024	• Does digital technology deployment enhance business performance through Sustainable business model innovation? • What are the implications of incorporating sustainability considerations into business model innovation, and how can organizations balance environmental, social, and economic factors to create sustainable value propositions that differentiate them in the market and drive competitive advantage?
Smart contracts	Business Model Innovation	Blockchain	SC	Ghadge et al. 2022; Hosseini Bamakan et al. 2021; Ding 2018; Kordestani, Oghazi, and Mostaghel 2023	• How can smart contracts facilitate the automation and streamlining of compliance and regulatory requirements in the pharmaceutical supply chain, ensuring adherence to quality standards and regulatory frameworks? • How can smart contracts facilitate the implementation of sustainable and responsible sourcing practices in the pharmaceutical supply chain, ensuring ethical procurement and fair trade, and how can organizations leverage this to differentiate themselves and achieve superior peerformance?
Patient Retention	Data Governance and Analytics	AI, Big Data	MA	Kulkov 2021; Liu et al. 2021	• How can personalized medicine and targeted interventions supported by AI and big data analytics improve patient adherence to treatment regimens and increase overall patient retention rates? • How can pharmaceutical companies leverage digital channels, such as social media and online communities, to engage and connect with patients, creating a sense of belonging and fostering a patient community that enhances patient retention and superior performance?
Data Accessibility, Governance, Transparency, Mining and	Data Governance and Analytics	Blockchain, AI, Big Data,	MK, SC, MA	Kulkov 2021; Zakari et al. 2022; Silva et al. 2020; Sharma, Kaur, and Singh 2020; Nguyen et al. 2022; Liu et al. 2021; Kumar Detwal et al. 2023; Rathi, Majumdar, and Chatterjee 2024	• How can data mining and analytics be employed to identify inefficiencies and bottlenecks in pharmaceutical manufacturing processes, supply chain operations, and market access strategies, allowing companies to optimize resource allocation, reduce costs, and improve speed to market, thereby gaining a competitive advantage?

Demand of Data					• What are the barriers and enablers to data sharing and collaboration among different stakeholders in the pharmaceutical industry, and how can innovative data-sharing platforms and incentives be designed to foster collaboration, knowledge exchange, and collective learning, driving a superior performance for all parties involved?
Forecasting production to Demand, Sales and Profits	Data Governance and Analytics	AI, Big Data, Digital Twins, IoT	MK, SC, MA	Kulkov 2021; Saha et al. 2022; Liu et al. 2021; Satwekar et al. 2022; Chen et al. 2020; Kumar Detwal et al. 2023; M. Sharma et al. 2023; Ertz, Centobelli, and Cerchione 2022	• What are the key challenges and opportunities in integrating real-time data from IoT devices and digital twins into production forecasting models, and how can the utilization of such data sources enhance the accuracy and timeliness of production forecasts, leading to improved profitability and a competitive edge in the market? • What are the key success factors in developing collaborative forecasting models and platforms that enable cross-functional collaboration and information sharing among different stakeholders, such as manufacturers, distributors, and healthcare providers, to improve forecasting accuracy and gain a competitive edge through improved supply chain coordination?
Risk Management	Data Governance and Analytics	AI, Digital Twin, Blockchain, IoT	SC, MK	Zakari et al. 2022; Zulfiqar et al. 2022; M. Sharma et al. 2022; Kumar Detwal et al. 2023; Junaid et al. 2023	• What are the key challenges and opportunities in integrating digital twin technology into risk management practices in the pharmaceutical industry? • How can digital twins enhance risk assessment, monitoring, and mitigation strategies, ultimately enabling companies to achieve higher levels of resilience, agility, and competitive advantage? • How can predictive analytics and machine learning algorithms be employed to forecast and prioritize risks in pharmaceutical manufacturing and supply chain operations, enabling companies to allocate resources effectively, optimize risk response strategies, and gain a competitive edge through improved risk-informed decision-making?
Venture Capitalism, Startup financing and acquisition	Scalability	IoT,Cloud,Big Data,Blockchain,AI, Robots, 3D, AR, VR	DD, CT, MK, SC, MA	Arief et al. 2022; Kulkov 2021; Ramos et al. 2022; Wu and He 2020; Liu et al. 2021	• How does the availability of venture capital funding impact the success and growth of digital health startups in the pharmaceutical industry? • How can pharmaceutical companies strategically leverage venture capitalist partnerships to gain a competitive advantage in accessing innovative technologies and driving digital transformation across the value chain?
Lack of Strategic Guidance over digital innovation	Scalability	IoT,Cloud,Big Data,Blockchain,AI, Robots, 3D, AR, VR	DD, CT, MK, SC, MA	Satwekar et al. 2022; Kulkov 2021	• What are the mechanisms and frameworks for assessing the potential impact and scalability of digital innovation initiatives in the pharmaceutical industry, and how can companies evaluate and prioritize investment opportunities to ensure strategic alignment and long-term competitive advantage?

Abbreviations: Drug Development (DD), Clinical Trials (CT), Manufacturing (MK), Supply Chain (SC), Market Access (MA), Pharmaceutical Industry (PI), Digital Transformation (DT), Artificial Intelligence (AI), Augmented Reality (AR), Virtual Reality (VR), Internet of Things (IoT)

Table 5. Future research agenda for the Organization's Theory Research area

Topic	Aggregated Area	Possible Related Technologies	Value Chain	Literature	Research Questions
Agile Decision Making	Decision Making and Support	AI, Big Data, IoT	DD, CT, MK, SC, MA	Kulkov 2021; Silva et al. 2020; Wu and He 2020; Liu et al. 2021; Satwekar et al. 2022; Kumar Detwal et al. 2023; M. Sharma et al. 2023; Ertz, Centobelli, and Cerchione 2022; Junaid et al. 2023	• What role does AI based decision-making play in optimizing the supply chain of pharmaceutical industry? • How can technologies such as AI, big data, and IoT be leveraged to support real-time decision-making, reduce lead times, and improve inventory management?
Process Lifecycle monitoring	Decision Making and Support	IoT, AI, Big Data, Cloud	MK, SC	Satwekar et al. 2022; M. Sharma et al. 2022; Liu et al. 2021; Ghadge et al. 2022; M. Sharma et al. 2023	• What are the key success factors for implementing cloud-based project lifecycle monitoring systems in the pharmaceutical industry? • How does the adoption of cloud technologies influence organizational change in terms of collaboration, data accessibility, and scalability?
Need of new Multidisciplinary Figures and digital trainings	HR Management	IoT,Cloud,Big Data,Blockchain,AI, Robots, 3D, AR, VR, Digital Twins	DD, CT, MK, SC, MA	Reinhardt, Oliveira, and Ring 2021; Arief et al. 2022; Liu et al. 2021; Ding 2018; Denicolai and Previtali 2020; Arief et al. 2022; Ramos et al. 2022; Al-Shura et al. 2018; Zulfiqar et al. 2022; M. Sharma et al. 2022; Wu and He 2020; Burrichter, Chen, and Marco 2022	• What are the challenges, barriers, risks and benefits in implementing new multidisciplinary roles and responsibilities in the pharmaceutical industry's digital transformation? • How can pharmaceutical organizations address these challenges to drive successful organizational change? • How can organizations foster a culture of continuous learning and adaptability through training initiatives to support the digital transformation of the pharmaceutical industry? • How can organizations tailor training programs to address the specific needs and roles within pharmaceutical Value Chain?
Workforce Turnover and Recruitment	HR Management	AI, Robots	DD, CT, MK, SC, MA	Kulkov 2021; Saha et al. 2022; Silva et al. 2020; Arief et al. 2022; M. Sharma et al. 2022; Burrichter, Chen, and Marco 2022; Satwekar et al. 2022; Alharthi, Cerotti, and Far 2020; Reinhardt, Oliveira, and Ring 2021	• How does the reduction of manual work through the implementation of robotic systems and automation technologies impact workforce dynamics, skill requirements, and job roles in pharmaceutical manufacturing? • What are the ethical barriers, benefits and challenges of deploying AI for the recruiting process?
Cultural Change and Technology Acceptance	Organizational Communication and Learning	IoT,Cloud,Big Data,Blockchain,AI, Robots, 3D, AR, VR, Digital Twins	DD, CT, MK, SC, MA	Saha et al. 2022; Silva et al. 2020; Aquino et al. 2018; Ding 2018; Denicolai and Previtali 2020; Arief et al. 2022; Al-Shura et al. 2018; Zulfiqar et al. 2022; Liu et al. 2021; Ghadge et al. 2022; Argiyantari, Simatupang, and Basri 2020; Solfa 2022; Alharthi, Cerotti, and Far 2020; Liu et al. 2021; Argiyantari, Simatupang, and Basri 2020	• What are the key cultural and individual's barriers and challenges that organizations face when implementing digital technologies? • How can organizations effectively communicate the purpose and benefits of the digital transformation to employees across different phases of the pharmaceutical value chain and drive cultural change and technology acceptance? • How do cultural differences across geographies and functional areas within the pharmaceutical industry influence the digital transformation process, cultural change, and technology acceptance? How can organizations effectively manage these differences? • How can organizations measure and assess the progress and impact of cultural change initiatives during the digital transformation of the pharmaceutical industry, and what are the key indicators of successful cultural change in this context?
Interoperability, Obsolescent IT Infrascrutures, and inefficient Information sharing across Functions	Organizational Communication and Learning	IoT,Cloud,Big Data,Blockchain,AI, Robots, 3D, AR, VR, Digital Twins	DD, CT, MK, SC, MA	Saha et al. 2022; Liu et al. 2021; Silva et al. 2020; Arief et al. 2022; Wu and He 2020; Kordestani, Oghazi, and Mostaghel 2023; Alharthi, Cerotti, and Far 2020; Ghadge et al. 2022; Chen et al. 2020; Reinhardt, Oliveira, and Ring 2021; Ertz, Centobelli, and Cerchione 2022	• How does inefficient information sharing impact decision-making processes and overall performance across different functions within the pharmaceutical industry, and what digital technology can be employed to enhance information flow and knowledge sharing? • How does the lack of interoperability and outdated IT infrastructures affect communication, collaboration, and knowledge sharing across different phases of the pharmaceutical value chain?

Managerial Awareness and Leadership	Organizational Communication and Learning	IoT,Cloud,Big Data,Blockchain,AI, Robots, 3D, AR, VR, Digital Twins	DD, CT, MK, SC, MA	Denicolai and Previtali 2020; Arief et al. 2022; Al-Shura et al. 2018; Zulfiqar et al. 2022; Wu and He 2020; Alharthi, Cerotti, and Far 2020; Liu et al. 2021; Ghadge et al. 2022; Satwekar et al. 2022	• What role does leadership play in shaping and driving cultural change during the digital transformation of the pharmaceutical industry, and how can leaders effectively inspire employees through the change process?
Organizational Readiness to innovation	Organizational Communication and Learning	IoT,Cloud,Big Data,Blockchain,AI, Robots, 3D, AR, VR, Digital Twins	DD, CT, MK, SC, MA	Satwekar et al. 2022; Alharthi, Cerotti, and Far 2020; M. Sharma et al. 2022; Kulkov 2021; Aquino et al. 2018	• What strategies can be employed to manage the transition from legacy systems to interoperable platforms and minimize disruption to ongoing operations, while maximizing the benefits of digital transformation across the value chain phases? • How can organizations assess their current level of readiness for digital innovation and identify areas of improvement across the value chain phases?

Abbreviations: Drug Development (DD), Clinical Trials (CT), Manufacturing (MK), Supply Chain (SC), Market Access (MA), Pharmaceutical Industry (PI), Digital Transformation (DT), Artificial Intelligence (AI), Augmented Reality (AR), Virtual Reality (VR), Internet of Things (IoT)

Table 6. Future research agenda for the Stakeholder's Theory Research area

Topic	Aggregated Area	Related Technologies	Value Chain	Literature	Research Questions
Environmental Footprint	Environmental	Digital Twins, AR, VR, Cloud, 3D, Big Data, AI, Blockchain	MK, SC, MA	Chen et al. 2020; Aquino et al. 2018; Ding 2018; Nguyen et al. 2022; Shamsuzzoha, Ndzibah, and Kettunen 2020; M. Sharma et al. 2022; Ghadge et al. 2022; Zakari et al. 2022; Hosseini Bamakan et al. 2021; Ding 2018; M. Sharma et al. 2022; Burrichter, Chen, and Marco 2022; M. Sharma et al. 2023; Ertz, Centobelli, and Cerchione 2022; Junaid et al. 2023	• How can the concept of circular economy be integrated into the pharmaceutical value chain to promote resource efficiency, waste reduction, and the reuse or recycling of materials? • What role can AR and VR technologies play in optimizing material usage and minimizing waste generation in pharmaceutical manufacturing? • In what ways can 3D printing technology be leveraged to reduce waste, enable on-demand manufacturing, and enhance the overall environmental performance of pharmaceutical production?
Sustainability Certifications (Integration with UN's SDGs Goals)	Environmental	3D, IoT, Cloud, Blockchain, AI, Big Data	MK, SC	Saha et al. 2022; Ding 2018; M. Sharma et al. 2022	• Does the integration of sustainability certifications into pharmaceutical companies enhance sustainability performance perception of patients? • How can blockchain technology facilitate the verification and validation of sustainability claims and certifications across multiple stakeholders in the pharmaceutical value chain?
Customization, Personalization, and Precision Medicine	Impact on Patient	IoT,Cloud,Big Data,Blockchain,AI, Robots, 3D, AR, VR, Digital Twins	MA, SC	Silva et al. 2020; Aquino et al. 2018; Ding 2018; Denicolai and Previtali 2020; M. Sharma et al. 2022; Kordestani, Oghazi, and Mostaghel 2023; Liu et al. 2021; Ghadge et al. 2022; Arief et al. 2022	• How can 3D printing technology be leveraged to customize drug dosage forms and delivery systems to meet individual patient needs and improve medication adherence in the context of precision medicine? • What role can AR, VR and AI-powered chatbots play in supporting patient self-management, treatment monitoring, and remote consultations for personalized medicine interventions? • What are the factors influencing patient acceptance, trust, and adoption of personalized medicine technologies and interventions, and how can these barriers be addressed through effective communication strategies and patient-centric engagement approaches?
Ensuring Drug Safety, Counterfeit Drug Prevention and Higher Accessibility to Drugs	Impact on Patient	AI, IoT, Cloud, Blockchain, 3D, Big Data	MA, SC	Kulkov 2021; Chen et al. 2020; Zakari et al. 2022; Zulfiqar et al. 2022; M. Sharma et al. 2022; Lima Jr et al. 2021; Silva et al. 2020; Aquino et al. 2018; Ding 2018; Nguyen et al. 2022; Liu et al. 2021; Hosseini Bamakan et al. 2021; Kordestani, Oghazi, and Mostaghel 2023; Ghadge et al. 2022; Ertz, Centobelli, and Cerchione 2022; Junaid et al. 2023	• How can AI-powered chatbots and virtual assistants enhance patient education and provide accurate information about drug usage, potential side effects, and interactions, contributing to higher drug safety awareness and patient empowerment? • How can big data analytics and predictive modeling be applied to identify patterns and trends in adverse drug events, enabling proactive measures in market access and supply chain to prevent potential harm to patients? • How the use of Blockhain can support in fighting counterfeited drug markets?
Data Transparency for Regulatory Validation	Regulatory Compliance	Blockchain, Big Data, IoT	DD, CT, MK, SC, MA	Zakari et al. 2022; Hosseini Bamakan et al. 2021; Nguyen et al. 2022; Arief et al. 2022; M. Sharma et al. 2022; Alharthi, Cerotti, and Far 2020; M. Sharma et al. 2023; Ertz, Centobelli, and Cerchione 2022; Junaid et al. 2023; Zakari et al. 2022; Hosseini Bamakan et al. 2021; Nguyen et al. 2022; Arief et al. 2022; M. Sharma et al. 2022; Alharthi, Cerotti, and Far 2020; M. Sharma et al. 2023; Ertz, Centobelli, and Cerchione 2022; Junaid et al. 2023	• How can blockchain technology be implemented in drug discovery to ensure transparent recording and verification of research data, facilitating regulatory validation and accelerating the development of new drugs? • What are the key considerations and requirements for establishing a secure and trusted data infrastructure based on blockchain technology to support regulatory validation processes across the value chain phases? • How can data governance frameworks be designed and implemented to ensure data integrity, privacy, and security in the context of data transparency for regulatory compliance, particularly when utilizing big data and IoT technologies?
Enhanced adherence to	Regulatory	IoT, Blockchain, Cloud, AI, Digital Twins	MK, SC	Silva et al. 2020; Arief et al. 2022; M. Sharma et al. 2022; Ghadge et al. 2022; Zakari et al. 2022; Kulkov 2021; Kordestani, Oghazi, and Mostaghel 2023	• How can IoT devices and sensors be utilized in the manufacturing phase to monitor and ensure real-time compliance with regulatory standards, such as Good Manufacturing Practices (GMP) and quality control measures?

Regulatory standards	Compliance				
Need for standardized data sharing protocols and Updated Regulatory Framework	Regulatory Compliance	Big Data, Blockchain, AI, 3D, Cybersecutrity, Digital Twins,	DD, CT, MK, SC, MA	Nguyen et al. 2022; Zulfiqar et al. 2022; M. Sharma et al. 2022; Kordestani, Oghazi, and Mostaghel 2023; Liu et al. 2021; Ghadge et al. 2022; Argiyantari, Simatupang, and Basri 2020; Kulkov 2021; Arief et al. 2022; Wu and He 2020; Chen et al. 2020; Kordestani, Oghazi, and Mostaghel 2023	• What are the key considerations in developing standardized data sharing protocols that enable seamless integration and interoperability across different systems and stakeholders in the value chain phases while addressing privacy concerns and ensuring compliance with data protection regulations? • How can the replacement of manual data improve regulatory adherence and reduce environmental footprint?
Eliminating Discrimination in HR recruitments	Governance	AI	MA	Kulkov 2021	• How can AI eliminate discriminations in the recruitment process of new employees? • What are the main barriers and benefits of deploying AI for this matter?
Patient-Data Security and Privacy	Governance	Cloud, Big Data, Blockchain	SC, MA	Silva et al. 2020; Nguyen et al. 2022; Denicolai and Previtali 2020; Arief et al. 2022; Zulfiqar et al. 2022; Kordestani, Oghazi, and Mostaghel 2023; Alharthi, Cerotti, and Far 2020; Liu et al. 2021; Ghadge et al. 2022	• What are the ethical and privacy considerations associated with the collection, analysis, and use of patient data for improving patient retention, and how can organizations establish robust data governance frameworks and practices to ensure compliance and maintain trust, ultimately strengthening their competitive advantage?
University Education Gap	Social	IoT,Cloud,Big Data,Blockchain,AI, Robots, 3D, AR, VR, Digital Twins	MA	Kulkov 2021; Silva et al. 2020; Liu et al. 2021	• What strategies and policies can be implemented to foster closer collaboration between academia and regulatory authorities, enabling universities to address the education gap and produce graduates with the necessary regulatory compliance competencies?

Abbreviations: Drug Development (DD), Clinical Trials (CT), Manufacturing (MK), Supply Chain (SC), Market Access (MA), Pharmaceutical Industry (PI), Digital Transformation (DT), Artificial Intelligence (AI), Augmented Reality (AR), Virtual Reality (VR), Internet of Things (IoT)

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Research Topic	**Aggregated Area**	**Possible Related Technologies**	**Value Chain**	**Literature**	**Research Questions**
New Value Creation	Business Model Innovation	Digital Twins, AI, Big Data, VR, AR, AI, Cloud, Digital Twins, 3D	DD, CT, MK, SC, MA	Saha et al. 2022; Satwekar et al. 2022; Kulkov 2021; Silva et al. 2020; Denicolai and Previtali 2020; Ramos et al. 2022; Liu et al. 2021; Festa et al. 2018; Burrichter, Chen, and Marco 2022; Ghadge et al. 2022; Argiyantari, Simatupang, and Basri 2020; Chen et al. 2020; Aquino et al. 2018; Wu and He 2020; M. Sharma et al. 2023; Ertz, Centobelli, and Cerchione 2022; Rathi, Majumdar, and Chatterjee 2024	• What are the key challenges and opportunities associated with integrating AI, big data, and advanced analytics into clinical trial processes, and how can organizations leverage these technologies to enhance patient recruitment, trial design, and overall trial efficiency for a competitive edge? • How can the implementation of digital technologies such as AI, VR, and AR revolutionize manufacturing processes in the pharmaceutical industry, improving productivity, quality control, and supply chain integration to achieve superior performance? • What are the implications of business process transformation and the adoption of digital technologies on market access strategies, pricing models, and reimbursement negotiations in the pharmaceutical

					industry, and how can organizations align these processes to secure a competitive position in the market?
Need of New Business Model	Business Model Innovation	IoT, 3D, AI, Blockchain, Big Data, Digital Twins	MA, MK, SC, DD, CT	Denicolai and Previtali 2020; Al-Shura et al. 2018; Wu and He 2020; Liu et al. 2021; Ghadge et al. 2022; Kumar Detwal et al. 2023; Rathi, Majumdar, and Chatterjee 2024	• Does digital technology deployment enhance business performance through Sustainable business model innovation? • What are the implications of incorporating sustainability considerations into business model innovation, and how can organizations balance environmental, social, and economic factors to create sustainable value propositions that differentiate them in the market and drive competitive advantage?
Lack of Strategic Guidance over digital innovation	Scalability	IoT,Cloud,Big Data,Blockchain,AI, Robots, 3D, AR, VR	DD, CT, MK, SC, MA	Satwekar et al. 2022; Kulkov 2021	• What are the mechanisms and frameworks for assessing the potential impact and scalability of digital innovation initiatives in the pharmaceutical industry, and how can companies evaluate and prioritize investment opportunities to ensure strategic alignment and long-term competitive advantage?

Paper 2: Triad of Digital Transformation: Holistic Orchestration for People, Process, and Technology

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Abstract:

Digital transformation (DT) is a critical area of focus as it disruptively transforms organizational business models, processes, and products. Despite being a prominent topic among IS scholars, the research has mostly centered around technological aspects, and there is a necessity for a broader research approach to deepen the understanding of DT's intricate dynamics, interdisciplinary nature, and cross-level perspectives, with practical guidance to provide actionable insights for organizations. Through Action Design Research (ADR), we elaborate a practical Digital by Design (DbD) framework grounded on theoretical foundations and emphasize the interconnected dimensions of People, Process, and Technology to enhance DT feasibility and viability. This research contributes to a deeper understanding of DT initiatives by recognizing the significance of (1) diverse organizational, process, and industry needs, (2) individual uniqueness concerning DT, (3) technology integration and scale-up patterns (4) cross-level empirical perspectives, and (5) interdisciplinary approach supporting organizations in navigating DT complexities and dynamics. Recognizing practical managerial challenges, the study offers a comprehensive guidance for designing and implementing DT into business processes.

Managerial Implications

This study introduces the Digital by Design (DbD) framework, providing practical managerial guidance for decision-makers for navigating the complexities of DT. By addressing challenges such as unclear vision, inadequate understanding of interconnected dimensions, and difficulties in prioritizing based on business needs, the DbD framework provides a structured approach for designing and implementing DT initiatives. Decision-makers can leverage the framework to develop

a clear vision, identify holistic attributes (people, process, and technology), define flexible boundaries, and position technology needs effectively.

Keywords: Digital Transformation, Pharmaceutical Industry, Framework, Risk Assessment, From Pilot to Scale up

1. INTRODUCTION

Digital transformation (DT) has garnered significant attention within the literature, and recent research has highlighted the formulation of a phased digital strategy (Baslyman, 2022a; Chanias et al., 2019a; Eller et al., 2020a; Matt et al., 2015; Satwekar et al., 2022; Tekic & Koroteev, 2019a; Verhoef et al., 2021a; Yeow et al., 2018a), understanding digital maturity and readiness (H. Chen & Tian, 2022; Ghosh et al., 2022a; Tekic & Koroteev, 2019a), recognizing diverse drivers (Brkić et al., 2020; Eller et al., 2020a), effective orchestration (Kindermann et al., 2022a; Satwekar et al., 2022), and strategic response to disruptions from digital technologies (H. Chen & Tian, 2022; Vial, 2019), as crucial elements towards the success of DT. However, the focus has often been directed towards technological aspects, overlooking the interdisciplinary nature and relationships across different levels of analysis (Nambisan et al., 2019). Despite being a prominent topic within the IS research, there is not enough research performed on theoretical frameworks guiding and driving a successful DT. Numerous studies (Ding, 2018; Festa et al., 2018; Satwekar et al., 2022; Wu & He, 2020) have elaborated this insufficiency, and emphasized the need for more comprehensive investigations. Academic scholars have consequently advocated for a redirection of focus within DT research by calling for a cross-level perspective analyses, interdisciplinary contributions, and an emphasis on the unique technology interests (Nambisan et al., 2019). Furthermore, design thinking is gaining attention, to innovate and reduce failures in digital innovation by focusing on understanding customer needs, developing customized solutions, and using prototyping techniques (Johansson-Sköldberg et al., 2013; Liedtka, 2015; Nakata, 2020b). The iterative and agile nature of design thinking aligns user/customer requirements with technological feasibility and business viability (Przybilla et al., 2022). This creates a necessity for a comprehensive elucidation of the main elements as people, process, and technology to complement with design thinking for the effective implementation and utilization of digital technologies to generate value from the DT initiatives. The People, Process and Technology (PPT) framework has been widely applied for the process improvements (Prodan et al., 2015a), higher education (Taher, 2023b), information systems risk management in small to medium

enterprises (Javaid & Iqbal, 2017b), smart tourism (Z. Chen et al., 2021b), and manufacturing process innovation deployment readiness (Sunmola & Javahernia, 2021b). The PPT framework provides a comprehensive approach for effectively managing the complex changes prompted by digital technologies and enables organizations to adopt a holistic perspective to drive positive outcomes by considering the intricate interactions and relationships between the elements of people, process and technology. As the paradigm on DT continues to evolve, it necessitates for a broader and more comprehensive research approach to enrich our understanding of the intricate dynamics underlying successful DT endeavors. To facilitate the intricate process, there is a need for practical frameworks that consider (1) addressing unique organizational needs (Chanias et al., 2019a; Eller et al., 2020a; Ghosh et al., 2022a; Tekic & Koroteev, 2019a; Verhoef et al., 2021a) (Brkić et al., 2020; Spremic et al., 2022a); (2) provide guidance for different technology exploration patterns (Nambisan et al., 2017; Satwekar et al., 2022); (3) consider the evolving needs of individuals (Eller et al., 2020a) (H. Chen & Tian, 2022; Matt et al., 2015; Satwekar et al., 2022; Spremic et al., 2022a; Vial, 2019); (4) clearly elucidate processes (Baslyman, 2022a; H. Chen & Tian, 2022; Lis et al., 2023a; Matt et al., 2015; Satwekar et al., 2022) (Brkić et al., 2020; Spremic et al., 2022a); and (5) provide multiple empirical perspectives (Ghosh et al., 2022a; Peruchi et al., 2022a; Yeow et al., 2018a). Owing to the complex dynamics of digital technologies within business processes, there is a need for deeper guidance to tailor successful DT outcomes. Consequently, a holistic comprehension of the interrelationships among the people, process, and technology dimensions would significantly contribute to the success of DT initiatives. Grounded on the above literature relevance, our study addresses the following research question: “How can the integration of antecedent dimensions (People, Process, and Technology) facilitate a successful digital transformation, and what are the implications of this integration for practitioners and the broader understanding of digital transformation processes?”

We focused our work to elucidate a Digital by Design (DbD) framework and provide a comprehensive theoretical and practical basis to the use of antecedent dimensions (People, Process and Technology)

and their interrelationships to suffice a successful DT. We have applied Action Design Research (ADR) methodology (Sein et al., 2011) to frame the antecedent dimensions (People, Process and Technology) for a case study in a biopharmaceutical company. Through the collaboration between practitioners (company managers, scientists) and academic scholar with abductive reasoning, we have integrated theoretical understanding to the practical approaches by using engaged inquiry approach (Van De Ven, 2007). Thus, resulting in the creation of theoretical foundation for Digital by Design (DbD) (Satwekar et al., 2023) and improvement in the existing Digital Innovation Management (DIM) framework (Satwekar et al., 2022).The implications of our work extend primarily in two directions. Firstly, through the instantization on a case study, we enhance the existing literature on DT by translating theory to practice, and fine-tune existing frameworks towards the demonstration of a practical application with a holistic approach. This addresses the current need for guidance in DT initiatives utilizing the emerging considerations, theoretical concepts, new logics and existing frameworks (H. Chen & Tian, 2022; Hanelt et al., 2021; Markus & Rowe, 2018; Matt et al., 2015; Nambisan et al., 2017, 2019; Przybilla et al., 2022; Satwekar et al., 2022; Svahn, Mathiassen, Lindgren, et al., 2017; Vial, 2019). Secondly, the study illuminates the incorporation of design thinking into the antecedent dimensions (People, Process, and Technology) to facilitate a successful DT. We provide a comprehensive understanding of the complex dynamics in the integrated use of design thinking, PPT framework, DIM framework, and the DT theories. This elucidation contributes to the literature on DT by emphasizing the use of design thinking and underscores the importance of taking a holistic and integrated approach considering the antecedent dimensions of People, Process, and Technology. This understanding is crucial for managers to effectively manage the complex dynamic structures between innovation processes and innovation outcomes (Boland et al., 2007; Nambisan et al., 2017) to foster a successful DT in today's rapidly changing and complex business environment.

2. THEORETICAL BACKGROUND

A. Navigating Digital Transformation

Technological evolution has ushered a significant wave of disruption for both society and companies, leading to the emergence of DT, that encompasses strategic (Bharadwaj et al., 2013; Matt et al., 2015; Vial, 2019) cultural (Karimi & Walter, 2015; Vial, 2019) and organizational (Selander & Jarvenpaa, 2016; Vial, 2019) changes aimed at creating new value (Svahn, Mathiassen, & Lindgren, 2017; Vial, 2019). Several IS scholars have provided valuable insights with different DT approaches and have put forward several recommendations. Firstly, it is important to formulate a digital strategy and have a phased execution. A continuous dynamic process model has been proposed for development and implementation of DT strategies, encompassing multiple stages/phases (Chanias et al., 2019a). The stages and imperatives of DT play a critical role in guiding organizations through their transformation journey. The DT stages encompasses digitization, digitalization, and digital transformation, and necessitates the focus on digital resources, organizational structure, digital growth strategies, and the establishment of metrics and goals as crucial factors for successful DT implementation (Verhoef et al., 2021a). Furthermore, the establishment and scale-up of digital innovation requires a hybrid stage-gate model that allows holistic perspective, contextual adaptability, flexibility, orchestrated collaboration, and incremental growth across phases (Satwekar et al., 2022). Thus, reflecting an importance of gaining a comprehensive understanding of practical aspects throughout the key stages of DT implementation (Baslyman, 2022a). These stages and imperatives offer a roadmap for organizations to navigate the complex process of DT. Secondly, to effectively navigate DT objectives, it is essential to comprehend digital maturity and readiness. Previous studies have examined different levels of digital maturity and interaction between external pressures and resource orchestration (H. Chen & Tian, 2022). Similarly, distinct DT strategies based on technology utilization and business model readiness have been investigated (Tekic & Koroteev, 2019a). These studies highlight the significance of evaluating organizational preparedness and maturity to drive the success of DT

initiatives. Thirdly, understanding the driving forces and motivations behind DT is crucial for aligning strategies and initiatives within organizations. Various drivers for DT have been identified, including technology orientation, customer-driven approaches, governance-led initiatives, and capability-based motivations (Brkić et al., 2020). Recommendations are provided for assessment of technological capabilities (Matt et al., 2015) along with the consideration of DT drivers as employee IT skills, digital strategy, and financial performance (Eller et al., 2020a). Furthermore, the alignment between IT and digital strategy is highlighted as a crucial driver to effectively leverage technological investments. These alignments provide insights into actions such as sensing, seizing, and transforming to ensure that technology initiatives contribute to overall DT objectives (Yeow et al., 2018a). Recognizing these diverse drivers enables organizations to tailor their DT strategies for developing a clear strategic direction, deliver value and sustain the transformation process. Finally, the orchestration plays a vital role in facilitating successful DT implementation. Investigations on the orchestration of digital innovation ecosystems and the importance of central actors or orchestrators highlight various routines involved in ecosystem orchestration (Kindermann et al., 2022a). These findings contribute to our understanding of the DT complexities involved in managing diverse actors and resources within digital innovation ecosystems (H. Chen & Tian, 2022; Nambisan et al., 2017; Satwekar et al., 2022). Disruptions caused by implementation of digital technologies necessitate strategic responses. Examinations of disruptions and strategic responses within the context of DT emphasize changes in value creation and organizational structure (Vial, 2019). Digital transformative capabilities, including digital sensing, seizing, and reconfiguring, have been proposed (Ghosh et al., 2022a) to provide insights for strategically managing disruptions during the DT process. Overall, the current research has highlighted the essential considerations, that encompasses the formulation of a digital strategy with phased execution, understanding digital maturity and readiness, recognizing diverse drivers, orchestration, and strategically responding to disruptions by digital technologies. These insights are indicative for organizations to structure their DT journeys and navigate the complexities. Furthermore, Nambisan *et al*. emphasize the importance of considering three key

implications for IS scholars engaging with DT (Nambisan et al., 2019). First, DT entails different levels of analysis (e.g., individual, organizational, community, regional, and societal). Therefore, research should integrate DT constructs across different empirical settings to provide significant contributions. Second, DT affects a broad range of disciplinary fields (e.g., Marketing, Operations Management, Strategy, Information Systems etc.). Thus, an interdisciplinary approach is needed to deliver more comprehensive perspectives. Third, research should identify the crucial role played by each digital technology to develop theoretical foundations for DT. This includes examining the interactions between design processes, stakeholder's needs and desired outcomes. Practitioners and scholars have predominantly focused on the technological aspects of DT (Lis et al., 2023b), with less consideration given to the relationships across different levels of analysis and interdisciplinary fields (Nambisan et al., 2019). Limited exploration on technology integration patterns (Baslyman, 2022a) and empirical perspectives leads to insufficient attention to diverse technology attributes and the holistic elements for facilitating the transition from proof of concept/pilot to routine (H. Chen & Tian, 2022; Tekic & Koroteev, 2019a; Verhoef et al., 2021a; Vial, 2019), within the complex organizational environments. Hence, further research is needed to understand how to effectively guide organizations in developing, executing, and assessing DT initiatives (Baslyman, 2022b; H. Chen & Tian, 2022; Matt et al., 2015; Nambisan et al., 2019; Peruchi et al., 2022b; Spremic et al., 2022b; Verhoef et al., 2021b; Vial, 2019).

B. People Process and Technology as Anecdotal Dimensions for DT

To delve into a deeper understanding of a business, the People, Process, Technology (PPT) framework can provide a comprehensive elaboration, particularly in the context of DT. PPT framework is a holistic model that has been widely recognized and utilized across various industries for years (Prodan et al., 2015b). The three dimensions of People, Process and Technology are regarded as key areas to facilitate process improvement (Prodan et al., 2015b). PPT framework has

been proven valuable in various contexts, i.e. DT in higher education (Taher, 2023a), information systems risk management in small to medium enterprises (Javaid & Iqbal, 2017a), smart tourism (Z. Chen et al., 2021a), and manufacturing process innovation deployment readiness (Sunmola & Javahernia, 2021a). The integrative nature of the PPT framework has the potential to drive successful DT outcomes by effectively balancing and coordinating the interactions and relationships between people, processes, and technology. Recently, the use of design thinking has been discussed to address the complexities of building digital innovation. Organizations are increasingly interested in the use of Design Thinking principles as a new way to innovate and reduce the prospects of failure (Johansson-Sköldberg et al., 2013; Liedtka, 2015; Nakata, 2020b). Design Thinking emphasizes the importance of need finding, developing individualized solutions, and utilizing prototyping techniques (Przybilla et al., 2022). A design process is widely used for creating and developing ideas for products, services, systems, or processes that are according to the needs and desires of end users (Nelson & Stolterman, 2012). User-centric design approach focuses on understanding customer needs (Nelson & Stolterman, 2012), while the iterative "Design thinking" approach is sensible to align customer needs with technology feasibility and business viability to deliver value (Brown, 2008). In our work, we adapted and refined the definitions of PPT framework (Prodan et al., 2015b) for a comprehensive design thinking based business centric approach towards DT. By holistically understanding the intricate relationships between people, process, and technology, organizations can leverage insights to navigate the complexities of DT, enabling successful implementation of digital technologies and achieving superior business performance. To bridge the gap between theory and practice, we have adopted an interdisciplinary approach that leverages design thinking principles and considers a user-centric approach to provide a comprehensive understanding for the dimensions of people, process, and technology. Design thinking approach ensures alignment between business needs and technological requirements, ultimately delivering value within the business process (Brown, 2008; Nelson & Stolterman, 2012). Design thinking recognizes the crucial role played by the digital technology and facilitates its appropriate positioning. However, organizations typically

employ a project review methodology based on stage-gate to build technological innovations, and recently there is an emphasis on the use of hybrid approaches consisting of agile stage-gate methodologies (Cooper & Sommer, 2016; A. F. Sommer et al., 2015) (Bierwolf, 2016; de Vasconcelos Gomes et al., 2021). To address the need for a phased structure, we adopted the digital innovation management (DIM) framework (Satwekar et al., 2022) that is based on new logics of digital innovations (Nambisan et al., 2017) and guides the creation of the digital innovations through phase-appropriate and incremental setup (Satwekar et al., 2022). While DIM framework empowers organizations to build digital innovations towards DT, it lacks structured granulation into relationships between People, Process, and Technology. We have attempted to enrich the DIM framework with explicit attention to the interplay between People, Process, and Technology dimensions, and provide a practically usable Digital by Design (DbD) framework. Our work considers the literature recommendations along with practitioner's experience to operationalize the DbD framework. DbD is grounded on the principles of Quality by Design (L. X. Yu et al., 2014) and includes quality risk-based foundations to guide and analyze the interplay between technology, business relevance, and stakeholders to deliver tangible value. DbD has been preliminarily applied on an artificial intelligence based case study, as outlined in a scientific technical article (Satwekar et al., 2023). While DbD has demonstrated the potential to facilitate the implementation of a digital innovation, it is still an emerging concept and lacks robust theoretical foundations in the management literature. This research aims to strengthen the theoretical grounding of DbD, providing a rationale and practical guidance for organizations engaged in digital innovation design and deployment in DT initiatives. In the next sections, we elaborate the DbD framework and its theoretical underpinnings by instantiation on a case study.

3. DIGITAL BY DESIGN FRAMEWORK

The pursuit of digital innovations follows a complex process from ideation, development, deployment, and management of digital technologies within an holistic DT initiative. IS research

highlights the paradoxes and dilemmas that are encountered by the organizations during the digitalization process (Bresnahan & Greenstein, 2014; Kallinikos et al., 2013; Lyytinen et al., 2016; Nambisan, 2013; Nambisan et al., 2017; Yoo et al., 2010b), with an increased focus on the materiality of the innovation process and outcomes (Boland et al., 2007; J. Lee & Berente, 2012; Nambisan et al., 2017). DT initiatives are based on digital innovations that require a more flexible innovation process, where the scope, features, and value of benefits evolve dynamically (Nambisan et al., 2017; Satwekar et al., 2022). By considering the literature recommendations, and the practicality of the implementations, we considered an integrated approach based on the existing theories, practical experience and leveraging design thinking principles to elucidate the Digital by Design (DbD) framework. Scholars have advocated for a phased approach in driving DT to deliver value through continuous improvement (Baslyman, 2022a; Chanias et al., 2019a; Satwekar et al., 2022; Verhoef et al., 2021a). To structure the main phases, we considered the Digital Innovation Management (DIM) framework due to its relatability, practicality, and simplicity, offering a phase-appropriate and incremental setup approach (Satwekar et al., 2022). DIM framework is built on the new theoretical logics on digital innovation i.e. a) Dynamic problem–solution design pairing, b) Technology affordances and constraints, c) Socio-cognitive sensemaking and d) Orchestration (Nambisan et al., 2017; Satwekar et al., 2022). Dynamic problem-solution design pairing emphasizes the iterative reshaping of scope and functionalities throughout the digital innovation journey. Setting phase-specific objectives and navigating between divergence and convergence of digital innovation opportunities facilitates the successful creation of value-generating digital innovations. Socio-cognitive sensemaking plays a crucial role in defining and discovering new opportunities with extended benefit scenarios, which needs to be negotiated and justified for stable adoption within organizations. Technology affordances and constraints considers the use of necessary IT systems & architecture on the need basis and allows step-by-step experience-based evaluation and building of digital technologies. It emphasizes the structuring of phase-appropriate business needs for new digital technologies, as well as repurposing existing digital technologies for different benefit outcomes.

Orchestration focuses on strategic and coordinated management of various elements to match the problem/opportunity with the digital innovation solution. By structuring roles and responsibilities, integration of various stakeholders, and tackling any systemic barriers, orchestration facilitates the smoother transition of the digital innovation into adoption, and shapes the digital value (Nambisan et al., 2017; Satwekar et al., 2022). The integration of the DbD steps within the main phases of DIM (Satwekar et al., 2022) along the new logics of digital innovations (Nambisan et al., 2017), enables organizations to leverage the strengths of both frameworks to develop a more comprehensive and effective DT approach. Elaboration of DbD steps within the DIM phases of Proof of Concept, Proof of Feasibility and Proof of Value is described further (Table 1).

DbD framework encompasses six main steps that guide the process of digitalization from initiation to its continuous evolution as per the changing dynamics of the business. The first step involves defining the Target Digitalized Business Profile (TDBP), which outlines the desired digitalized business profile and its associated characteristics. It serves as a strategic vision for the future digitalization state with the identification of high-level expectations and value. This coincides with Proof-of-Concept phase of DIM and relates to the elaboration of an initial understanding and confidence in the value proposition. The second step in DbD entails delving into a comprehensive exploration of the People, Process, and Technology dimensions to gain a deeper understanding. Through the adaptation of the PPT framework (Prodan et al., 2015b), we consider “People” as individuals possessing the necessary skills and knowledge to execute tasks within a business process and contribute to the success of an organization. “Process” entails a series of interconnected value-added business activities that involve specific inputs and produce specific outputs. “Technology” refers to the hardware, software, instrumentation, machines, systems, and the necessary conducive elements (for proper functioning and utilization of the technology) to perform tasks effectively and efficiently within business processes. These dimensions have been considered crucial for achieving successful process innovation outcomes (D. R. Sjödin et al., 2018; Sunmola & Javahernia, 2021a). Through the design thinking principles, the Critical Workforce Attributes (CWA) for people, Critical

Process Attributes (CPA) for the business process, and Critical Technology Attributes (CTA) for the use of technology, are necessary to be identified based on their critical relevance in achieving the Target Digital Business Profile (TDBP). By focusing on these key critical attributes, organizations can effectively align the considerations from People, Process, and Technology with the desired DT outcomes. The process of digitalization involves dependencies with technology that facilitates improvement of the existing activities to bring efficiency into the new or established business process. The touch points between the business process and technology are critical to define the positioning of the technology to deliver value. This relates to an understanding around the unique technology interests that enables the DT (Nambisan et al., 2019). DT is driven by people and requires specific capabilities to embrace change and adopt new digital technologies in the business processes. In the third step, the inter-relationships among the CWA, CPA and CTA comprises characteristics for defining the Critical Business Attributes (CBA) with a risk-driven approach. CBAs play a crucial role in guiding business strategies and operations by enabling organizations to adopt a focused approach, make informed decisions, prioritize user/customer expectations, ensure business continuity, foster competitiveness, and drive value generation. Thus, CBA elucidates the relationships across different levels of analysis and interdisciplinary fields (Nambisan et al., 2019) within the DT initiative. The fourth step is focused to define a Digitalization Design Space (DDS) to manage the transformation with a degree of flexibility, by considering the dynamic nature of digital innovation, with evolving scopes, features, and value of benefits (Hanseth & Lyytinen, 2010; Lyytinen et al., 2016).This provides a region to establish Digitalization Control Strategy (DCS) to monitor tangible benefit outcomes as the fifth DbD step. DbD steps 2 to 5 corresponds within the Proof of Feasibility phase of the DIM framework, by focusing on the feasibility/ pilot demonstration of the digital innovation to assess its real-world applicability. This phase includes comprehensive stakeholder involvement and streamlining the digital innovation within the established business setup. Finally, the Digitalization Lifecycle Management (DLM) ensures that the deployed digitalized process is continuously evaluated for evolving business needs, and upcoming technologies as the sixth DbD

step. This aligns to the Proof of Value phase of the DIM framework, wherein the digital innovation is integrated and adopted within the day-to-day operations of the business process and additional benefit synergies are continuously explored and evaluated. DLM fosters a structured and systematic approach for continuous evaluation and adaptation across the anecdotal dimensions of People, Process, and Technology to ensure organizational agility and responsiveness to changing dynamics. In the following sections, we provide elaboration into the research design and the operational instantization of DbD framework on a use case.

Table 1 Connecting the logics and phases of Digital Innovation Management with DbD

Insert Table 1 Here

4. RESEARCH DESIGN

A. Case study

Our study was conducted at *Merck Healthcare's Global Analytical Development organization* and within the Analytical Excellence and Program Management department to address the challenges and complexities associated within the operations of the life cycle management (LCM) center of excellence functional unit. LCM Unit is based at the Guidonia-Rome, Italy site and manages analytical methods for 21 biotech products from 8 sites with at least 40 functions. Analytical methods are of utmost importance in the pharmaceutical industry, as they play a critical role in ensuring the quality, safety and efficacy of drugs (Martin et al., 2013; Verch et al., 2022), thereby ensuring compliance with regulatory needs (Ganesh & Mohankumar, 2022; Heikkinen et al., 2023; G. A. Van Norman, 2016; Volpentesta et al., 2022). Analytical data generated by the analytical methods are essential for assessing the quality attributes, identify impurities, and measure the potency of pharmaceutical products throughout their life cycle (Parr & Schmidt, 2018; Verch et al., 2022).

Analytical methods enable pharmaceutical companies to monitor and control the manufacturing process, detect any deviations or failures, and take appropriate corrective actions. LCM unit operates to coordinate the troubleshooting, failure investigations and changes to the manufacturing process/ technologies due to the constantly evolving state-of-art analytical methods and the need to adapt to new regulatory recommendations. The complex and challenging operative process of the LCM unit highlighted the need for efficiency and simplification. Recognizing the limitations of the current basic IT tools, it was deemed necessary to implement an advanced Industry 4.0 technology to improve the LCM unit's operations. The research group recognized the significance of digitalization in Life Cycle Management (LCM) operations, from both academic and practitioner perspectives, and acknowledged the relevance for DT. The LCM use case presented a valuable opportunity to investigate from practical lens the suitability of the existing frameworks and theoretical guidance from the DT literature. By combining academic rigor with practical implementation considerations, this study serves to bridge the gap between theoretical concepts and practical applications (Vial, 2019), while simultaneously providing valuable managerial insights and guidance in leveraging digital technologies within the DT initiatives.

B. Methodology

We employed the Action Design Research (ADR) methodology (Sein et al., 2011) to integrate a new IT artifact into an ongoing operational context while advancing theoretical understanding. We adopted engaged inquiry approach (Van De Ven, 2007) involving collaboration between practitioners (company managers, scientists) and academic scholars over a 12-month period. This collaboration enabled abductive reasoning (Sein et al., 2011), resulting in the creation of theoretical foundation for Digital by Design (DbD) (Satwekar et al., 2023) and improvement in the Digital Innovation Management (DIM) framework (Satwekar et al., 2022). The methodological flowchart (

Figure 1) elucidates the research approach, featuring the main phases of the DIM framework (Satwekar et al., 2022) on the right side. These phases intricately correspond to the detailed steps within the DbD framework depicting the sequential research activities conducted in alignment with ADR methodology (Sein et al., 2011)**,** offering a comprehensive exploration of solution design and implementation in a real-world setting. The research was performed on a *practice-inspired problem,* drawing methodological insights from design thinking (Brown, 2008; Johansson-Sköldberg et al., 2013; Lichtenthaler, 2020; Nelson & Stolterman, 2012; Przybilla et al., 2022), principles of quality by design (L. X. Yu et al., 2014), and business process management (Aguilar-Savén, 2004; Hammer, 2014; Kaplan & Norton, 1996; Vom Brocke & Rosemann, 2014; Zellner, 2011) *literature.* An iterative bidirectional exchange of knowledge between the academic scholars and practitioners was instrumental in synthesizing insights from the literature and practitioner feedback (Sein et al., 2011). *To comprehend the knowledge on the LCM use case, ten semi-structured interviews were conducted with knowledgeable individuals actively involved in the LCM operations. The interviews employed non-directive questioning, triangulation with informants at various hierarchical levels, and anonymity to ensure interview validity* (Eisenhardt, 1989). *From the interactions, a thorough understanding on the LCM process, challenges, gaps, and opportunity areas was developed.* This collaborative process aimed to achieve a *holistic and profound* understanding of the research problem, and thereby facilitated the creation of Target Digitalized Business Profile (TDBP) as the first structured step of DbD. The investigation in the subsequent Proof of Feasibility phase (DIM framework) involved the identification and elaboration of critical attributes for workforce (CWA), process (CPA) and technology (CTA) within the second step of DbD. To define these attributes, we developed the constructs based on the literature adopted from business process management (Van Looy & Shafagatova, 2016) and Technology Acceptance and Adoption (Farr & Ford, 1990; Lai, 2017; Venkatesh et al., 2003, 2012). *The constructs were structured hierarchically, organized into "Macro areas" representing People, Process, and Technology dimensions. The macro areas were further granulated into "Micro areas" representing indicators such as balanced scorecard, and*

finally into "Items" encompassing the specific constructs relevant to the use case. By triangulating the literature, CWA, CPA, CTA, and interview information, we developed a reflective 7-point Likert measurement scale (where "1" indicates strongly disagree and "7" indicates strongly agree) and constructed the "items" suitable for the use case specific survey research. We collected 14 survey responses and categorized the target population into roles (Execution, Coordinators, Sponsors) and IT expertise levels (Not Frequent, Comfortable, Proficient) to gain insights and cross-reference critical areas (Table 2).

Table 2 Survey categorization and responses

Insert Table 2 and Figure 1 Here

Figure 1 Engagement between scholars and practitioners – connecting DbD with DIM

Survey dataset was analyzed looking at descriptive statistics such as mean, median, and standard deviation, categorizing answers ≤ 4 as negative (neutral and below) and > 4 as positive (above neutral). To delve deeper, we conducted frequency analysis and clustered the negative and positive counts for each item, micro and macro area's respectively. The outcome of the Likert-survey along the measurement construct was elaborated by plotting the percentage difference between the positive and negative frequencies to observe the trending pattern for the constructs. We applied weights to the survey items mapping it to the macro and micro areas, to enable a balanced comparison. Macro dimensions of People, Process and Technology was assigned the weight of 1, and it was further broken down accordingly into respective micro areas, and then into items. Use of these design weights was essential for equitable comparison across the macro dimensions of people, process, and technology. This was particularly important because the macro areas comprised different numbers of micro areas and their varying corresponding items, resulting in an uneven distribution. This

methodology ensured that our findings accurately reflected the characteristics and trends for elaborating within the main dimensions of People, Process and Technology. A prioritization score for the CWA, CTA, and CPA was computed through a *Qualitative Risk Assessment Analysis* (QRAA) (Edition, 2018), and critical business attributes (CBA) were defined from a workshop between academic scholars and practitioners. Although, many authors and practitioners have regarded "Analytic Hierarchy Process" as the most promising technique for prioritization (Karlsson et al., 1998; Mustafa & Al-Bahar, 1991), this technique has limitations when handling numerous criteria, and requires overwhelming efforts for evaluation (Karlsson et al., 1998). Similarly, "Minimal Spanning Tree" technique was a potentially faster alternative, but more sensitive to judgmental errors (Karlsson et al., 1998). Therefore, QRAA was included in our study as it is a simpler, faster and reliable technique favoring routine practical use. Integration of QRAA with survey data was implemented to leverage expert judgment in providing nuanced insights into risk interdependencies and contextual intricacies. Survey outcome was able to identify prevalent scenario's, but presented limitations in characterizing and capturing qualitative dimensions inherent in complex scenarios and inter-relationships among the elements. QRAA elucidated qualitative factors intrinsic to risks, offering insights into subjective judgments, and fostered expert opinions to perform near accurate quantification of scenarios with respect to associated risk, likelihood and impact. Academic scholars and practitioners contributed together to frame the Digitalization Design Space (DDS) by iteratively reviewing literature and the information from the practical experience. The information from QRAA provided flexibility in considering response strategies for high ranked scenarios. This facilitated the formulation of IT user requirements for the development of the relevant IT artefact. Our inclusive approach allowed us to leverage both academic rigor and practical relevance, ultimately enhancing the robustness and applicability of our research findings.

5. EXPOSITORY INSTANTIZATION ON USE CASE

A. Defining the Target Digitalized Business Profile (TDBP)

A Business Process Management (BPM) approach was utilized to gain insights into the current operational activities, tools, and challenges of the LCM process (Aguilar-Savén, 2004; Hammer, 2014; Kaplan & Norton, 1996; Vom Brocke & Rosemann, 2014; Zellner, 2011). BPM involves employing methodologies to analyze, model, execute, and monitor a business process with the aim of enhancing efficiency and end-user satisfaction (Hammer, 2014). BPM approach converges on the idea of analyzing performance metrics to achieve continuous improvement within a business unit (Kaplan & Norton, 1996; Vom Brocke & Rosemann, 2014), and also encompasses participative styles that involve users in the design of activities (Hammer, 2014; Vom Brocke & Rosemann, 2014). Therefore, a participative Business Process Management (BPM) approach was adopted with a combination of workshops, one-on-one interviews, and design thinking techniques to comprehensively gain knowledge on the LCM use case and identify the shortcomings of the existing LCM process. These collaborative efforts allowed us to define the Target Digitalized Business Profile (TDBP) for the first DbD step within the Proof-of-concept phase of the DIM framework (Table 3). This participatory approach ensured that the insights and perspectives of stakeholders were integrated into our assessment, ultimately contributing to a more holistic and informed understanding of the use case needs in terms of digitalization.

Table 3 Target Digitalized Business Profile (TDBP) for operative LCM process

Insert Table 3 Here

Scouting efforts were undertaken to identify and evaluate internal and external IT solutions. However, achieving a close alignment with the Target Digitalized Business Profile (TDBP) proved to be a challenge. Within the exploration, cloud-based platforms emerged as a promising option due to their ability to enhance efficiency and effectiveness of business processes by guaranteeing remote access

to data and business applications, real-time collaboration, process automatization, enhanced data security and scalability (Yang & Tate, 2012). Recognizing this potential, the organization established a team of IT developers to collaboratively build a simple meeting management application based on the cloud technologies. This application aimed to instill confidence in the cloud technology and showcase its potential to customize and digitize the complex steps of the LCM operational process. Further discussions were conducted with stakeholders to identify the relevant functionalities for best fitting the purpose and value to final users. The simple cloud-based prototype was the end-result of DIM *proof of concept* phase, that provided a confidence to pave the way for stakeholder approvals for proceeding into the DIM proof of feasibility phase.

B. Comprehensive Exploration of People, Process, and Technology Dimensions

During the proof of feasibility phase of DIM framework, a significant focus was on identifying and defining Critical Workforce Attributes (CWA), Critical Process Attributes (CPA), and Critical Technological Attributes (CTA). This was accomplished through the approach of design thinking (Brown, 2008; Johansson-Sköldberg et al., 2013; Lichtenthaler, 2020; Nelson & Stolterman, 2012; Przybilla et al., 2022). Design thinking facilitated the feedback from the users and a detailed understanding of their specific needs (Lichtenthaler, 2020; Liedtka, 2018; Przybilla et al., 2022). Using the ADR methodology (Sein et al., 2011), an in-depth understanding of the challenges inherent in the daily routines of the current *AS-IS* LCM process was deducted provided a structured and systematic approach for investigating and analyzing the complexities and issues associated within the daily practices (Bardon et al., 2017; Dobusch et al., 2019; Satwekar et al., 2022). The utilization of the ADR methodology facilitated a rigorous examination of the existing processes, enabling the identification of areas for improvement and the development of effective strategies for addressing those challenges. People, Process and Technology are pivotal elements for digital innovation adoption (Satwekar et al., 2023), and by aligning the interview data with literature analysis, the study revealed

relevant DT insights within the macro areas (Table 4). Analysis of the interview data showed that the DT insights reported by the interviewees are typically related to four key clusters 1) Learning and Adoption Support, 2) Integration and Compatibility, 3) Task Management and Collaboration, and 4) Process Streamlining. These clusters emerged as common themes and areas for improvement identified through the triangulation of interview information and literature.

Table 4 Interview information processing & mapping to literature reported DT insights.

Insert Table 4 Here

To further granulate within the macro-areas, we extended our literature evaluation to explore the effective promotion of technology adoption among end-users, with a specific focus on the technology acceptance and adoption literature (Farr & Ford, 1990; Lai, 2017; Venkatesh et al., 2003, 2012). Introduction of digital innovations bringing a significant transformation necessitates the critical assessment of how people respond to the changes (Venkatesh et al., 2003). The existing routines of people within a business process may have established behavioral patterns and have a tendency to resist to changes (Bicchieri, 2016; Bicchieri & Funcke, 2018). Understanding and managing people's responses to these changes are vital for successful technology implementation and integration into the business process to ensure the desired outcomes and benefits are realized. Among the various theories and models on technology acceptance, Unified Theory of Acceptance and Use of Technology (UTAUT) (Venkatesh et al., 2003) has been recognized and regarded as effective in explaining why users accept or reject a technology in a given context (Samaradiwakara & Chandra, 2014). Therefore, we readapted the features from UTAUT with relevant construct definitions and operationalized these to fit within our LCM use case for the technology micro areas (Table 5). Through the iterative analysis of the interview information and the BPM literature (Aguilar-Savén, 2004; Hammer, 2014; Vom Brocke & Rosemann, 2014; Zellner, 2011), we identified relevant constructs for the micro areas

under the process and people (Butler et al., 1997; Cross & Lynch, 1988; Kaplan & Norton, 1996; Neely et al., 2000; Van Looy & Shafagatova, 2016). Balanced score card model (Kaplan & Norton, 1996), is a widely adapted framework to translate strategic objectives into operational terms (Vom Brocke & Rosemann, 2014). However, the model can become too abstract and may not provide concrete indicators (Butler et al., 1997; Van Looy & Shafagatova, 2016). To address this, we adopted the early work of Van Looy and Shafagatova (Van Looy & Shafagatova, 2016), which provided an extensive list of operationalized metrics based on balanced score card. By triangulating our interview information, we readapted the literature metrics to build our measurement constructs relevant for the LCM use case. Starting from a large list of operational indicators, we have fine-tuned to select a measurement construct consisting of 3 macro areas, 11 micro areas, and 28 items (Table 5).

Table 5 Definitions of constructs for survey measurement

Insert Table 5 Here

The comprehensive analysis of the *AS-IS* state of the operative LCM process was performed by using the measurement constructs across the macro areas, micro areas and items. The outcome of the Likert survey along the measurement construct provided the positive and negative frequencies as clustered for macro areas, micro areas, and items. Likert responses (> 4) were calculated for positive frequencies, and (≤ 4) for negative frequencies. These data were processed considering the application of design weights (each macro dimension corresponding to 1 signifying 100%) and elaborated as percentage difference (positive – negative). The outcome provided the prevalent trends that reflected the inclination of the constructs towards the positive or negative side (Figure 2).

Figure 2 Perspectives from the survey responses

Insert Figure 2 Here

1) Macro area's perspectives

Frequency analysis for the AS-IS operative LCM process from the survey indicated a positive trend for people, and negative trend for the process and technology macro areas. This reflects that the LCM process has inefficiencies, and the use of current technology has significant challenges and areas for improvement. The respondent's negative expression on the current digital tools highlights a technology gap in facilitating the LCM operations. These findings emphasize the need for improvements in the process and technology aspects of the operative LCM process. By focusing on these macro areas, organizations can identify and implement targeted interventions and strategies to enhance the operations, mitigate challenges and optimize the utilization of technology for improved outcomes. On the other side, People showing a positive trend indicates the establishment of their comfort zone with the existing process and technology set-up. This may pose a challenge during the introduction of new technologies and routines in the context of digitalization. Careful attention is needed to balance the existing people attributes and effectively navigate the change process, to ascertain people engagement throughout the DT journey. A deeper understanding into the micro areas was further assessed for each of the macro dimensions.

2) Micro area's perspectives

People showed a positive trend for "Performance Expectancy, Effort Expectancy and Social Influence". This indicate that operative LCM process is perceived as easier and facilitating within

the internal community. The negative trend on the “Facilitating Conditions” reflects the inefficient organizational and technical infrastructure support for the LCM operations. This aligns with the overall negative trend observed in the process and technology macro areas. Process micro areas only showed a positive trend for the “Planning” micro area, indicating that organizations have been successful in establishing effective planning for LCM tasks. However, the remaining micro areas on “Trivial Workload, Process Waiting and Process Efficiency” showed a negative trend, and reflected challenges with the workload, and efficient execution of the LCM process. Technology micro area of “Interoperability” showed a minorly positive trend and indicated that the existing basic technology used within the LCM operations is interoperable with other systems/tool. This was indeed expected as the *AS-IS* process does not have a complex digital tool, but is based on simple Microsoft office applications as Word, Power Point, Project, Excel, Outlook, Teams, Sharepoint etc. However, the “Information Accessibility and Response Time” showed a negative response and indicated that the current IT tools are not efficient to process information, provide intelligent insights and there is no two-way interaction with the current digital tools. LCM coordinators were the primary source of information and the use of existing Microsoft Office applications required significant effort to enhance information accessibility. Overall, these findings highlighted the need for improvements in various aspects of the operative LCM process. Hence, a managerial guidance was offered for several areas, including enhancing facilitating conditions, aligning processes with performance expectations, improving workload management, addressing process blockages / waiting times, and promoting greater process efficiency. Additionally, it was recommended to enhance information accessibility and reduce response time by implementing better IT tools/digital technologies that enable intelligent insights and facilitate seamless information access. These recommendations aimed to provide a practical direction and support to practitioners in enhancing operational performance and achieving improved outcomes for DT initiatives by catering to the holistic needs of people, process and technology.

3) Items perspectives

The items perspectives provided a detailed granularity for the micro areas of people, process, and technology. From the overall 28 items, 10 items indicated a positive trend with 6 for people, 3 for process and 1 for technology. Among the top 5 positive items, the respondents perceived the *AS-IS* process to be easier and was facilitated by a good understanding of the current IT tools (*E_exp3, E_exp1*), with the adoption supported by colleagues (*Si_2*). The current IT tools have been helpful to users in terms of work scheduling and prioritization within the LCM task planning process (*Plan_2*). Since, basic IT tools were used in *AS-IS* process, it favored the sharing of information/data integration across the systems (Int_2). These positive findings reflected the strengths and advantages of the current operative LCM process. Respondents' positive experiences with ease of use and understanding of IT tools, as well as the support they receive from colleagues, contributed to a more efficient and effective workflow. The top 5 negative items, were predominantly from the macro categories of Technology and Process, indicating a critical need for attention and improvement. On the technological front, respondents expressed concern regarding the time lapse for the system to identify and address problems (Resp_1), signifying a need for quicker issue resolution by the IT tools. Similarly, negative trend with the efficacy of alarms for failure events (Resp_2*)* indicated a necessity for a timely alert mechanism. Within the process dimension, respondents highlighted that significant time is taken by problem-solving (Eff_1), potentially affecting productivity. Furthermore, the time required to rectify errors originating from human mistakes (Eff_2), and instances of document processing errors (Eff_3) were also reflected negatively. These findings underscore the importance of refining technology and optimizing processes to minimize delays, enhance reliability, and streamline workflows in the LCM operations for improving operational outcomes, and delivering value through DT.

C. Risk-Driven Approach to DT - Creation of the Critical Business Attributes (CBA)

The survey results provided valuable insights into the positive and negative aspects of the *AS-IS* LCM process. However, it's important to recognize that these findings represent a single dimension and provide prevalent trends. For a comprehensive understanding, it is necessary to consider qualitative information on risk interdependencies and contextual intricacies. Therefore, we combined the survey insights and Qualitative Risk Assessment Analysis (QRAA) (Edition, 2018), to gain a deeper understanding of the identified areas. QRAA was conducted with a 5-member team comprising diverse LCM stakeholders, and the assessment provided a criticality score to prioritize the CWA, CPA, and CTA of the *AS-IS* state (QRAA Outcome Appendix Table 1). QRAA enabled the cross-reference and cross-validation of the survey findings, and reduced the potential for bias, with a more comprehensive view on the LCM operations. Critical Business Attributes (CBA) were defined by clustering the ranked CWA, CPA and CTA using a qualitative approach based on similarities and relevance. The clustering provided the identification of 6 CBA's (Table 6).

Table 6 Critical Business Attributes (CBA) for the LCM operative process

Insert Table 6 Here

CBA 1, CBA 2 indicated the challenges of information overload and the influence of community acceptance, that might lead to frustration, reduced productivity, and resistance to adoption (Bicchieri, 2016; Venkatesh et al., 2003). Information overload can be managed by properly structuring the knowledge, setting boundaries, and leveraging technology-based tools to curate specific information. Furthermore, practical training and hyper care support can facilitate successful adoption and effective use of the new digital technology. Comprehensive and tailored training packages (Asfaw et al., 2015; Elnaga & Imran, 2013) were recommended to accommodate varying levels of technical proficiency and the specific roles of individuals within the LCM operations.

Additionally, establishment of a hyper-care phase was suggested for continuous user support, feedback, and guidance (Y.-H. Lee et al., 2011), along with the frequent upskilling training sessions for the effective use of digital technologies (Bicchieri, 2016; Bicchieri & Funcke, 2018). Such support system helps to build confidence, overcome resistance, and provide insights into best practices for technology utilization (Sykes et al., 2009). CBA 3, CBA 4, and CBA 5 reflected the need for equipping the LCM operations with technology, to manage information complexity, reduce delays and errors, efficiently manage stakeholders, ensure transparency in LCM status, assign clear accountabilities for action tracking, and streamline processes for rapid responses. The digital technologies are needed to be designed to address these multifaceted needs with a user-centric approach that can manage the intricacies of information, provide accessibility, and facilitate a transparent process with the tracking of accountabilities. Monitoring along the constructs of macro-micro-items provides a comprehensive overview of the LCM operations, aiding in tracking and identifying areas for improvement. Continuous monitoring of user satisfaction (Hsieh et al., 2012; Isaac et al., 2017; Lwoga, 2014; Poon, 2008) was recommended as an intervention strategy. Finally, CBA 6 was related to the challenges imposed by siloed systems and compatibility with legacy systems for data exchange. Interoperability will be needed to enable different systems to work seamlessly together and prevent data fragmentation (Bernstein et al., 2009; Loutas et al., 2011). As the number of systems interconnected within the operational environment increases, it becomes paramount to not only ensure seamless data exchange but also to carefully manage the security of these applications (Craigen et al., 2014; Singer & Friedman, 2014).

D. Flexibility with Digital Design Space (DDS)

DDS (Digital Design Space) represents a conceptual region where design options and decisions are explored to digitally transform the operative business process, ensuring the delivery of business value within a range of flexibility. The DDS was constructed based on the *AS-IS* state of the process, potential risks, and elaborated for the elements that are crucial for the successful DT of the current

LCM process (Appendix Table 1). DDS provided the initial boundaries that are flexible to accommodate the evolving scopes, features and benefits in DT initiatives. The DDS was structured to be adaptable and scalable to accommodate changes in the LCM operations over time, that may be due to technology upgradation or changes in work practices. Further details are provided in the appendix Table 1.

E. Establishing Digitalization Control Strategy

Through the understanding of the digitalized design space (DDS), IT user requirements were defined for the digital technology dedicated to LCM operations (data confidential, not included). These requirements were based on CBAs, thereby relating to the CWA, CPA and CTAs. The requirements were systematically classified to facilitate prioritization and the features were considered with flexibility that ensured the delivery of the expected value. Unique technology needs of the business were translated into IT requirements for developing into a digital technology. Thus, setting a Digitalization Control Strategy (DCS). DCS served as an alignment between the business needs and technology features necessary for bringing tangible value. DCS sets a guideline for building digital innovation as purpose-driven and intricately linked with the overarching DT goals.

F. Digitalization Lifecycle Management

Digitalization Lifecycle Management (DLM) is focused on the continuous monitoring and evolution of digitalized business processes. In a rapidly evolving technological landscape, the ability to adapt and capitalize on emerging technologies is vital for an organization's competitiveness. Digital technologies are continuously changing with evolving benefit scenarios. For instance, the emergence of Natural Language Processing (NLP), a subfield of artificial intelligence dedicated to computer-human language interaction, holds a great potential in healthcare (Sivarethinamohan et al., 2021; Zhou et al., 2022). NLP extends its capabilities to content generation, language translation, sentiment analysis, data extraction, and classification, encompassing a wide array of functions from automating report generation to facilitating global

communication (Sivarethinamohan et al., 2021; Zhou et al., 2022). In the context of the LCM use case, the inclusion of NLP within the digital LCM application would bring multifaceted advantages, thereby enhancing operational efficiency and elevating user experiences throughout the DT journey. The continuous monitoring and upgradation of digitalized business processes is essential for ensuring that they remain relevant and effective in a rapidly changing world. By taking a proactive approach to digitalization, organizations can ensure that their DT initiatives are continuously successful in the long term.

6. DISCUSSIONS

Our study aims to bridge the gap between theory and practice in DT by translating theoretical concepts into practical applications and providing guidance for organizations. We provide theoretical contribution by providing significant insights to enhance existing theories and frameworks on DT. In our study, we have operationalize the use of PPT framework (Javaid & Iqbal, 2017b; Sunmola & Javahernia, 2021b), BPM (Adjei et al., 2021; Brkić et al., 2020; Szelągowski et al., 2022; Szelagowski & Berniak-Woźny, 2020; Ulas, 2019; Van Looy & Shafagatova, 2016; Yang & Tate, 2012) technology acceptance (Bharadwaj et al., 2013; Lai, 2017; Magni et al., 2021; Robles-Gómez et al., 2021; Venkatesh, 2022; Venkatesh et al., 2003; Williams et al., 2015) based on design thinking principles (Brown, 2008; Johansson-Sköldberg et al., 2013; Lichtenthaler, 2020; Nelson & Stolterman, 2012), to effectively address the need for a structured and practical guidance towards technology integration and its establishment into the business, from an initial proof of concept/pilot phase to the routine use (H. Chen & Tian, 2022; Hanelt et al., 2021; Matt et al., 2015; Nambisan et al., 2017, 2019; Satwekar et al., 2022; Svahn, Mathiassen, Lindgren, et al., 2017; Tekic & Koroteev, 2019a; Verhoef et al., 2021a; Vial, 2019). We extend the granularity into the DIM framework (Satwekar et al., 2022) with DbD framework (Satwekar et al., 2023) by investigating the orchestration and emphasizing the crucial attributes that ensure the viability of digital innovation, by considering multiple empirical lens of analysis (Ghosh et al., 2022a; Peruchi et al., 2022a; Yeow et al., 2018a)

across the three antecedent dimensions (People, Process, and Technology) (Javaid & Iqbal, 2017b; Sunmola & Javahernia, 2021b), and elucidate their interplay by recognizing the interdisciplinary nature of DT (Nambisan et al., 2019). Grounded on the principles of Quality by Design (L. X. Yu et al., 2014), our approach brings quality risk-based foundations to examine the interactions between design processes and desired outcomes (Nambisan et al., 2017) to offer practical guidance to organizations in developing, executing, and assessing DT initiatives (Matt et al., 2015; Vial, 2019). We fine-tune existing theories and demonstrate their practical application to address the current need for guidance in DT initiatives (H. Chen & Tian, 2022; Hanelt et al., 2021; Markus & Rowe, 2018; Matt et al., 2015; Nambisan et al., 2017, 2019; Przybilla et al., 2022; Satwekar et al., 2022; Svahn, Mathiassen, Lindgren, et al., 2017; Vial, 2019). Bridging the theory with practice we provide the elucidation of DbD framework with conceptual understanding and practical demonstration of how digitalization can be effectively designed and implemented in organizations. Our contribution to the DT literature brings an enhanced understanding of DT by elucidating the vital role of antecedent dimensions (People, Process, and Technology). We also emphasize the significance of technology integration, organizational transformation, and the interplay of various dimensions throughout the DT journey. By examining these aspects, our research provides valuable insights into the multifaceted nature of DT and its implications for organizations. The elaboration on each step of the DbD framework, based on its underlying theoretical foundations, is further provided with detailed managerial guidance that addresses the challenges faced by practitioners (Table 7**Errore. L'origine riferimento non è stata trovata.**).

Table 7 DbD: Theoretical Foundations, Managerial Guidance and Practitioners Challenge

Insert Table 7 Here

From a managerial perspective, we provide valuable guidance for decision-makers and practitioners on navigating the complexities of DT (Table 7). DbD framework is articulated by recognizing the practical challenges faced by practitioners in implementing DT initiatives such as unclear vision and strategy, difficulty in understanding interconnected dimensions, inability to prioritize based on business needs, rigid practices hindering adaptability, lack of alignment between business and technology, and challenges in monitoring and controlling benefits. DbD framework provides a comprehensive approach for organizations to design and implement DT into their business processes by providing a clear vision, identifying holistic attributes (people, process and technology), defining flexible boundaries, and positioning technology need effectively. This guidance can help organizations to overcome DT challenges and develop a comprehensive tangible DT strategy grounded on the principles of Quality by Design (L. X. Yu et al., 2014) with quality risk-based foundations to guide and analyze the interplay between technology and business relevance. DbD framework acknowledges the interconnectedness of different disciplines and guides managers in addressing the multifaceted challenges and opportunities associated with the integration of digital technologies in organizations. This understanding is crucial for managing the complex dynamics between innovation processes and outcomes (Boland et al., 2007; Nambisan et al., 2017).

While the DbD framework can be generalized to other use cases, it is essential to recognize that assessing CWA, CPA, and CTA requires tailored evaluations aligned with the unique characteristics of each use case. Therefore, the adaptation of micro areas and items should be performed on a case-by-case basis to suit the particular business context and effectively design value from digital innovation. For instance, within the macro area of technology, our study focused on micro areas - interoperability, information accessibility, and response time, which aligned well with our specific use case. Pertaining to the digital technologies and its perceived use towards generating value, practitioners might need to consider other micro areas like security, automation, scalability etc. This customization ensures that the DbD approach effectively addresses the specific needs, challenges, and opportunities of each organization, promoting successful DT initiatives. Furthermore, how to

measure the success for a DT initiative and structuring a standardized criteria to evaluate the DT success is an important research area necessitating further exploration. Future research is necessary to assess DbD framework's effectiveness and efficiency across different industries and contexts. Distinct set of challenges may exist in a particular sector or industry, and it would be interesting to investigate how the DbD framework adapts to these unique circumstances to tailor DT strategies based on industry-specific characteristics. This research avenue would further enhance generalizability of the DbD framework, enrich the literature on DT, and provide valuable DT guidance for organizations within specific sectors. The use of Likert-scale survey and QRAA was effective in capturing key insights within the scope of our investigation. However, it is important to recognize that organizations often vary in their practices and preferences for assessment methodologies. Therefore, as long as the overarching aim of understanding prevalent trends in business processes and gathering qualitative information on risk interdependencies and contextual intricacies on the attributes remains coherent, the organizations may adopt to flexible tools that are best suited to their use cases or established assessment practices. The emphasis would be on sustaining contextual coherence in the outcomes, enabling organizations to seamlessly interchange tools within the DbD framework. Thus, enhancing the broader applicability and adaptability of the DbD framework. Our study is limited by its focus on cloud technology and further studies may be undertaken to elaborate the DbD framework on other emerging digital technologies, such as artificial intelligence, blockchain, and Internet of Things. Understanding how various technologies interact and differently impact DT initiatives, can provide valuable insights for tailoring DT strategies for organizations.

7. CONCLUSIONS

The healthcare sector is on its way for a rapid DT, with continuous emergence of new technologies and innovations. While this presents a wealth of opportunities to improve patient outcomes and

revolutionize healthcare delivery, there are challenges associated with the uncertainty around these advanced digital technologies, which leads to slowness in adoption. As technology races forward at an unprecedented pace, the gap between the technology's potential and its actual utilization is widening. To circumvent these challenges, our study provides a practical and comprehensive approach for designing and building DT. Grounded on the existing theories and frameworks on DT, we emphasize the pivotal role played by the antecedent dimensions of people, process, and technology in the successful implementation of DT initiatives. The findings from our study not only contribute to the academic understanding of DT but also offer valuable managerial insights for organizations, researchers, and practitioners for navigating the complexities of digital transformation and harnessing its potential for creating value. Looking ahead, our study opens up avenues for further research in the field of DT facilitating ongoing progress in the ever-evolving landscape of technology based transformation.

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Tables and Figures:

Table 8 Connecting the logics and phases of Digital Innovation Management with DbD

Digital Innovation Management (DIM)		**Digital by Design (DbD)**
Digital Innovation Logics	**DIM Phases**	
1. Dynamic problem-solution design pairing: Iteratively reshape and navigate digital innovation to create value, with phase-specific objectives. 2. Socio-cognitive sensemaking: Define and discover new opportunities with extended benefit scenarios. 3. Technology affordances and constraints: On need basis, evaluate and build digital technologies step -by-step	**Proof-of-Concept (PoC)** To demonstrate a confidence in the idea. Gaining of understanding to elaborate a forecast business case with a Go/No Go decision.	**1. Defining the Target Digitalized Business Profile (TDBP)** Detail the target business value and demonstrate the concept with selective Technology.
	Proof-of-Feasibility (PoF) Critical business needs were addressed to assess the deployment of the solution in the real-like business settings, and involvement of relevant stakeholders.	**2. Comprehensive exploration of People, Process, and Technology Dimensions** Identification of critical attributes for workforce – CWA (people), process- CPA, and technology – CTA.
		3. Risk-Driven Approach to DT – Creation of Critical Business Attributes (CBA) Elaboration of the relationships and interdependencies between the CWA, CPA and CTA to define critical business attributes (CBA).
		4. Flexibility with Digitalization Design Space (DDS) Elaboration of digital design space for the critical attributes, as a region that assures delivery of business value by accommodating the evolving scopes, features, and value of benefits during the transformation.

with experience-based evaluation. 4. Orchestration: Strategic and coordinated management of elements for resolving systematic barriers to have smooth adoption and shaping of digital value.		**5. Establishing Digitalization Control Strategy** Establishment of control measures on the critical attributes to ensure the consistent performance of the new digitalized business process to deliver value.
	Proof-of-Value (PoV) Digital solution is deployed in routine and managed for iterative value.	**6. Digitalization Lifecycle Management** Continuous monitoring and upgradation of the digitalized business process as per the emerging needs of the business and evolution of technologies.

Table 9 Survey categorization and responses

IT Expertise	Execution	Coordinators	Sponsors	Total (IT expertise)
Not frequent	1	1	0	**2**
Comfortable	3	5	2	**10**
Proficient	1	1	0	**2**
Total (role)	**5**	**7**	**2**	**14**

Table 10 Target Digitalized Business Profile (TDBP) for operative LCM process

Characteristics	Target Value
Applicability	Coordination of LCM managerial processes
Focused Objectives	- Simplify operational complexity. - Automate repetitive actions. - Enhanced monitoring and tracking with global stakeholders. - Standardize and make information & accountability accessible at all levels. - Reduce email and meeting overload. - LCM knowledge management repository.
Current State and Challenges	- Complex processing of information by manual repetitive actions. - Manual monitoring and tracking. - No standardization of knowledge. - High frequency of meetings. - Email exchange overload. - Lack of a suitable digital tool.
Compliance	Application is within a non-GxP system
Business Case	One or more from below, to be defined as long/short term 1. Meeting the focused objectives 2. Strategic & competitive fit 3. Positive NPV
Scale	Scalable at global organizational level, minimum as a central IT system at site.
Dependencies	Existing IT systems and software's – data formats, connectivity, and exchange.

Potential Risks	1. A new unproven technology 2. Connectivity with legacy IT systems 3. User experience: ease of use (non-IT operators), satisfaction & adoption

Table 11 Interview information processing & mapping to literature reported DT insights.

Interview's extract	DT insight	Literature evaluation	Macroarea
Interviewee 3: *"In my opinion, technology should primarily help us to do our job better. Despite the tools we use being very simple (e.g., PowerPoint, Excel, or shared folders), they are sometimes too dispersive, and in the end, I feel like I'm less productive."*	Optimize the tools adopted to enhance performance	(Bharadwaj et al., 2013; Lai, 2017; Magni et al., 2021; Robles-Gómez et al., 2021; Venkatesh, 2022; Venkatesh et al., 2003; Williams et al., 2015)	People
Interviewee 7: *"It took me a while to understand how all it works. Hope that it won't be so hard with a new tool".*	Expectations on learning curve for new tools.		
Interviewee 9: *"I would expect the organization to allow viability and support through peers, external experts, and top management."*	Ensuring support for innovation.		
Interviewee 10: *"Training and assistance are necessary to be engaged to adopt new digital tools"*	Facilitating adoption of digital tools through training and assistance.		
Interviewee 5: *"Communication among old and new systems is difficult."* **Interviewee 2:***"Visualizing previous steps is crucial to not be left behind."* **Interviewee 4:** *"Planners use a diverse tool than ours, thus Compatibility between tools adopted is necessary to be coordinated."*	Ensuring compatibility between diverse digital tools/systems	(Adjei et al., 2021; Brkić et al., 2020; Szelągowski et al., 2022; Szelagowski & Berniak-Woźny, 2020; Ulas, 2019; Van Looy & Shafagatova, 2016; Yang & Tate, 2012)	Technology
Interviewee 8: *"I lose a lot of time to access information and to understand where to insert it."* **Interviewee 10:***"It is hard to link the exact Information and the exact folder."* **Interviewee 3**: *"Perhaps, I spend too much time in searching an information."*	Improving information accessibility and retrieval.		
Interviewee 6: *"I sometimes lose track because of the tool's complexity."* **Interviewee 2:** *"Tools don't allow you to follow up an information as fast as you should."* **Interviewee 9:** *" I always notice problems, after a while."* **Interviewee 7:** *"Time to address a problem could be reduced if the tools were more responsive."*	Improving responsiveness of digital tools to reduce delays and inefficiencies.		
Interviewee 4: *"Job scheduling sometimes is not clear because current tools don't facilitate the flow."* **Interviewee 10:** *"Sometimes we are*	Improving task scheduling and alignment in digital tools.	(Brkić et al., 2020; Butler et al., 1997; Edition, 2018; Gabryelczyk et al.,	Process

misaligned on the expiring dates of a task."		2022; Hammer, 2014; Pridmore & Godin, 2021; Van Looy & Shafagatova, 2016; Vom Brocke & Rosemann, 2014)	
Interviewee 2: *"I receive almost 500 mail per week."* **Intervieewee 7:** *"We end up in too many meetings."* **Interviewee 10:** *"I spend too much time in tracking back an information in my email box."*	Reducing information overload and meeting frequency.		
Interviewee 1: *"We don't have notifications of the advancement of the tasks, so we end up in some delay."* **Interviewee 2:** *"Task's validation goes through different stakeholders, which need to be instantly updated for the efficient LCM outcome."*	Improving task tracking and stakeholder communication.		
Interviewee 6: *"When a problem occurs, I have to track everything from the start."* ***Interviewee* 8:** *"Since tools are too dispersive, mistakes can happen."* **Interviewee 1:** *"The process per se is very well structured, but these minor downfalls waste our time."*	Reducing errors and streamlining processes in digital tools.		

Table 12 Definitions of constructs for survey measurement

Macro area	Micro area	Items (code)
People: Individuals with the right skills and knowledge to execute tasks and contribute to organizational success *I find the tool:*	***Performance expectancy*:** "Degree to which an individual believes that using the new system will help him or her to attain gains in job performance" (Venkatesh et al., 2003)	• Effective to get my job done sooner. (P_exp1) • Useful to be more productive (P_exp2)
	***Effort expectancy**:* "Degree of ease associated with the use of the new system" (Venkatesh et al., 2003)	• Easy to learn (E_exp1) • Useful for further digital tools adoption (E_exp2) • Clear and understandable in accordance with my skills (E_exp3)
	Social Influence: "Degree to which a user is influenced by others in using the new system" (Venkatesh et al., 2003)	• Adoption is supported by external experts (Si_exp1) • Adoption is supported by my peers (Si_exp2) • Adoption is supported by top management (Si_exp3)
	Facilitating Conditions: "Degree to which an individual believes that an organizational and technical infrastructure exists to support the use of a new system" (Venkatesh et al., 2003)	• Training was sufficient (Fc_exp1) • When a problem occurs it's easy to find help and solve it (Fc_exp2)
Process: Entails a series of interconnected value-added business activities that involve	***Planning***: "Determining the specific activities, tasks and procedures required to achieve a process outcome"	• Coordination between different stakeholders (Plan_1) • Job scheduling and how to prioritize activities (Plan_2) • Levels of control & monitoring information (Plan_3)

specific inputs and produce outputs. *I find the tool allows to optimize:*	***Trivial Workload***: "Activities that are relatively simple and require minimal effort, time, or resources to complete"	• Time spent in meetings (Triv_1) • Number of emails, notifications, and messages (Triv_2) • Number of tasks handled by an employee (Triv_3)
	Process Waiting: "Length of time a process is not actively running"	• Time lag between current sub-process and next steps (Wait_1) • Time between the arrival of a request and its processing (Wait_2)
	Process Efficiency: "Systematic approach of identifying, analyzing, and resolving problems or downfalls in a particular process"	• Time spent on solving problems (Eff_1) • Time to redo work due to human-error (Eff_2) • Number of instance documents processed free of error (Eff_3)
Technology: Refers to the hardware, software, machines, systems, and the necessary conducive elements to perform tasks effectively and efficiently within business processes *I find the tool allows to optimize:*	***Interoperability***: "Ability of different technologies or systems to communicate and work together effectively and efficiently."	• Compatibility with legacy IT systems (Int_1) • Data integration for different tasks (Int_2) • Connectivity with other systems (Int_3)
	Information Accessibility: "Easiness to access relevant information to perform tasks and make informed decisions"	• Time to enter an information (Inf_acc1) • Time to get access to information (Inf_acc2)
	Response Time: "Time taken by the system to process a request and provide a response to the user"	• Time between issuing and addressing a problem (Resp_1) • Alarms on failures event (Resp_1)

Table 13 Critical Business Attributes (CBA) for the LCM operative process

CBA No.	**Critical Business Attributes**	**CWA, CTA, CPA**	**QRAA Score** (total)
CBA 1	The operational process needs to be optimized to reduce information overload and enable effective multitasking for improved team productivity.	Triv_1 Triv_2 Triv_3 Inf_acc2	110
CBA 2	Adoption is to be driven through community acceptance and with necessary training and support.	E_exp2 Fc_2 Si_1 Si_2 Si_3	135
CBA 3	Business process to be equipped with technology that manages information complexity, minimizing delays/errors and efficiently managing stakeholders.	Plan_1 Eff_2 Inf_acc1 Resp_1	144
CBA 4	Clarity on overall LCM status, accountabilities to track actions, minimize lag/delays and facilitate faster response.	Plan_2 Wait_1 Wait_2 Eff_1 Resp_2	175
CBA 5	Digital tool provides effective information and controls as aligned to the needs of the operative process and is easy to operate for facilitating user engagement and onboarding.	E_exp1 E_exp3 Fc_1 P_exp1 P_exp2 Plan_3	66

CBA 6	Technological set-up to provide higher level of business efficiency by addressing the limitations imposed by siloed systems and having compatibility to legacy IT systems.	Int_1 Int_2 Int_3 Eff_3	20

Table 14 DbD: Theoretical Foundations, Managerial Guidance and Practitioners Challenge

DbD Steps	Theoretical Foundations	Managerial Guidance	Practitioners Challenge
1. Defining the Target Digitalized Business Profile (TDBP)	This step aligns with the concept of formulating a digital strategy and phased execution (Baslyman, 2022a; Chanias et al., 2019a; Eller et al., 2020a; Matt et al., 2015; Satwekar et al., 2022; Tekic & Koroteev, 2019a; Verhoef et al., 2021a; Yeow et al., 2018a), emphasizing the importance of a vision for the desired digitalized business profile.	• Develop a clear vision for digitalization, outlining high-level expectations and value. • Involve perspectives from stakeholders. • Identify characteristics of the desired digital state to guide the transformation journey. • Set goals for the digitalization process that align with the organization's overall strategy.	Many organizations struggle with formulating a clear vision and strategy for DT. The absence of a well-defined digitalized business profile and associated characteristics can lead to strategic misalignments, conflicts, overlook potential opportunities, wasted resources, and ineffective implementation.
2. Comprehensive exploration of People, Process, and Technology Dimensions	Grounded in the PPT framework (Prodan et al., 2015a), focused on defining CWA, CPA, and CTA through the approach of design thinking (Brown, 2008; Johansson-Sköldberg et al., 2013; Lichtenthaler, 2020; Nelson & Stolterman, 2012; Przybilla et al., 2022), and structuring of unique technology interests that enables the DT (Nambisan et al., 2019), by focusing on Technology Acceptance and Adoption (Farr & Ford, 1990; Lai, 2017; Venkatesh et al., 2003, 2012).	• Conduct discussions with stakeholders to understand their specific needs within an ongoing business activity and elaborate the context in the dimensions of people, process and technology. • Apply design thinking principles to define constructs for micro areas and items using operationalized metrics based on balanced score card (Van Looy & Shafagatova, 2016) (People & Process) and UTAUT (Venkatesh et al., 2003) (Technology). • Conduct a simple Likert measurement survey with the stakeholders to identify CWA, CPA, and CTA to analyze prevailing situation of the business process. • Extend the qualitative information with QRAA (Edition, 2018) to leverage expert judgment in providing nuanced insights into risk interdependencies and contextual intricacies.	Managers often face difficulties in comprehensively understanding the interconnected dimensions of people, processes, and technology within the business process. This leads to inadequate understanding of the existing state, and actual needs of the business. Thus, resulting in a disconnect between the desired outcomes.
3. Risk-Driven Approach to DT – Creation of Critical Business Attributes (CBA)	Integrate DT constructs across multiple empirical perspectives (Ghosh et al., 2022a; Peruchi et al., 2022a; Yeow et al., 2018a), to define characteristics essential for user/customer expectations, business continuity,	• Based on the prevalent trend facilitating the QRAA scoring, identify the prioritization for CWA, CPA, and CTA. • Elucidate the dependencies and relationships among CWA, CPA, and CTA and define CBA that are crucial for success and value creation.	Without a clear understanding of business needs or value proposition, organizations may struggle to prioritize and focus their digital transformation efforts.

	competitiveness, and value generation.		
4. Flexibility with Digitalization Design Space (DDS)	DT initiatives involve flexible innovation processes with dynamic evolution of scope, features, and value of benefits for digital innovations (Nambisan et al., 2017; Satwekar et al., 2022).	• Explore design options and decisions to deliver value with flexibility. • Define DDS as a region, for accommodating the evolving scopes, features, and value of benefits during the transformation. • Establish boundaries that guide the Digitalization Control Strategy (DCS) as a guidance for technology exploration.	Traditional practices may lack flexibility, making it difficult to adapt for changes in technology and business needs. Organizations may become locked into rigid systems or solutions that are very specific, costly, hinder scalability, and restrict organization's innovation potential.
5. Establishing Digitalization Control Strategy (DCS)	Addressing unique organizational needs (Chanias et al., 2019a; Eller et al., 2020a; Ghosh et al., 2022a; Tekic & Koroteev, 2019a; Verhoef et al., 2021a) (Brkić et al., 2020; Spremic et al., 2022a), with increased focus on the materiality of the innovation process and outcomes (Boland et al., 2007; J. Lee & Berente, 2012; Nambisan et al., 2017).	• Elaborate unique technology needs of the business into IT user requirements based on DDS. • Produce a tangible actionable list of features that are contributing towards the desired value.	The lack of alignment between business needs and technology features can result in resistance, inefficiencies, and failure to deliver value. This leads to wasted resources, dissatisfaction among users, and decreased productivity.
6. Digitalization Lifecycle Management (DLM)	Aligns to the phased approach advocated by scholars to navigate the complexities, minimize risks, engage stakeholders to deliver value with continuous improvement (Baslyman, 2022a; Chanias et al., 2019a; Satwekar et al., 2022; Verhoef et al., 2021a).	• Develop a strategy to monitor and control the digitalized process for evolving business needs, and technologies. • Implement a structured and systematic approach for continuous evaluation and adaptation. • Monitoring the constructs across the macro areas of People, Process, and Technology, as well as relevant use case specific micro areas and items, ensures organizational agility and responsiveness to changing dynamics.	Organizations commonly face challenges in monitoring and controlling the tangible benefits of digitalization efforts. In the absence of effective evaluation and adaptation, there is a risk of stagnation or failure to address evolving challenges during the digital transformation journey.

Figure 3 Engagement between scholars and practitioners – connecting DbD with DIM

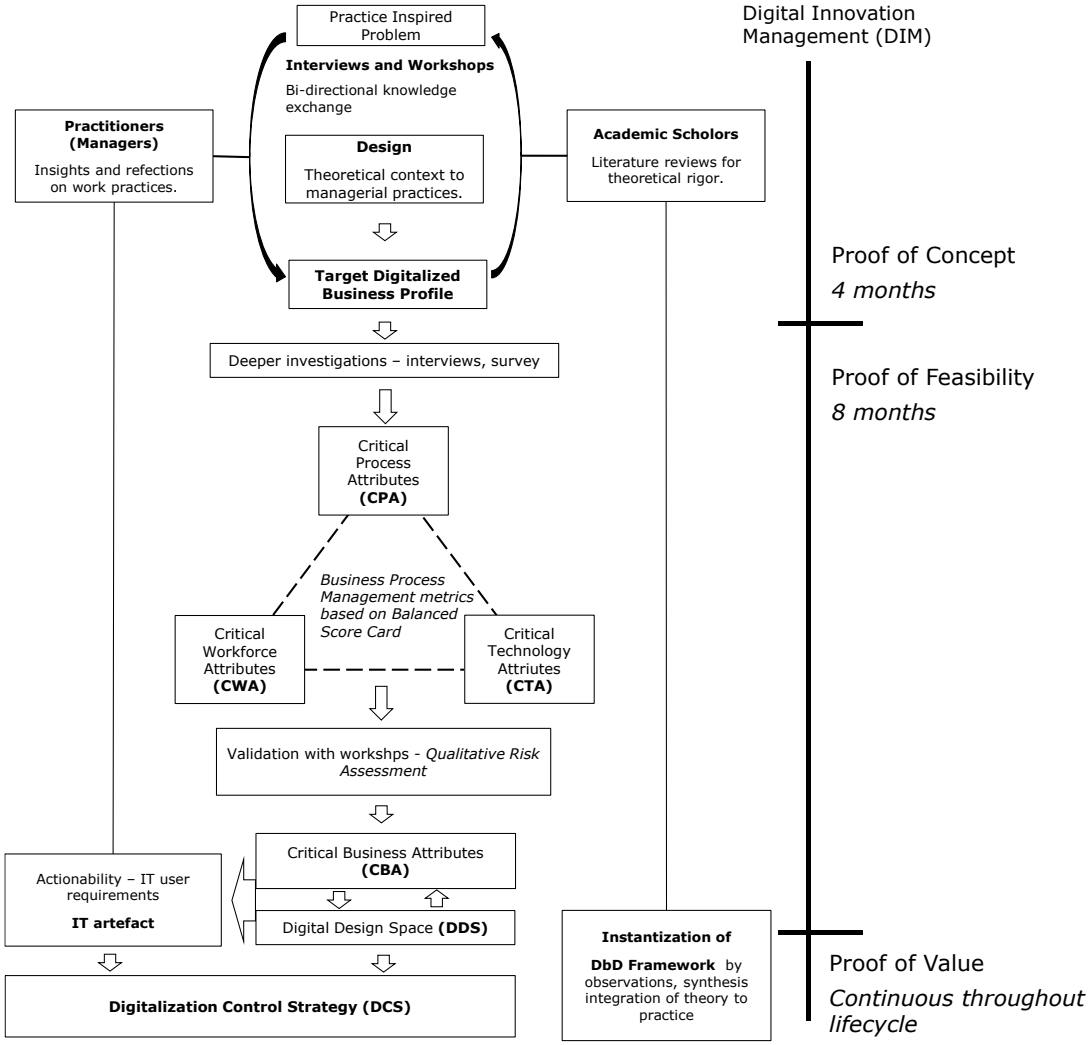
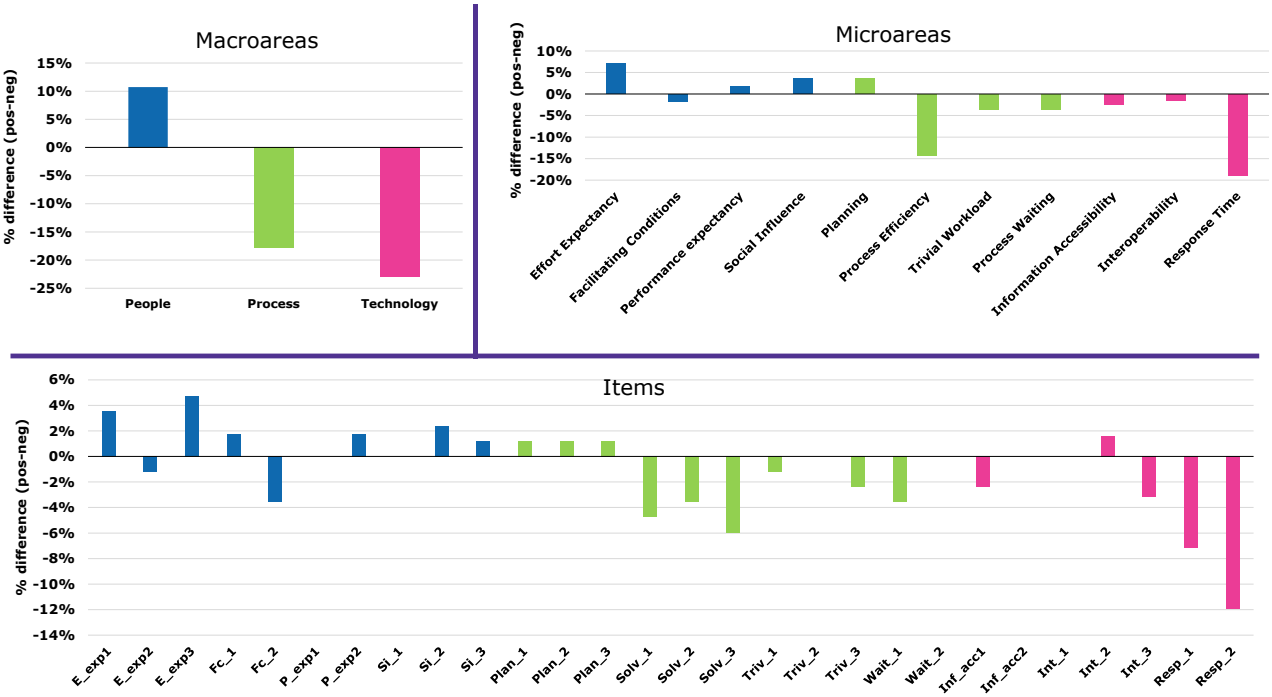


Figure 4 Perspectives from the survey responses



Paper 3: Developing an AI framework for Stakeholder Engagement: Insights from Indian and Italian pharmaceutical companies

Abstract

Digital transformation (DT), particularly Artificial Intelligence (AI), is increasingly recognized as a critical enabler of competitive advantage. However, research linking DT and stakeholder engagement remains limited, particularly in exploring its interdisciplinary, industry-specific and single-technology implications. This study addresses this gap by presenting insights from 16 in-depth interviews with experts in Italian and Indian pharmaceutical companies, employing a qualitative methodology based on fieldwork semi-structured interviews. After an in-depth analysis based on coding technique, three key themes emerged, offering a nuanced understanding of how organizations can achieve successful AI initiatives while fostering Stakeholder Engagement. These themes informed the development of a comprehensive framework that integrates: (i) External Stimuli, (ii) Innovation of the organization's fundamentals, including (a) Structural, (b) Cultural, and (c) Technological Means Transformation, and ultimately (iii) AI relevant Stakeholder Engagement initiatives. Overall, this study contributes to theoretical advancements in Stakeholder Theory and provides actionable insights for practitioners aligning AI initiatives with stakeholder expectations. Ultimately, this study lays the foundation for effective AI deployment in contexts demanding sustainable and stakeholder-centric innovation.

Keywords: Digital Transformation; Stakeholder Engagement; AI; Organizational Innovation; Pharmaceutical Industry

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Introduction

Digital Transformation (DT) is recognized as a crucial driver of competitive advantage and an imperative for businesses (e.g. Gong and Ribiere, 2021; Verhoef et al., 2021; Bennich, 2024). Scholars agree that this transformation is more than a mere technological shift, adoption, or use. Rather, it reflects the organization's strategy, values, culture, leadership, and people (Goran, LaBerge, and Srinivasan, 2017). DT is considered to create value for its stakeholders by strategically leveraging its key resources and capabilities (Gong and Ribiere, 2021), however, there is a dearth of multidisciplinary, industry and single digital technology-oriented studies (Nambisan, Wright, and Feldman, 2019) contributing to Stakeholder Theory perspective. In the DT context, a technology gaining particular interest is Artificial Intelligence (AI) (Holmström, 2022), evidencing benefits such as improving operations, economic performance, decision-making, sustainability (Holmström, 2022; Magistretti, Dell'Era, and Petruzzelli, 2019; Iansiti and Lakhani, 2020). The ability to deploy and use AI in ways that add value to the organization still varies, and so do the related stakeholder engagement practices (Holmström, 2022). One essential aspect of DT is the radical improvement of an organization and the redefinition of its value proposition for a broad range of stakeholders. For AI efforts to be successful, it is crucial to engage stakeholders who may vary widely in their interests, influence, motivations, and capacities. Thus, it becomes essential to understand how to align strategies with the potentially diverse perspectives of these heterogeneous actors. This article addresses a key research question: *How should companies carry on digital transformation initiatives, in particular AI-related, while aligning with multiple stakeholder's demands?* To investigate it, the study introduces a framework that addresses stakeholder engagement towards AI, built following a fieldwork study through 16 in-depth semi-structured interviews between the Indian and Italian Pharmaceutical Industries. The choice of the research setting is based on three considerations: (i) it presents a crucial domain for investigating digital transformation, in particular AI, given complex challenges stemming from stringent regulatory frameworks and quality control standards, which often hinder digital innovation paces; (ii) it retains a central role in healthcare provision, underscoring

broader stakeholders' implications of DT and AI adoption, beyond mere operational enhancements disrupting the whole pharma value chain, from drug discovery to market access; (iii) the comparative analysis between Indian and Italian pharmaceutical sectors offers valuable insights into diverse organizational approaches within the same industry, with Italy's emphasis on innovative Drug R&D contrasting India's manufacturing focus. By summarizing these perspectives, the study aims to provide a comprehensive understanding of the DT phenomenon, particularly AI, and stakeholder engagement approaches. By applying the Coding Technique (Corley et al. 2004), three AI-relevant themes emerged and were interpreted to create a framework for navigating effective AI stakeholder engagement via: (i) External Stimuli, (ii) Innovating Organization's Fundamentals and (iii) Stakeholder Engagement. The theoretical implications of this investigation are twofold. First, this study provides insights into driving successful initiatives to address organizational, technological, and industrial needs through the identification of three themes relevant to DT practices aimed at different stakeholders. Second, it provides solid theoretical foundations for effectively engaging stakeholders, fostering organizational innovation, and integrating external stimuli into AI technology deployment. These insights provide industry professionals a clear roadmap for aligning DT — particularly AI— with stakeholder engagement strategies.

b. Theoretical Framework

Digital Transformation and Stakeholders Theory: an integrated approach to study AI

The study of Digital Transformation (DT) is an appealing business research area. Management theories such as dynamic capabilities theory or resource-based view, while addressing comprehensively the intersection between digital technologies and innovation (e.g., Vial, 2019; Malik et al., 2022; Warner et al., 2022), have not yet delved deep into the emerging implications of multiple stakeholders involved in the digital transition process. Stakeholder's theory (Friedman and Miles, 2006; Freeman, 2010), posits that organizations must endeavor to achieve long-term benefits for their stakeholders but still, there is little knowledge about the integration with DT. Previous research found

that stakeholder-oriented approaches contribute to shaping DT strategy (Hu et al., 2024), digital open innovation for sustainability (Del Vecchio, Secundo, and Garzoni, 2024) and small entrepreneurial digital engagement (Candelo, Casalegno, and Civera, 2022) but nonetheless lacks a clear theoretical framework in which to create relevant contributions.

According to Nambisan (2019), three primary considerations must be included when investigating DT phenomena. First, DT influences micro, meso, and macro levels so the scholarly inquiry ought to integrate coherent principles across diverse empirical contexts. Stakeholder's Theory, by considering a wide range of actors influenced by and influencing a company's choices, can provide a broader empirical lens to evidence their emerging needs amidst DT disruptions (Freudenreich, Lüdeke-Freund, and Schaltegger, 2020; Miller, McAdam, and McAdam, 2014). Second, DT research should contribute to different subject fields, while current literature elaborates on single streams, such as organizational change (e.g. Matt et al., 2015; Verhoef et al., 2021; Satwekar et al., 2022) digital maturity (e.g. Chen and Tian, 2022; Spremic, Zentner, and Zentner, 2022) or designing a coherent strategy (e.g. Vial, 2019). This inadequately emphasizes the importance of aligning DT with diverse streams of research. Third, DT itself does not stand as the focal point of investigation; instead, research should delineate the pivotal roles of each technology within their context, elucidating and addressing single technology and industry implications. This results in scrutinizing the interplay among design processes, stakeholders' requisites, and the organization's desired outcomes in navigating a new digital project (Satwekar et al., 2024). The current literature lacks clarification in integrating single digital technologies with specific organizational processes and industries; therefore, failing to address the distinctiveness of various digital technologies (Vial 2019), how to transition between different phases of DT while satisfying the needs of various stakeholders (Tekic and Koroteev, 2019), and how they can be leveraged to create value within different business contexts (Eller et al., 2020; Kindermann et al., 2022). By emphasizing the focus on diverse groups of interest, stakeholder theory supports the investigation of the impact of single digital technology on diverse stakeholders, within an individual industry. Coherently, this paper aims to elaborate on (1)

understanding how to align DT practices with the views of stakeholders, specifically within the pharmaceutical industry, (2) integrating individual industries and single technology implications, in particular that of AI and (3) deploying interdisciplinary and multiple theoretical and empirical perspectives, synthesizing insights from different streams of research and industry stakeholders to provide a comprehensive understanding of how interdisciplinary approaches can contribute to the advancement of DT in the management research field.

AI is one of the most intriguing technologies in DT as it affects how firms innovate (Marcello M Mariani and Wamba 2020; M M Mariani et al. 2023) support organizational processes (Lu, 2019) improve decision-making (Verganti, Vendraminelli, and Iansiti 2020; Kakatkar, Bilgram, and Füller 2020), enhance operational efficiency (Belhadi et al., 2024) and develop sustainable business models (Di Vaio et al., 2020). Few studies have attempted to connect AI initiatives while engaging with multiple emerging stakeholders demands. Stakeholder engagement is defined as "A stakeholder's cognitive, emotional, and behavioral resource endowment in his/her role-related interactions, activities, and/or relationships" (Hollebeek, Kumar, and Srivastava, 2022; Katsikeas, Viglia, and Hollebeek, 2023). This concept has garnered interest across various disciplinary fields, with research sources adapting accordingly to the final stakeholder to be engaged; psychological and behavioral studies for customer engagement (Perez-Vega et al., 2021), or environmental studies to address broader societal impacts (Watson et al., 2018). This investigation aims to expand the understanding of AI Stakeholder Engagement, incorporating technology-specific, interdisciplinary, and multilevel empirical perspectives (Nambisan, Wright, and Feldman, 2019). Being AI a socio-cognitive technology, its introduction affects both organizational and individual spheres (Kanungo, Liu, and Gupta, 2024), raising novel research avenues, particularly in designing stakeholder engagement into organizational structures as a long-term strategy. However, little research has been conducted in understanding how organizations should navigate AI, including diverse motivations, dynamics, potential conflicts, and impacts of multiple stakeholders involved (Katsikeas, Viglia, and Hollebeek 2023; Perez-Vega et al. 2021; Wijayati et al. 2022), this paper aims to fill this gap.

c. METHODOLOGY

c.1 Research Setting

This research aims to explore how stakeholder engagement and digital transformation (DT), in particular AI, should be integrated into the firm's strategy and organizational structure to create tangible value for multiple stakeholders (Katsikeas, Viglia, and Hollebeek, 2023). It provides multiple empirical lenses, multidisciplinary contributions, and a single technology perspective through explorative qualitative fieldwork based on semi-structured interviews (Eisenhardt, 1989).

The research focuses on the pharmaceutical industry, which has a strong interest in AI, as it is transforming business operations and helping organizations leverage data and make predictions at lower costs (Gama and Magistretti 2025), thus, investigating how stakeholders respond to these new implementations is of significant interest.

c.2 Data Collection

Data collection started by reviewing archival materials, including industry reports, technical and management literature, as well as online blog articles discussing pharmaceutical digital transformation, with particular emphasis on AI. Table 1 highlights the relevance of stakeholders in relation to AI, based on the archival data reviewed.

Insert Table 1 Here

Following a thorough archival data examination, in line with the qualitative fieldwork methodology, pharmaceutical organizations in Italy and India with a strong reputation for excellence in this domain were identified for semi-structured interviews. Several compelling factors substantiated the selection of this research context. First, Pharmaceutical Industry represents a critical domain in studying the introduction of digital transformation, especially AI, as it is characterized by intricate challenges concerning stringent regulatory frameworks (Brunetta, Boccardelli, and Lipparini, 2015) and control

standards that may impede the rapid pace of innovation. Second, given the industry's pivotal role in healthcare through the development of life-saving medications, the implications of AI deployment extend beyond mere operational efficiencies, encompassing broader stakeholders' societal and ethical considerations. Third, the comparative study between Indian and Italian sectors offers valuable insights into the diverse approaches adopted by organizations operating within the same industry but at different empirical levels. The Indian pharmaceutical industry is recognized for its large-scale production of generic drugs at competitive prices (Reddy and Sharma, 2016), indicating a solid orientation on manufacturing (Sharma et al., 2022). In contrast, the Italian pharmaceutical industry is recognized worldwide for its R&D of innovative drugs (Kraus et al., 2021). These substantial peculiarities retain important implications regarding digital transformation, particularly with AI; by covering different roles of the pharmaceutical value chain, these clusters will adopt different structures to respond to new challenges, representing different global avenues of this sector. Overall, after an in-depth analysis of archival material considering DT, in particular AI, implications in the pharmaceutical industry, 16 semi-structured, in-depth interviews were performed with a sample of 9 Indian and 7 Italian field experts, covering the entire pharmaceutical value chain stages, actively involved in relevant initiatives within their respective organizations. The interviewees are diverse professionals from Asia and Europe, holding key roles in the pharmaceutical industry (Table 2).

Insert Table 2 Here

Their positions range from general management to specialized functions like industrial operations, institutional affairs, supply chain management, and research and development. In the Italian context, the participants include General Managers, a Chief Industrial Operations Officer, a Chief Institutional Affairs Officer, and an R&D Scientist. These professionals work in organizations of varying sizes, from companies with over 1,000 to over 5,000 employees, and their companies generate significant

revenue streams ranging from $400 million to over $5 billion. The general managers and chief officers bring high-level strategic and operational perspectives, while the R&D scientist offers insights into innovation and technological advancements within the industry. In the Indian context, the interviewees are General Managers, Manufacturing Quality Control Managers, Supply Chain Managers, and R&D Scientists. The companies they represent vary widely in size, with employee numbers ranging from 50 to 20,000; revenue streams differ significantly, from $1 million to $2 billion. These interviewees provided perspectives on large-scale manufacturing and quality control processes, as well as the challenges faced by smaller companies in the pharmaceutical sector. Overall, interviewees provided a comprehensive view of the pharmaceutical industry's digital transformation, in particular AI, across different levels of the organization and diverse market conditions. Interviews were led both in Italian and English, online and/or physically, between June 2022 and December 2023, for an average duration of 45 minutes to 1 hour. Data were recorded and manually transcribed. Anonymity and non-directive questioning to ensure data validity, encouraging respondents to speak without pressure, were adopted.

c.3 Research Design

Research originated reviewing archival documentation, including technical and management relevant literature, industry reports, and relevant material available on the internet, such as pharma-specific blogs, which served as the foundation for developing the interview's structure. The semi-structured interviews allowed a balance between openness to new insights and adherence to the protocol. Interviews evolved around six main open questions to comprehensively explore the emerging needs and relations with relevant stakeholders when embarking on new DT initiatives, with a particular emphasis on AI initiatives. To start the interview, the interviewers asked about the industry's shift toward new digital technologies, in general, inviting respondents to share their perspectives on the most interesting advancements and organizational changes resulting from digital transformation, as well as AI, and implications for key stakeholders, such as employees. Secondly, the conversation

explored how AI impacts cultural change within organizational structures and processes, focusing on technology acceptance. The next question addressed the challenges in tracking, ensuring transparency, building trust within the supply chain, and the overall impact on suppliers and patients. Further, the interview focused on the company's environmental policy, strategy, or initiatives, asking for specific examples of how digital transformation, in particular AI, supported these efforts. This question covered the environmental, social, and governance (ESG) implications of the company's actions, considering DT impacts for a wide range of stakeholders such as Local Communities, Patients or the Environment. In the fifth question, the interviewers explored the impacts of digital technologies, in particular AI, in personalized medicine, asking how these technologies are deployed to tailor individual treatments and what challenges exist regarding data transparency. The final question sought the respondent's thoughts on the trade-off between costs and revenues resulting from DT and sustainability initiatives. Figure 1 summarizes the Research Design, including Data Collection, Analysis and Validity.

Insert Figure 1 Here

Data Analysis

Data analysis was conducted in the NVivo 12 program in four main stages: open coding, first-order, second-order, and third-order codes. First, the open coding technique was used to thoroughly examine the data, generating 233 open codes. Subsequently, information were gathered and organized into categories. In the first-order coding phase (Corbin and Strauss 1990), authors derived 80 first-order codes. The listed topics collectively provided a comprehensive overview of DT in the Pharmaceutical Industry, including the role of AI in enhancing process efficiency, decision-making, and environmental performance monitoring, as well as the increasing reliance on agile startups to foster drug discovery, often preferred over internal R&D, along with barriers like cultural resistance,

structural limitations, and a lack of regulatory clarity. In the second-order phase, results were rationalized and the initial themes were scrutinized into 14 relevant themes. Multiple topics were highlighted in this phase, such as Competition and partnerships as driving forces to enhanced AI deployment, the cultural and organizational shift needed to deploy digital innovation, data playing a pivotal role in enhancing AI-based decision-making and optimizing processes, supporting sustainable practices while growing awareness and commitment coherently to new organizational and institutional perspectives. Ultimately, the last phase, the third-order coding stage, further categorized data into five final themes: *External Stimuli, Renovating Organizational Fundamentals, and Stakeholder Engagement* with AI emerging as the preeminent digital technology within the research setting, covering the entire value chain from drug discovery, clinical trials, manufacturing, and supply chain management to Market Access (Deloitte, 2019)[5].

d. Findings

d.1 External Stimuli to AI

Across the interviews, many AI-relevant factors emerged; these were generated, influenced, and linked to various *"External Stimuli"*. Table 3 represents relevant Interviewee's quotes.

The first recurring theme worth mentioning is the workforce turnover and the demand for new talent related to AI, as this technology is increasingly acknowledged in both Italian and Indian contexts for its potential to streamline processes, enhance decision-making, facilitate research of new molecules through platforms, and optimize operational efficiency to mitigate sustainability impacts. The Indian context generally displays a more enthusiastic embrace of diverse generations of new technologies, Italy demonstrates a deeper understanding and proficiency, leading to a more nuanced appreciation of its benefits but, most importantly, awareness of the challenges, which is a common sentiment rooted in the ongoing digital transition:

[5] *Intelligent Pharma Industry, Forging the Links across value chain - Deloitte Centre for Helath Solutions*

"We are simply in a transitional moment, and in the future, younger generations will be increasingly accustomed to digital technologies, while older generations will retire." (Interviewee 1, Italy)

Moreover, the introduction of AI needs to be reshaped profoundly in relation to institutional actors. Even if they appear to have been engaging with the AI trend *"recently considering the acceptance of AI-sourced molecules" (Interviewee 5),* these entities emerge as not keen on new technological paradigms, causing delays in AI-oriented treatments concerning Personalized Medicine. In the view of many interviewees, Regulatory institutions' slow uptake of DT, in general, impedes the effective proposal of new AI patient treatments, with interviewees highlighting a perceived:

"Fragmented institutional counterpart's readiness to digital transformation and AI and disparities in knowledge and readiness between Northern and Southern Italy." (Interviewee 5, Italy)

Another important point relates to the relevance of data privacy and compliance with regulations, as well as its pivotal element in allowing the capturing of specific benefits to feed AI-algorithms:

"One of the main concerns is the protection of patients' data privacy and compliance with regulations." (Interviewee 2, Italy)

Overall, improved access and regulation to health records would enable the transition towards a more patient-centric business-to-consumer (B2C), emphasizing the importance of innovating the patient journey toward personalized medicine:

"(...) to transition away from the conventional B2B model towards a more Patient-centric B2C paradigm." (Interviewee 6, Italy)

Another significant theme that has emerged is the imperative to foster collaborative partnerships *"with IT giants such as IBM or Microsoft to drive AI" (Interviewee 2, Italy).* This underscores the necessity of new alliances to experiment with this technology. Collaboration and Competition are widely acknowledged in management literature as essential for success. Interviewees have

underscored, indeed, the significance of competition in driving their initiatives, such as being afraid *"about Amazon entering in our Market." (Interviewee 5, Italy)*. They have also highlighted collaborative partnerships as key drivers for digital projects:

"I had the opportunity to collaborate with a company based in Germany that has a manufacturing plant in India. (...) I believe this example is very interesting because foreign companies can provide a significant boost to the digital transformation of the Indian pharmaceutical industry."

(Interviewee 8, India)

Moreover, one salient external driver from the conversations revolves around Mergers and Acquisitions of Innovative Startups to pursue enhanced performance. Particular attention is given to investing in start-ups to deploy AI for developing new drugs in the Italian Context, as:

"AI startups are much more agile and adaptable than big multinationals. They do not have to overcome the significant organizational barriers that big corporations traditionally struggle with."(Interviewee 1).

The interviews shed light on the external stimulus to AI of mergers and acquisitions involving startups acquiring DT know-how, particularly in deploying AI for drug development, providing immediate access to competencies they might not have developed in-house.

d.2 Innovating Organizational Fundamentals for AI Deployment

Once a company acknowledges External Stimuli, it must reorganize its structures and processes to integrate AI, addressing Innovation for Organizational Fundamentals. Table 4 represents relevant Interviewee's quotes.

The first resounding theme echoing throughout the discussions is committing to new structural investments in IT and changing organizational data approaches. This transformation is about redefining collaborative possibilities and fostering agility in responding to market dynamics through organizational change, highlighting the strategic importance of different digital technologies such as

Cloud, IoT, or Blockchain to pivot AI deployment. Challenges in replacing current systems may become a potential obstacle to maintaining quality in the short term. Controversially, shifting from manual data handling to digitized information systems is a difficult step to make, but most likely beneficial in streamlining operations, avoiding time-consuming processes, and sources for errors associated with manual data entry:

"Many of the processes still involve manual information writing, digitization will make everything much more efficient."(Interviewee 9, India)

Nonetheless, challenges persist due to the persistent reliance on paper documents, reflecting a prevailing adherence to traditional methods and the scarcity of successful applications of potential technologies like Blockchain in eliminating manual reporting steps. Thus, despite progress towards digitization and attempts at digitizing information, the influence of stakeholder preferences on organizational practices suggests that companies often mirror the preferences of their counterparts as long as they favor traditional paper-based processes:

"As for technologies like Blockchain, I haven't seen many successful applications yet, but I believe it could be useful as it would eliminate many manual reporting steps with regulatory institutions." (Interviewee 2, Italy)

The interviewees emphasized that organizations could leverage data-driven approaches to improve operational performance and enhance decision-making by feeding AI Algorithms. This acknowledgment underscores the industry's evolving landscape, where practitioners increasingly rely on advanced technologies to drive informed decisions toward improving efficiency:

"Digital transformation in the pharmaceutical sector is increasingly gaining ground and, above all, bringing various benefits: data accuracy, tracking and tracing, and assistance in interpretation." (Interviewee 11, India)

Integrating AI with other digital technologies emerged as a common strategy among practitioners, enabling efficient data tracking, comprehension, and real-time monitoring, thereby optimizing workflows and ensuring product quality:

"Technologies such as Artificial Intelligence, Blockchain, and IoT can help with both tracking and understanding data." (Interviewee 15, India)

Another important theme that emerged is that of Cultural Shifts. Successful initiatives are often related to key processes such as understanding the needs and expectations of end users, testing and validating ideas before scaling up, as well as equipping users and potential users with the necessary skills to use new digital tools and technologies effectively. Indeed, the adoption of the above-mentioned technologies is guided by perceived needs, encouraging even non-digital natives to embrace technological shifts and techniques such as design thinking and prototyping by helping to identify and validate these needs may be the object of pilot programs:

"I am convinced that the real driving force behind digital transformation is the perceived need. If there is a problem that can be solved through DT, then even non-digital natives will perceive the value and make the shift. Internally, we often conduct pilot programs based on prototyping and Design Thinking techniques." (Interviewee 1, Italy)

Additionally, given the fast rate of evolution of digital technologies, training ensures that users are not only able to fully exploit the potential of technologies but also stay updated with the latest tools and methodologies, fostering a culture of continuous improvement and adaptability:

"I have undergone extensive training, and I have changed my way of seeing digital transformation over time. (...). However, I am convinced that after a few months and with good training programs, it's easy to grasp the logic of the new tools, even in a short time (e.g., 6 months)." (Interviewee 16, India)

Additionally, training initiatives promote interdisciplinary collaboration and multidisciplinary skills development:

"I try to promote training as much as possible and guide HR towards personnel with multidisciplinary skills, especially in IT." (Interviewee 3, Italy)

This strategic approach enhances individual competencies, accelerates the organization's capacity for innovation and adaptation, and drives organizational agility and resilience. Organizations may delegate this process by simply acquiring innovative startups, facilitating the sharing of knowledge, resources, and expertise, ultimately driving collaborative efforts towards scientific advancement and leveraging the expertise and agility of startups to complement internal operational efforts:

"Large companies increasingly delegate their projects to smaller entities because they are more agile and capable of adapting to changes." (Interviewee 9, India)

Furthermore, an Italian interviewee (Interviewee 2) asserted that to build awareness of the benefits of digital transformation, in particular AI, among employees:

"Organizations should start from the perceived problem within the process and solve it using design thinking and prototyping techniques. (…) this approach was beneficial for integrating Generative AI to efficient inventory management operations."

Increasing awareness is key as it supports comprehension and articulates the significance of DT initiatives. Overall, **c**ommitting and communicating the underlying values ensures that, both internally and externally, all the stakeholders are driven by the need for continuous development and adaptation to new technologies, overall, enhancing support at multiple levels. Another interesting theme that emerged from the interviews is that Data and AI deployment are pivotal to achieving better ESG objectives, such as to: *"I see data and AI exploitation as a value to obtain tangible sustainability results" (Interviewee 1)*. This revolves around the symbiotic relationship between AI and its collective impact on improving operational and Sustainability efficiency. However, concerns about the reasoning behind AI decisions and employees have been raised:

"(…) It's always important that data is interpreted by people and not blindly relying on outcomes produced by a machine." (Interviewee 14).

In this context, the transition from manual to digitized information and the novel approaches, such as Design Thinking and Training, may facilitate organizational and cultural shifts in how employees and the organization leverage AI by improving final users' awareness.

d.3 AI for Stakeholder Engagement

The final theme elaborates on how organizations set their AI strategies to engage stakeholders. The following subsection addresses AI engagement with major Pharmaceutical industry stakeholders: *Employees, Patients and Institutional actors, Local Communities, Society and Environment, Suppliers, Shareholders, and the Scientific Community.* Table 5 represents relevant Interviewee's quotes. To start the elaborations, considering significant implications directed to *Patients, Shareholders and Scientific community*, engagement strategies arise from the acquirement of AI-based Drug Development startups. Contrasting sentiments prevail within the Indian sector, where there exists a degree of apprehension towards investing novel business model approaches. This hesitance stems from concerns regarding a potential reduction on profit margins and the need to maintain alignment with existing business models, mainly directed at manufacturing activities. Agility and adaptability of AI startups is highly valued within Italian interviewees (e.g. Interviewee 1), highlighting their ability to navigate organizational barriers that often impede larger multinational corporations, which is most likely an imperative, as:

"It is certainly more convenient to invest in a drug that has passed the initial trial stages and hope for its success." (Interviewee 6)

Stakeholder engagement practices must remain mindful of the importance of how the organization reacts to these endeavors. As companies integrate AI into practice, it is essential to recognize its profound impact on *Employees*. Here, authors delve into some key considerations highlighted during the interviews. First, it is imperative to recognize that AI is a pivotal medium in revolutionizing decision-making processes. Nevertheless, effectively utilizing these insights necessitates a holistic approach beyond mere technical proficiency. In particular, Interviewee 14 addresses caution against blindly relying on machine-generated outcomes. This serves as a sobering reminder of the importance of human interpretation. While AI holds immense promise in augmenting decision-making processes, it is essential to preserve the role of human expertise in deriving meaningful insights. In this context,

as underscored by Interviewee 3, the paramount importance of imparting comprehensive training and fostering ongoing professional development initiatives cannot be disregarded both in Italy and India:

- *"I try to promote training as much as possible and guide HR towards personnel with multidisciplinary skills." (Interviewee 3, Italy)*
- *"(...) training initiatives in cooperation with technology partners to introduce employees to new routines." (Interviewee 8, India)*

Therefore, it is imperative to foster a culture of continuous learning wherein employees actively assimilate AI technologies and are equipped with the requisite competencies to navigate this evolving landscape. The existence of a generational divide within the workforce warrants diligent attention, as noted by multiple interviewees (Interviewee 1, 11 and 13), particularly older employees less likely to accept new technologies (Interviewee 16). This is added to the discernible disparity in agility between AI startups and traditional conglomerates, posing challenges and opportunities to facilitate knowledge exchange. Moreover, by prioritizing the needs and preferences of *Patients*, a culture of innovation, enduring trust, and loyalty should also be cultivated within the *Suppliers* ecosystem. Given a discernible shift toward a more consumer-centric paradigm, as noted by multiple interviewees (e.g. Interviewee 6, 13). This transformation not only redefines the dynamics of patient engagement but also necessitates a fundamental reorientation in supplier relationships. Interviewee 13 eloquently underscores the pivotal role of AI and IoT technologies in augmenting cold chain management protocols, thereby safeguarding the quality and integrity of products:

"Cold chain management is essential, and technologies like IoT & AI can greatly improve visibility and control over expiring drugs." (Interviewee 13)

This assertion underscores the significancy of data analysis facilitated by AI in realizing personalized medicine's goal, highlighting suppliers' pivotal role in enabling this digital transition. By integrating AI and other digital technologies decision-makers can enhance supply chain efficiency while advancing patient care and environmental stewardship, such as:

"We have implemented various technologies aimed at tracking and tracing process information. For example, thanks to IoT, we can monitor environmental conditions during production and transportation. In general, the production facility will become increasingly interconnected to streamline operations." (Interviewee 11)

This resonates with the broader objective of integrating different technologies for enhanced sustainable practices, for *Local Communities, Society and Environment* articulated by multiple Interviewees (1, 11 and 12) AI may support mitigating environmental impacts through enhanced optimization of resources, minimization of waste, integrating AI with track-and-trace technologies such as IoT in monitoring sustainable performance. As articulated by Interviewee 1, highlighting the role of AI in enhancing decision-making and operational efficiency across various fields, including supply chain management:

"I strongly believe in the use of AI to enhance decision-making across various fields, from inventory calculation to market demand forecasting. I consider AI in the context of Supply Chain a significant boost for operational efficiency and effectiveness." (Interviewee 1)

Overall, the profound impact of AI extends across diverse domains, the envisioned utilization of AI-powered analytics holds immense potential in optimizing operations and bolstering overall performance. While exploring AI integration within the pharmaceutical landscape, several key insights have surfaced, illuminating both opportunities and challenges with *Patients* and *Institutional Actors.* Interviewee 12 aptly highlights the significance of Blockchain and AI integration in streamlining processes, underscoring their potential for information deployment:

"The technologies I consider most important are Blockchain and AI. From my experience, I have seen that their integration can be useful for tracking information and creating insights to streamline processes." (Interviewee 12)

As Interviewee 2 observes, the issue of interoperability among different systems poses a formidable challenge, with data fragmentation impeding seamless exchange and analysis:

"Another challenge is interoperability between various healthcare systems and the quality of collected data. Often, data is scattered across different platforms, and the lack of common standards can complicate data exchange and analysis." (interviewee 2)

This underscores the critical need for standardized protocols to ensure cohesive data integration and utilization between companies and Institutional actors such as Hospitals, Pharmacies, and Regulatory

bodies. Similarly, Interviewee 3's insights into the increasingly tailored nature of personalized medicine underscored the imperative of aligning technology applications with patient-centric objectives:

"Thanks to the use of AI and other technologies, drug commercialization will be increasingly target-driven." (Interviewee 3)

Amidst these advancements, it is crucial to acknowledge that the divide within institutional actors plays a critical role, as:

"(...) Personalized medicine is a mirage, until we do not analyze properly data, which can be analyzed through AI." (Interviewee 13)

Clear guidelines and standards are essential to safeguard patient data privacy committing further in *"(...) who owns the data." (Interviewee 1)* In general, it highlights as a final point how companies are closely linked to those of *Regulatory Institutions,* as: *"(...) until they (regulatory institutions) do not update, there won't be an application field for precision medicine." (interviewee 5)*.The element that primarily illuminated the need for enhanced AI stakeholder engagement initiatives stems from the current situation in which:

"Companies reflect their customers and stakeholders. For now, ours are still inclined towards the traditional way of doing things" (interviewee 5).

If the pharmaceutical industry intends to adopt AI to integrate it into the Drug Discovery phase, it must establish an ongoing dialogue with *Regulatory Institutions,* as it is essential for enabling a smooth and efficient transformation toward AI-driven innovations in the sector as:

"The tradeoff will be possible only if regulatory institutions understand the importance of adapting requirements to new technologies." (Interviewee 9)

Insert Tables 3, 4, 5 Here

Discussions

Theoretical Contributions

The study describes several relevant phenomena to be considered when analyzing digital transformation, particularly successful AI deployment, and relevant stakeholder engagement processes. As a result of the interviews, AI emerged as the most impactful DT technology in the pharmaceutical industry, in line with current literature elaborations (e.g. Mak and Pichika 2019; Miozza, Brunetta, and Appio 2024; Kulkov 2021). Literature recall the importance for single industry, technology-oriented, multidisciplinary investigations with different empirical lenses (Nambisan et al. 2017; Nambisan, Wright, and Feldman 2019) thus the three identified themes were iterated to build an AI Framework for Stakeholder Engagement, as represented in Fig. 2.

Insert Figure 2 Here

The study underscores the necessity of prioritizing stakeholders' long-term satisfaction as organizations undertake DT initiatives, particularly AI, firmly aligning with the principles of Stakeholder Theory (Freeman and Dmytriyev, 2017; Baden-Fuller and Morgan 2010; Freudenreich, Lüdeke-Freund, and Schaltegger 2020). These principles advocate for balancing the diverse interests of stakeholders as a cornerstone of long-term organizational success. Extending this theoretical foundation, this research demonstrates how DT, especially through the adoption of AI, fundamentally redefines stakeholder relationships and opens new avenues for engagement. Unlike conventional transformation processes, AI introduces unprecedented dynamism, creating both opportunities and complexities that require organizations to harmonize their technological ambitions with stakeholder needs and values (Appio et al. 2021; Bresciani et al. 2021). One of the pivotal findings of the study is the influence of external stimuli—such as regulatory pressures, competitive dynamics, and sustainability mandates—on organizational preparedness for AI adoption values (Gama and Magistretti 2025). This finding resonates with prior studies emphasizing the critical role of external

drivers in shaping DT trajectories (Vial 2019; Wetzels 2021). This research goes further by shading light on how these external forces interact with internal factors, including organizational culture, structure, and leadership, to determine the success of AI integration (Warner and Wäger 2019; Warner et al. 2022). For instance, Italian pharmaceutical firms leveraged strategic alliances with IT leaders such as IBM and Microsoft to fast-track AI adoption, while their Indian counterparts relied heavily on traditional business models to achieve digital competitive advantage. These findings highlight the importance of adopting context-sensitive strategies that align external pressures with an organization's internal capabilities and resources (Appio et al. 2023, 2021). This research also emphasizes AI's transformative potential, not just as a tool for operational efficiency but as a catalyst for profound organizational and cultural change (Colovic 2022). This finding aligns with the broader DT literature, which underscores the significance of people and processes in driving meaningful change (Sjödin et al. 2020; Merín-Rodrigáñez, Dasí, and Alegre 2024). Both Italian and Indian firms identified workforce training as a critical enabler for bridging generational divides and fostering digital literacy, thus preparing employees for AI-integrated workflows. Design thinking emerged as a particularly impactful approach for fostering innovation, with Italian firms highlighting the importance of iterative problem-solving and prototyping to tailor AI solutions to organizational needs (Verganti, Dell'Era, and Swan 2021; Auernhammer and Roth 2021). Such practices underline the need for organizations to cultivate a culture of adaptability and continuous learning as they navigate the challenges of AI adoption (Nishant, Kennedy, and Corbett 2020). The interplay between AI deployment and sustainability imperatives represents another critical dimension of this study. While previous research has documented AI's potential to enhance environmental performance by optimizing resource use and reducing waste (Vinuesa et al. 2020; Gama and Magistretti 2025) the findings offer more granular insights into how this potential is realized within specific organizational contexts. For example, AI-enabled tools in the pharmaceutical sector are addressed to monitor environmental conditions during production and logistics, ensuring compliance with sustainability goals. Italian firms leverage AI to enhance transparency and traceability across their value chains,

thereby improving ESG reporting and stakeholder communication and reporting(Galaz et al. 2021; Tiwari and Khan 2020). These findings align with prior works (e.g. Tseng et al. 2021; Mao et al. 2020)which underscore AI's dual role as a driver of operational efficiency and a vehicle for addressing broader societal challenges; AI becomes a bridge that connects organizational strategies to global sustainability objectives, offering firms a competitive edge while addressing pressing environmental concerns. The study also sheds light on how AI is reshaping the paradigms of stakeholder engagement. The advent of AI-enabled tools allows organizations to engage more effectively with a wide range of stakeholders, including employees, patients, suppliers, and local communities. This transformation is especially evident in the shift from a B2B to a B2C model within personalized medicine. Through AI-driven personalized treatments and real-time interactions, patients are transitioning from passive recipients of care to active participants in their healthcare journeys, a shift described by Italian respondents as a "paradigm change" (Denicolai and Previtali 2020; Kulkov 2021). Similarly, AI-enhanced supplier engagement was reported to foster greater transparency and improve decision-making processes within pharmaceutical value chains. These findings extend the theoretical understanding of stakeholder engagement by demonstrating how AI creates new opportunities for collaboration and co-creation, fundamentally altering traditional engagement frameworks (Katsikeas, Viglia, and Hollebeek 2023; Zirar, Ali, and Islam 2023; Nishant, Kennedy, and Corbett 2020), and highlights the synergies of integrating AI with other digital technologies, such as Blockchain and IoT, to create cohesive digital ecosystems, in line with authors (Vial 2019; Nambisan et al. 2017a) who argue that DT is most effective when approached as an interconnected system rather than a series of isolated technological upgrades. Blockchain was identified as a key enabler of data security and regulatory compliance, while IoT was praised for its ability to monitor supply chain conditions in real-time. These technological synergies not only enhance operational performance but also broaden the scope of stakeholder engagement, allowing organizations to address emerging demands with greater agility and precision. Overall, this study offers a rich, contextually nuanced understanding of how AI transforms stakeholder engagement, bridging theoretical gaps and

providing actionable insights for practitioners. By integrating AI into stakeholder-centric strategies, organizations might not only navigate the complexities of DT but also align their operations with sustainability and societal goals. These findings underscore the importance of adopting a holistic approach to digital transformation, considering the interplay of external drivers, internal capabilities, and emerging technological synergies. Future research should expand on these insights by exploring the scalability of the framework across other industries and examining how evolving technologies continue to redefine the boundaries of stakeholder engagement.

Managerial Contributions

This study presents valuable managerial implications, offering actionable guidance to help organizations enhance AI-driven stakeholder engagement. The identified themes and the developed framework highlight strategic priorities that managers must address to align organizational objectives with stakeholder needs in the DT era. The study underscores the importance of fostering strategic alliances and embracing dynamic competitive dynamics. To accelerate AI adoption and innovation, managers must actively seek partnerships, such as collaborations with technology providers or institutional actors, as in the Italian firms' alliances with global IT giants, like IBM and Microsoft, that illustrate how partnerships can bridge technological gaps and ensure successful implementation. Second, the integration of methodologies like Design Thinking into organizational processes emerges as critical for navigating the complexities of AI adoption. Managers should prioritize fostering an environment of iterative problem-solving, prototyping, and experimentation to develop tailored AI solutions, to facilitate innovation and ensure that the solutions align with unique organizational and stakeholder needs. Firms in the study highlighted the role of design thinking in addressing challenges related to employee training and integrating AI into daily operations, emphasizing its potential to enhance both technological readiness and organizational adaptability.

The study also stresses the need to leverage data for effective decision-making and stakeholder communication. Managers must invest in robust IT infrastructure and advanced analytics capabilities

to enable secure, accurate, and impactful data utilization. Digitized data is instrumental in enhancing transparency, optimizing resource management, and fostering stakeholder trust. Moreover, integrating sustainability principles into data-driven strategies ensures that operations align with evolving environmental and societal expectations, ultimately contributing to long-term viability and stakeholder satisfaction. AI's transformative potential as a driver of sustainability also requires managers to embed sustainability at the core of business strategies. The findings reveal that AI can optimize resource allocation, reduce waste, and improve supply chain transparency through integration with tools such as IoT-enabled or Blockchain systems. Managers must view sustainability not as an ancillary objective but as a central component of organizational strategy, using AI to address environmental, social, and governance (ESG) demands. Firms employing AI to monitor environmental compliance or enhance ESG reporting demonstrate how sustainability-driven AI strategies can improve stakeholder engagement and competitive positioning. The study further identifies the managerial imperative of adapting organizational structures and processes to facilitate AI integration. Transitioning from manual to digitized workflows requires careful planning and investment in technological upgrades. Managers must navigate the shift from B2B to a consumer-centric B2C approach, particularly in industries like healthcare, where patient-oriented strategies are becoming increasingly critical. Personalized treatments enabled by AI demand that managers rethink stakeholder engagement strategies to meet evolving consumer demands effectively. Cultural transformation within organizations is another significant managerial focus highlighted by the study. Managers should foster a culture that embraces technological advancements by encouraging entrepreneurial thinking, bridging generational divides, and promoting continuous learning. Tailored training programs that enhance digital literacy and workforce readiness are essential to equip employees for AI-driven workflows. Fostering a culture of openness to technological shifts helps address resistance to change and ensures alignment across all levels of the organization. Regulatory engagement also emerges as a key managerial responsibility. Managers can proactively collaborate with regulatory bodies to navigate evolving compliance requirements and mitigate barriers to AI

adoption. Effective communication of underlying DT, in particular AI, values— internally to employees and externally to stakeholders such as suppliers or regulatory institutions—ensures greater buy-in and alignment with organizational objectives. Finally, leadership plays a pivotal role in navigating the complexities of AI initiatives. Effective leaders should balance technological, organizational, and stakeholder priorities to drive successful outcomes. Integrating diverse elements, from IT infrastructure upgrades to sustainability imperatives and cultural shifts, is crucial. This study emphasizes that leadership is not merely about technological expertise but also about fostering a vision that harmonizes innovation with stakeholder-centric values.

Limitations and Future Research

This study, while yielding valuable insights, is not without limitations, highlighting the need for further research to deepen and broaden the understanding of AI-driven stakeholder engagement. First, the generalizability of the findings is constrained by the specific context of the countries, industries, participants, and organizations examined. The unique characteristics of the pharmaceutical sector—such as stringent regulatory frameworks and the critical nature of its products—may limit the applicability of findings to other industries. Future research could investigate how AI influences stakeholder engagement in diverse sectors, such as manufacturing, retail, or energy, where competitive landscapes, regulatory environments, and stakeholder influence might present different challenges and opportunities. By exploring such variations, researchers could provide more comprehensive insights into how contextual factors shape stakeholder engagement and DT outcomes. Second, although this study adopted a multilevel perspective to examine themes for stakeholder engagement, it may not have fully captured the intricate complexities and dynamic interactions among stakeholders. The study's reliance on qualitative interviews, while valuable for exploring nuanced perspectives, is inherently limited by the subjective nature of respondents' answers. Stakeholder relationships often involve fluid power dynamics, interdependencies, and evolving interests, which are challenging to capture in a single research effort. Future studies could employ

longitudinal designs to observe how these dynamics unfold over time or integrate system dynamics modeling to simulate the interplay between stakeholder interests and technological advancements. Another limitation concerns the environmental implications of AI deployment. While this study highlighted the potential of AI to enhance environmental performance, it also acknowledges the significant energy consumption associated with AI technologies from a broader value chain perspective. This duality points to an important area for future research: exploring how organizations can integrate AI sustainably, balancing its potential to optimize resource use with efforts to mitigate its environmental footprint. Studies could investigate strategies to improve AI energy efficiency, such as leveraging renewable energy sources, optimizing algorithms, or employing edge computing solutions, while assessing the long-term environmental trade-offs of AI deployment. Finally, the themes identified in this study, while valuable for understanding stakeholder engagement, would benefit from further quantitative validation. Future research could operationalize these themes through robust measurement frameworks and test their applicability across different organizational contexts. Researchers could employ large-scale surveys or experimental designs to examine how multilevel stakeholder interests, power dynamics, and dependencies evolve in response to specific DT technologies. Furthermore, examining the role of AI in advancing specific ESG areas—such as decarbonization, social equity, or governance transparency—could provide targeted insights into how DT technologies shape organizational contributions to sustainability goals.

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Tables and Figures

Table 1 - Interviewee Characteristics

	Country	Role	Number of Employees	Revenue Streams
Interviewee 1	Italy	General Manager	+3000	+ 5 B $
Interviewee 2	Italy	Chief Industrial Operations Officer	+5000	+1 B $
Interviewee 3	Italy	General Manager	+1500	+800 M $
Interviewee 4	Italy	General Manager	+1500	+ 1 B $
Interviewee 5	Italy	Chief Institutional Affairs	+1500	+ 800 M $
Interviewee 6	Italy	General Manager	+1500	+400 M $
Interviewee 7	Italy	R&D Scientist	+1000	500 M $
Interviewee 8	India	Manufacturing Quality Control	+ 20000	+ 2 B $
Interviewee 9	India	Supply Chain Manager	+1000	+ 30 M $
Interviewee 10	India	General Manager	+50	+2 M $
Interviewee 11	India	Manufacturing Quality Control Manager	+50	+5 M $
Interviewee 12	India	Manufacturing Quality Control Manager	+1000	+ 30 M $
Interviewee 13	India	R&D Scientist	+ 20000	+ 2 B $
Interviewee 14	India	General Manager	+50	+1 M $
Interviewee 15	India	R&D Scientist	+ 20000	+ 2 B $
Interviewee 16	India	Manufacturing Quality Control Manager	+10000	+ 1 B $

Table 2 – Pharma Industry Stakeholders and their relevance with AI

Stakeholders	**AI Relevance**
Employees	Employees are critical for deploying and managing digital transformation and AI initiatives, as they ensure technology effectiveness by deploying tools during operations.
Patients	Patients are the ultimate beneficiaries of pharmaceutical advancements resulting from digital transformation and AI deployment, which lead to more personalized treatments, improved patient care, and improved health outcomes.
Institutional Actors	Regulatory bodies and governmental agencies play a crucial role in shaping the pharmaceutical digital transformation and AI landscape. Their support and alignment with relevant initiatives are essential for ensuring compliance, safety, and efficacy of new technologies.
Local Communities	Pharmaceutical companies often operate within specific local communities, and their operations can significantly impact these areas. By engaging with local communities and considering their needs and concerns, companies can build strong relationships and ensure that their digital transformation efforts contribute positively to the local economy and environment.
Society and Environment	Digital transformation Technologies, particularly AI, can contribute to improving ESG performance, so it is important to consider the broader societal and environmental impacts.
Suppliers	Suppliers are integral to the pharmaceutical supply chain, and collaboration on AI initiatives can lead to improved performance across the whole drug Value Chain.
Shareholders	Shareholders are interested in the company's financial performance and long-term growth. Engaging shareholders and demonstrating the value of digital initiatives can secure the necessary funding and support for these projects.
Scientific Community	Deploying digital technologies, in particular AI, can facilitate data sharing, enhance research capabilities, and accelerate the discovery of new drugs.

Table 4 - AI and External Stimuli

	Subarea	Italy	India
External stimuli to AI	Industry	• *"Fragmented institutional counterpart's readiness to digital transformation and AI and disparities in knowledge and readiness between Northern and Southern Italy." (Interviewee 5)* • *"There is also a strong demand for IT skills, and this push must come from the top at the corporate level. Therefore, I think workforce turnover is once again a prerogative of the companies." (Interviewee 2)* • *"We were all scared about Amazon entering in our Market." (Interviewee 5)* • *"with IT giants such as IBM or Microsoft to drive AI" (Interviewee 2).* • *"I believe it is true that there is currently a need for a cultural and generational shift." (Interviewee 1)*	• *"In my opinion, there is still a lack of expertise, but this is due to the fact that we are in a transitional period." (Interviewee 13)* • *"I had the opportunity to collaborate with a company based in Germany that has a manufacturing plant in India. (...) I believe this example is very interesting because foreign companies can provide a significant boost to the digital transformation of the Indian pharmaceutical industry." (Interviewee 8, India)* • *"I am particularly interested in the world of AI startups. There are two types: Scientific Platforms and R&D. Both, in my opinion, can give a great boost to the pharma industry; in fact, M&A activities are commonplace." (Interviewee 13)*
	Regulatory	• *"One of the main concerns is the protection of patients' data privacy and compliance with regulations." (Interviewee 2)* • *"Regulatory institutions are not competent enough. (...) recently considering the acceptance of AI-sourced molecules." (Interviewee 5)"* • *"I would like to see a digital approach from institutions to address data treatments and personalized medicine." (Interviewee 1)* • *"Regulatory institutions are not ready for DT. They have a more traditional approach; therefore, until they do not change, there won't be an application field for precision medicine or DT." (interviewee 5)* • *"(...) Currently, there are many incentives, both from the Central government and the European Union on Sustainability." (Interviewee 7)*	• *"However, there is a strong issue regarding privacy. Many people are not even aware that their data is being used by third-party companies for their own purposes." (Interviewee 13)* • *"The issue of data is of particular importance here in India. Recently, the Personal Data Protection Act was enacted, which I invite you to look into. Only now, thanks to this law, companies, including pharmaceutical ones, can use data for personal purposes." (Interviewee 12)* • *The only limitation to comply with is that these data must be completely anonymous. That said, cybersecurity is also very important in our sector." (Interviewee 12)*

Table 5 - AI and Organizational Innovation

	Subarea	Italy	India
Organizational	Culture	• *"Organizations should start from the perceived problem within the process and solve it using design thinking and prototyping techniques. (...) This approach was particularly useful for integrating Generative AI to efficient inventory management operations." (Interviewee 2)* • *"I am convinced that the real driving force behind digital transformation is the perceived need. If there is a problem that can be solved through DT, then even non-digital natives will perceive the value and make the shift. Internally, we often conduct pilot programs based on prototyping and Design Thinking techniques." (Interviewee 1)*	• *"I have undergone extensive training, and I have changed my way of seeing digital transformation over time." (Interviewee 16)* • *"To facilitate this process, our company places great importance on training." (Interviewee 9)* • *"However, I am convinced that after a few months and with good training programs, it's easy to grasp the logic of the new tools, even in a short time (e.g., 6 months)." (Interviewee 16)*

		• *"I try to promote training as much as possible and guide HR towards personnel with multidisciplinary skills." (Interviewee 3)* • *"We are attracting new talent from Consumers industries to deploy AI and patient-centric techniques." (Interviewee 6)* • *"We are addressing collaborative partnerships with IT giants such as IBM or Microsoft to drive digital transformation and AI." (Interviewee 2)"* • *"Throughout my career, I have seen many people who had great difficulties with technology, even just using a computer." (Interviewee 3)*	• *"I believe we have become accustomed to DT, and if I were to give you a number, I would say we are at a high level of technology acceptance, around 70% versus 30%. Usually, those in the 30% are the older employees ." (Interviewee 11)*
	Means	• *"We are using customized Chat GPT to support decision-making and assist in everyday operations." (Interviewee 4)* • *"As for technologies like Blockchain, I haven't seen many successful applications yet, but I believe it could be useful as it would eliminate many manual reporting steps with regulatory institutions." (Interviewee 2, Italy)* • *"DT means integrating data to enhance Decision Making. We have many USE cases aiming to implement digital technologies like AI or blockchain, so I believe it's a phenomenon that will continue to be successful. (Interviewee 1)* • *"We are refining analysis techniques for customer profiling and segmentation using AI." (Interviewee 6)*	• *"Technologies such as Artificial Intelligence, Blockchain, and IoT can help with both tracking and understanding data." (Interviewee 15)* • *Many pieces of information are now transitioning from paper to the digital Cloud. We are increasingly using software that streamlines the transcription process of lab information." (Interviewee 16)* • *"Digital transformation (AI) in the pharmaceutical sector is increasingly gaining ground and, above all, bringing various benefits: data accuracy, tracking and tracing, and assistance in interpretation." (Interviewee 11, India)* • *"We have implemented a cloud function that allows us to track processes in real-time." (Interviewee 11)* • *"We use simple technologies like GPS, but also more complex ones like IoT and Cloud. This is especially true for Cold Chain Management, as IoT and Cloud ensure the quality and preservation of drugs (Interviewee 16)* • *"We have implemented various technologies aimed at tracking and tracing process information. For example, thanks to IoT, we can monitor environmental conditions during production and transportation. In general, the production facility will become increasingly interconnected to streamline operations." (Interviewee 11)* • *"One technology that stands out is the use of IoT, which can be very helpful. However, the most pressing issue within the Indian context is maintaining high drug quality." (Interviewee 12)*
	Structure	• *"Big pharma companies are investing a lot of money to increase both skills and the presence of AI technologies in processes." (Interviewee 4)* • *"To clarify, digital transformation stems from the industry's need to comply with high-quality standards, as through DT, you have more data which forms the basis for organizing and planning a process effectively. (Interviewee 1)* • *"I think cybersecurity, cloud computing, and blockchain, together with AI, are the most focused-on technologies in the pharmaceutical industry." (Interviewee 4)*	• *"I see that a possible challenge could be the replacement of existing systems. The obstacle of investments could slow down the progress towards personalized medicine." (Interviewee 9)* • *"Regarding IT infrastructures, my organization is heavily involved in investments because they are crucial for the success of digital transformation and AI." (Interviewee 16)* • *"Many of the processes still involve manual information writing, digitization would make everything much more efficient."(Interviewee 9)* • *My company has started a project to have a Data Lake, and the major challenge that is emerging is the transcription from paper to digital." (Interviewee 16)*

			• *"IT investment is needed to track environmental impacts in the supply chain and detect counterfeit drugs." (Interviewee 1)*

Table 6 - AI and Stakeholder Engagement

	Italy	**India**
Stakeholder Engagement	• *"Another challenge is interoperability between various healthcare systems and the quality of collected data. Often, data is scattered across different platforms, and the lack of common standards can complicate data exchange and analysis." (interviewee 2)* • *"Thanks to the use of AI and other technologies, drug commercialization will be increasingly target-driven." (Interviewee 3)* • *"(AI) startups are much more agile and adaptable than big multinationals. They do not have to overcome the significant organizational barriers that big corporations traditionally struggle with."(Interviewee 1)* • *"I strongly believe in the use of AI to enhance decision-making across various fields, from inventory calculation to market demand forecasting. I consider AI in the context of Supply Chain a significant boost for operational efficiency and effectiveness." (Interviewee 1)* • *"DT and AI are a means to achieve enhanced Sustainability performance." (Interviewee 2)* • *"I see data and AI exploitation as a value to obtain tangible sustainability results." (Interviewee 1)* • *"(…) training initiatives in cooperation with technology partners to introduce employees to new routines." (Interviewee 8)* • *"To innovate the patient journey towards Personalized medicine." (Interviewee 6)* • *"DT (AI) is not a value in itself but rather a means to achieve sustainability because this constitutes and complies with the higher corporate vision." (Interviewee 1)* • *"We need to understand how to bridge the gap between sustainable initiatives and economic returns." (Interviewee 1)* • *"Companies reflect their customers and stakeholders. For now, ours are still inclined towards the traditional the traditional way", (Interviewee 5)*	• *"Cold chain management is essential, and technologies like IoT & AI can greatly improve visibility and control over expiring drugs." (Interviewee 13)* • *"DT and AI can reduce environmental impacts by improving operational efficiency." (Interviewee 12)* • *"From a sustainability standpoint, AI can contribute to more efficient resource management, reducing waste and environmental impact." (Interviewee 12)* • *"Digital transformation itself can help us improve. I'm referring to track and trace technologies, such as IoT and AI, which aid in monitoring sustainable performance. Consequently, we can intervene to make improvements." (Interviewee 11)* • *"(…) Personalized medicine is a mirage, until we do not analyze properly data, which can be analyzed through AI." (Interviewee 13)* • *"The technologies I consider most important are Blockchain and AI. From my experience, I have seen that their integration can be useful for tracking information and creating insights to streamline processes." (Interviewee 12)* • *"(…) it's always important that data is interpreted by people and not blindly relying on outcomes produced by a machine." (Interviewee 14)* • *"Large companies increasingly delegate their projects to smaller entities because they are more agile and capable of adapting to changes." (Interviewee 9)* • *"I believe it's a domino effect: if institutions prioritize DT, then companies must adapt accordingly." (Interviewee 10)* • *"The tradeoff will be possible only if regulatory institutions understand the importance of adapting requirements to new technologies." (Interviewee 9)*

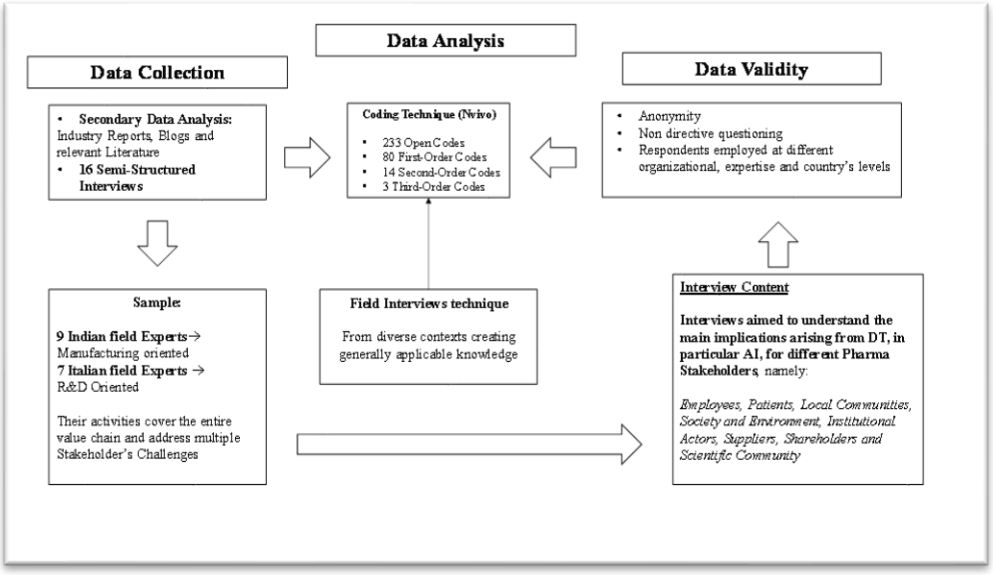

Figure 1 - Methodology

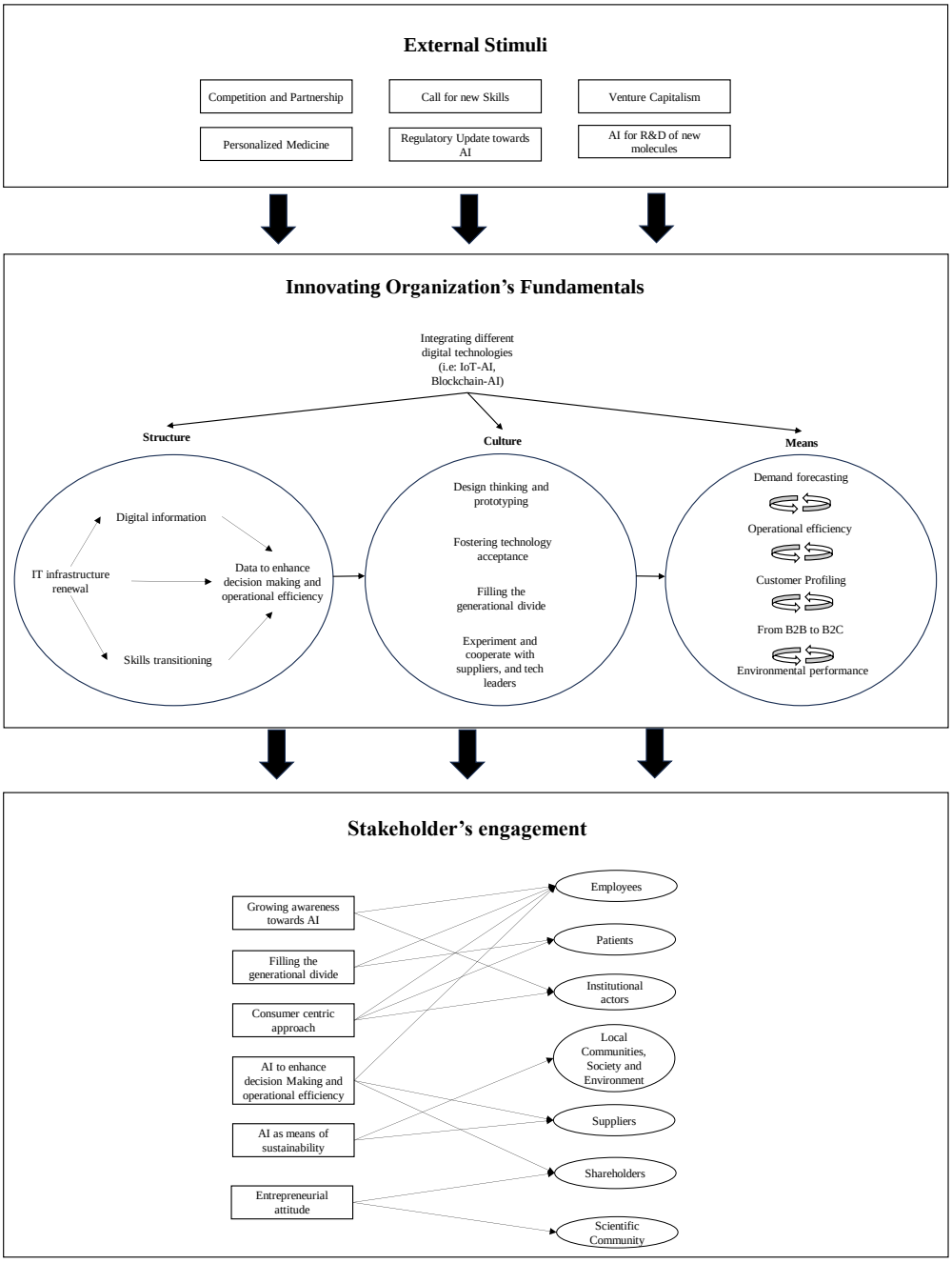

Figure 2- AI Framework for Stakeholder Engagement

Paper 4: Untapping the Role of AI for Sustainable Development Goals and Economic Performance: evidence from Pharmaceutical Industry

Abstract

In today's rapidly evolving landscape, organizations across industries are increasingly seeking to capitalize on the opportunities offered by digital transformation, particularly through Artificial Intelligence (AI). However, many organizations struggle to fully harness the potential of these emerging technologies. This study contributes to the ongoing discourse on the organizational factors that drive effective AI adoption, focusing on how organizational readiness influences AI adoption and its subsequent impact on performance. Specifically, we explore the relationship between Strategic and Cognitive readiness and AI adoption, examining their role in advancing Sustainable Development Goals (SDGs) and Economic Performance. Using data from 511 organizations in the pharmaceutical industry and employing structural equation modeling, our analysis reveals that (i) strategic and cognitive readiness positively influence AI adoption; (ii) AI adoption mediates the positive relation between strategic and cognitive readiness and SDG performance; (iii) AI adoption significantly improves economic performance via enhanced SDG attainment; (iv) SDG performance enhances economic performance; and that (v) this relationship is more pronounced in smaller organizations. Our findings contribute to the ongoing research on the organizational determinants of effective AI adoption and highlight the critical role of this technology in supporting both SDG achievement and economic viability.

***Keywords**:* Sustainable Development Goals, Organizational Theory, Digital Transformation, AI, Economic Performance

Abbreviations

Artificial Intelligence (AI), Sustainable Development Goals (SDGs), Structural Equation Model (SEM), Internet of Things (IoT), augmented reality (AR), virtual reality (VR), Small and Medium Enterprises (SMEs), Exploratory Factor Analysis (EFA), Confirmatory Factor Analysis (EFA), Economic Performance (ECP)

1. Introduction

Digital transformation, particularly Artificial Intelligence (AI), is nowadays regarded as a crucial element for enhancing efficiency and improving the quality of a wide range of organizational activities (Davenport & Ronanki, 2018; Iansiti & Lakhani, 2020). However, despite its vast potential and significant company investments, AI does not always yield the expected benefits (Cubric & Li, 2024; Kinkel et al., 2022; Zirar et al., 2023). The complexity of this technology requires that organizations be adequately prepared and ready for adoption to fully leverage its anticipated benefits (Agarwal et al., 2010)(e.g. Cao et al., 2021).

One of the areas where AI has the most significant potential- but also the greatest risks- is sustainability. The reported potential impacts of AI on sustainable development point to both positive (Neal et al., 2016) and negative (e.g., Courtland, 2018) effects. For example, AI can help organizations operate more efficiently, use resources more sustainably, and reduce and manage waste more effectively. On the other hand, excessive reliance on and blind adoption of AI technologies can lead to negative sustainability impacts, including the possibility of fueling massive energy-consuming data sets and large data centers (Nishant et al., 2020). This body of research suggests that more AI theory is needed to recognize how organizations propel and manage AI, what models and structures can favorably support its adoption, and what boundary conditions influence the relationship between AI adoption and sustainable outcomes.

The present study aims to contribute to this debate by shedding new light on the organizational conditions that foster AI adoption in organizations and the relationship between AI adoption and organizational performance. Despite previous research on AI adoption, it remains

unclear what the relationship is between AI adoption and the ability of organizations to achieve sustainability-related goals, and what organizational conditions are conducive to effective deployment. As the reference context, we have selected the pharmaceutical industry, as it is significantly influenced by the introduction of this technology throughout the entire value chain, from drug research and development to final patient consumption. At the same time, the industry is actively involved in the implementation of new sustainable models, making it consistent with the Sustainable Development Goals (SDGs). In the methodology section, we illustrated the alignment points between the benefits of using AI in the pharmaceutical industry and their relevance to SDGs 3, 9, 12, and 17.

To validate our study, we developed and tested a Structural Equation Model (SEM) in Lisrel, based on 511 respondents, whose primary assumption is that organizations should first be strategically and cognitively prepared for digital innovation– looking at their readiness – to deploy AI. Drawing on previous research on organizational readiness for new technologies adoption (Lokuge et al., 2019; Nambisan et al., 2017, 2019; Venkatesh, 2022; Venkatesh et al., 2003, 2012; Vial, 2019), our model proposes several underlying dimensions that contribute to explain AI exploitation, and specifically on strategic and cognitive readiness. Moreover, recent studies suggest that AI can support the pursuit of SDG objectives (Berente et al., 2021; Brevini, 2020; Floridi et al., 2021; Hao, 2019; Lin, 2021; Sjödin et al., 2023; Strubell et al., 2019; Yu et al., 2022); yet, the way organizations enhance both SDG and Economic outcomes through AI adoption is overlooked in past research. The present study intends to reduce this gap by addressing how organizational readiness and AI attain the dual goal of economically viable performance while considering improved SDG performance. Responding to the emergent need for organizations to address social and environmental challenges as well as capture the complexity inherent in real-world insights while maintaining significant economic performance (Merín-Rodrigáñez et al., 2024; Nishant et al., 2020; Zhao et al., 2023).

The present study makes several contributions to existing literature. First, it advances the emerging scientific debate on the role of AI in achieving the Sustainable Development Goals (SDGs) (Appio et al., 2023; Khakurel et al., 2018; Nishant et al., 2020). We demonstrate that AI adoption serves as a significant organizational predictor of SDG performance, which, in turn, correlates with improved economic performance. Previous research has highlighted the ambivalent relationship between AI and SDGs, noting that AI can yield both positive and negative outcomes. Our findings reveal that organizational readiness is a critical factor influencing AI adoption, acting as a crucial organizational lever to enhance both sustainability and economic performance.

Second, by illustrating that both strategic and cognitive readiness positively predict AI adoption, our study sheds light on the factors that facilitate AI adoption within organizations. While much of the existing literature on technology adoption has predominantly focused on organizational readiness for change, our study introduces new insights by showing that the ability to exploit AI's potential entirely is closely tied to the strategic importance attributed to the technology and the cognitive preparedness of organizational users.

Third, this study contributes to the ongoing debate regarding the impact of AI in the pharmaceutical industry (e.g. Dicuonzo et al., 2023; Miozza et al., 2024). While prior research has extensively examined the role of AI across various segments of the value chain—including drug development, testing, distribution, market access, and pharmacovigilance (Satwekar et al., 2022, 2023)—our findings offer a fresh perspective. We show that organizational readiness and AI adoption can lead to enhanced performance across different areas of the pharmaceutical value chain, with small and medium-sized enterprises (SMEs) being particularly well-positioned to reap the benefits of AI adoption in terms of their lighter business structures.

The rest of the paper is organized as follows. In Section 2 we discuss our conceptual model and propose our research hypotheses. In Section 3 we explain the study design. In Section 4 we present the results. In the last section, we discuss our findings' main theoretical and managerial implications and conclusions.

2. Literature Review and Hypothesis Development

AI is widely recognized as one of the most significant technologies driving digital transformation in the contemporary era (Davenport & Ronanki, 2018; Di Vaio et al., 2020; Kinkel et al., 2022; Sjödin et al., 2023). Its impact is profound, enhancing decision-making processes (Cao et al., 2021; Dwivedi et al., 2021), improving operational efficiency (Kinkel et al., 2022), and boosting overall organizational performance (Sjödin et al., 2023). At the macro level, digital technologies notably influence sustainable development, with AI playing a pivotal role in optimizing environmental resource deployment, waste management, and supply chain footprint (Appio et al., 2023). At the organizational level, AI is widely believed to transform decision-making across a broad spectrum of value chain activities, including production, finance, human resource management, marketing, and R&D activities (Mak & Pichika, 2019; Nishant et al., 2020; Zirar et al., 2023)

Empirical evidence suggests, however, that organizations often struggle to successfully exploit and adopt AI (Cao et al., 2021), particularly, at the individual and social levels (Dwivedi et al., 2021; Kinkel et al., 2022) and the lack of organizational readiness is among the factors that contribute to explaining AI adoption failures (e.g. Lokuge et al., 2019; Satwekar et al., 2022). The use of expert systems to augment or even substitute decision-making is well-documented in both the literature and practice (Bader et al., 1988; Kahneman et al., 2016). However, the mere potential of expert systems, such as AI, to support decision-making does not automatically translate into improved organizational efficiency or effectiveness. Research has highlighted that strategic commitment to technology is crucial. The benefits of AI can be undermined when organizations fail to define clear long-term objectives, do not integrate AI adoption into the broader organizational strategy, or neglect to communicate the strategic goals underlying technology adoption (Dwivedi et al., 2021; Makridakis, 2018; L. Wang et al., 2015; P.-H. Wang & Wang, 2016; X. Wang et al., 2015; Zirar et al., 2023). Together, these factors are essential components of an organization's strategic readiness—its ability to align resources, capabilities, and strategic

initiatives to effectively respond to current and future challenges, including those posed by emerging technologies (Lokuge et al., 2019).

Equally crucial for the successful adoption of AI is the readiness of organizational members to embrace and effectively utilize the technology. This concept, often called cognitive readiness, refers to the preparedness and capacity of individuals, groups, or entire organizations to respond effectively to complex and dynamic situations through applying cognitive skills (Lokuge et al., 2019). Cognitive readiness encompasses employees' general predisposition toward new technology, their perceptions of possessing the necessary skills to use AI, and their ability to understand the rationale behind specific decisions, classifications, or forecasts generated by AI systems (Dwivedi et al., 2021; Schneider & Leyer, 2019). Based on this reasoning, we propose the following hypothesis:

H1.a: Strategic readiness is positively related to AI adoption.

H1.b: Cognitive readiness is positively related to AI adoption.

AI is deemed particularly promising for its potential benefits in terms of business performance (e.g. Sjödin et al., 2023). However, recent management research has converged on the view that AI also has the potential to reconcile and integrate economic performance and sustainability implications (Merín-Rodrigáñez et al., 2024; Nishant et al., 2020). AI adoption appears particularly suitable to help organizations and societies to attain SDGs, as defined by the United Nations (Di Vaio et al., 2020; Vinuesa et al., 2020). In a recent study published in Nature, Vinuesa et al. (2020) suggest that AI could help achieve 79 % of the SDGs. Achieving sustainability goals is increasingly recognized as being closely intertwined with attaining economic and profitability objectives, particularly in highly institutionalized fields (Meyer & Rowan, 1977), where key stakeholders demand that business activities align with traditional business logic while simultaneously prioritizing sustainability (e.g. Trullen & Stevenson, 2006). In general, We argue that strategic and cognitive readiness for digital innovation significantly

contributes to the effective management of AI within organizations, thereby enhancing both SDG performance and economic outcomes (Courtland, 2018; Gupta et al., 2021; Vinuesa et al., 2020). By strategically embracing digital innovation and AI, organizations empower employees to learn, allocate resources more effectively, and optimize processes, collectively improving performance while advancing SDG objectives (El-Haddadeh et al., 2021; L. Li, 2022). Additionally, organizations with strong cognitive readiness are better equipped to integrate digital technologies into their operational frameworks, leading to enhanced operational efficiency, superior decision-making, and innovative business solutions that address societal and environmental challenges (Akbarighatar et al., 2023; El-Haddadeh et al., 2021; Hradecky et al., 2022; L. Li, 2022; Mikalef & Gupta, 2021).

Based on the above discussion, we propose the following research hypotheses:

H2: AI adoption is positively related to SDG performance

H3.a: AI adoption mediates the positive relationship between Strategic Readiness and SDG performance

H3.b: AI adoption mediates the positive relationship between Cognitive Readiness and SDG Performance

H4: SDG performance is positively related to economic performance

H5: AI Adoption is positively related to economic performance

H6: SDG Performance mediates the positive relationship between AI adoption and economic performance

Our Research context, the Pharmaceutical Industry, is highly characterized by the coexistence of a diverse population of organizations, including large Big companies and highly innovative small and medium-sized enterprises (SMEs). Due to their complex and often rigid organizational structures, exploiting innovation for large companies is challenging (Wickert et al., 2016); consequently, a common trend is to collaborate with highly innovative SMEs (Kamran et al., 2023;

Keshavarzi Arshadi et al., 2020), because of their reduced hierarchical layers, bureaucracy, and structural inertia (Bohlmann et al., 2024; Polites & Karahanna, 2012).

Recent literature suggests that SMEs are more likely to benefit from adopting emerging digital technologies, including AI, as they are often led by more educated, experienced, and younger owners (McElheran et al., 2024), shaping competitive dynamics, innovation processes, and operational strategies (e.g., Corvello et al., 2024; Cubric & Li, 2024). Additionally, small firms tend to have more substantive and effective approaches to sustainability, driven by implicit convictions and beliefs rather than formal structures and codes of conduct, which are more common in larger organizations (Wickert et al., 2016). This orientation makes SMEs more inclined to adopt AI and embrace the SDGs for enhanced flexibility, creativity, and innovation performance (Mariani et al., 2023)(Dosi et al., 2023; Rafols et al., 2014; Schuhmacher et al., 2023). Overall, by leveraging agile and flexible infrastructures, SMEs play a fundamental role in bridging AI deployment gaps technology deployment. Therefore, studying this phenomenon in the context of varying company sizes, such as that of the Pharmaceutical Industry, offers the opportunity to critically elaborate on policy development, industry collaborations, and targeted investments. More formally, we hypothesize that:

H7: Organizational size moderates the relationship between SDG performance and Economic performance such that this relationship is stronger for small and medium-sized organizations rather than large organizations.

Figure 1 illustrates our conceptual model.

FIGURE 1 ABOUT HERE

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3. Methodology

3.1 Research Setting

In order to empirically test the above hypotheses, we grounded our research in the Pharmaceutical Industry, where AI has the most significant potential, affecting the whole drug Value Chain, from Discovery Activities to Market Access (Hariry et al., 2022b; Harrer et al., 2019; Miozza et al., 2024). Additionally, being an industry with significant impact in terms of environmental (e.g. CO2 emissions, energy, and resource consumption) and social impacts (e.g. development of treatments for curing diseases), it offers a fertile landscape for exploring the implementation of Sustainable Development Goals (SDGs). In the following lines, we will contextualize the role of AI in the pharmaceutical industry derived from a synthesis of archival material (academic literature, available information on the Internet and consulting reports) and cross-check its role in achieving SDGs through 16 targeted interviews with key practice experts. Table 1 summarizes the discussion below.

The first phase of the drug value chain consists of Drug Development activities. In this context, AI offers the potential to accelerate the cure for a wide range of diseases, including rare conditions such as Alzheimer (e.g. Wojtara et al., 2023; Zhang et al., 2023), by analyzing vast amounts of data — including molecular structures and biological pathways— to identify promising drug candidates. Furthermore, AI can support the organization of the clinical trials phase, particularly, by integrating and analyzing patient-specific data -such as electronic medical records, handwritten documents, medical imagery, and socioeconomic data, to identify eligible participants more efficiently and accurately than traditional trial methodologies (Hariry et al., 2022b).

The second phase of the drug value chain is Manufacturing. This phase involves several highly regulated stages, from raw material processing to final product packaging, where AI offers significant improvements. In particular, AI-powered predictions can optimize equipment utilization, forecast maintenance needs, production waste, energy consumption, and product

quality control, leading to more efficient and reliable processes that adhere to the high standards required for drug production (Hariry et al., 2022b; Kulkov, 2021; Sharma et al., 2020).

The third phase of the drug value chain encompasses all activities related to delivering drugs to patients, from storage and logistics to final usage. AI's relevance in this phase is multifaceted. In particular, when coupled with IoT devices and blockchain technology, AI can enhance cold chain management by continuously monitoring environmental parameters during drug transportation, as well as planning for more environmentally friendly routes to transport drugs. This real-time data transmission enables better decision-making and optimization of supply chain environmental and social performance, most importantly preventing the commercialization of expired and counterfeit drugs (Chamekh et al., 2017). Moreover, AI, integrated with other digital technologies such as Augmented Reality, Virtual Reality, and Robotics, can support inventory management activities by automating warehouse operations that would otherwise require human labor, particularly in potentially hazardous environments, thereby improving safety. Furthermore, AI offers significant benefits in achieving personalized medicine by analyzing patient genomics and proposing personalized treatment plans to patients (Kulkov, 2021).

After archival material screening, we cross-checked our archival material information with 16 interviews with key experts to contextualize the use of AI for SDG in the pharmaceutical industry. The data collection methodology is described in the next section. Overall, AI is pivotal in achieving:

i. **SDG 3 – Good Health and Well-being**: By accelerating the development of new drugs and clinical trials, AI contributes to improving global health outcomes and reducing the burden of diseases, as more efficient drug development processes can potentially result in life-saving medications being made available sooner. Additionally, by enhancing manufacturing efficiency and quality control, AI ensures the consistent availability of safe and effective medications. Through integration with technologies such as IoT and blockchain, AI also helps prevent the commercialization of expired and counterfeit drugs.

ii. **SDG 9 – Industry, Innovation, and Infrastructure**: AI drives innovation in drug development processes, fostering the creation of smart factories, leading to production line optimization, predictive maintenance, smart logistics, and supporting the realization of personalized medicine.

iii. **SDG 12 – Responsible Consumption and Production**: AI-driven optimization in manufacturing directly supports responsible production practices. Specifically, the implementation of AI allows companies to optimize resource waste during operations and to plan transport routes that reduce transportation costs and fuel consumption during transportation.

iv. **SDG 17 – Partnerships for the Goals**: The development and implementation of AI in drug development often involve collaborations between scientific researchers and a wide range of stakeholders, such as cloud computing providers, regulatory bodies, and research institutions for drug approvals fostering knowledge sharing, supply chain sustainability and preventing the commercialization of expired and counterfeit drugs.

TABLE 1 ABOUT HERE

3.2 Data Collection

As mentioned above, we have chosen the pharmaceutical sector as the reference context, as it is a fertile ground for studying the implications of AI and SDGs. Our data collection was conducted in two phases. The first phase (i) consisted of archival material analysis and interviews with key pharmaceutical experts to validate the interconnectedness of AI and SDG. In particular, archival material included multiple sources of information such as academic works, technical reports available information on the Internet. Afterward, we conducted 16 interviews with key experts to link AI and SDG attainment further in the pharmaceutical industry and ultimately design our survey items. Interviews were conducted with diverse professionals holding key roles, such as

General Managers, Chief Officers (Industrial Operations, Institutional Affairs), Supply Chain Managers, Manufacturing Quality Control Managers, and R&D Scientists. Representing companies of various sizes —from 50 to 20,000 employees—and revenue ranges from $1 million to over $5 billion, offering comprehensive and relevant insights about AI impact across different organizational levels and value chain phases. These discussions were structured around six open-ended questions to explore emerging impacts, challenges and opportunities arising from AI adoption under the SDGs lens across the Value Chain: (i) Drug Development activities, (ii) Manufacturing, (iii) Patient Access.

Based on this knowledge, in the Second Phase (ii) of our data collection, we developed a questionnaire covering the following themes: AI adoption, strategic and cognitive readiness, economic performance, and Sustainable Development Goals (SDG) performance. The survey items related to organizational readiness and AI adoption were drawn from existing literature. At the same time, due to a lack of relevant measurement scales, insights from our expert interviews and archival material were used to operationalize the relationship between AI and SDGs in the pharmaceutical industry, ensuring the development of appropriate items. Prior to distribution, we conducted a pilot test of the questionnaire, seeking feedback from the key experts to enhance clarity and ease of use. Once the survey items were qualitatively validated, the survey was administered between June and December 2023, gathering 511 responses. To encourage transparent responses to sensitive information, the questionnaires were administered anonymously.

3.3 Sample Representativeness

Our dataset, composed of 511 responses, correctly represents the pharmaceutical industry, encompassing key stages of the industry's value chain, particularly Drug Research & Development, Manufacturing, and Patient Access. These stages are crucial touchpoints in the adoption of AI both in terms of operational efficiency and broader sustainability considerations. Following this reasoning, the sample captures diverse expertise, ensuring a holistic perspective on

AI-driven changes across the pharmaceutical sector (see discussion above). In general, the Pharmaceutical Industry exhibits low variability in terms of innovation, as it is constrained and limited by stringent regulatory and quality standards whose primary objective is to safeguard patient safety (Harrer et al., 2019; Kulkov, 2021; Satwekar et al., 2022). Introducing AI, a disruptive innovation, does not constitute an exception. Across the three described phases, this technology is being deployed following a slow yet uniformly defined trend across all industry players (e.g. Deloitte Report 2022, Deloitte Report 2024, Mckinsey Report 2025)

Both reports and literature highlight that the industry is consistently investing and implementing AI, as it not only brings micro-level improvements (e.g., process optimization) but also contributes to the broader macro trend envisioned and acknowledged by all industry experts: *Personalized Medicine* (Trenfield et al., 2022). Therefore, regardless of a company's specific characteristics or business model, firms are collectively moving toward AI adoption.

The sample's composition encompasses the various realities within the pharmaceutical value chain, ensuring that survey respondents are knowledgeable about AI. To ensure further reliability of our sample, we included an exclusion question: *Do you use AI within your company?* (Yes/No) to filter out non-acknowledged respondents.

To ensure respondent anonymity, it was not possible to collect company names. However, we gathered information about their company size and turnover. This approach allowed us to validly represent the pharmaceutical sector, showing the varying types of enterprises within the same industry, from large multinational corporations to smaller, specialized firms, and their economic performance as outlined by multiple Industry Reports (e.g. Deloitte Report 2018, European Federation of Pharmaceutical industries and Associations Report, Deloitte Report 2022, Deloitte Report 2024, Mckinsey Report 2025). Accordingly, given the complexity and specialization of the industry, achieving a broad representation of key stakeholders—spanning scientific, operational, and commercial domains — strengthens the sample’s representativeness and generalizability of findings, capturing sector-wide trends rather than being skewed by the

perspectives of a single subset of professionals. Furthermore, turnover data were collected to enhance dataset representativeness, exhibiting a distribution commensurate with company size. As demonstrated in Table 2 and Figure 2, the sample accurately reflects the economic and financial structure of the pharmaceutical sector, encompassing its diverse composition across company size and revenue distribution.

TABLE 2 ABOUT HERE

3.4 Variables and Measures

3.4.1 Cognitive Readiness and Strategic Readiness

Two key dimensions to comprehensively assess an organization's preparedness for digital innovation were identified in our study: Strategic Readiness and Cognitive Readiness. Each dimension is measured using specific items that capture different aspects of the organization's capacity to embrace and implement new digital technologies identified by Lokuge et al. (2019). Strategic Readiness is composed of three items capturing how well the organization is positioned in terms of planning, goal setting, and communication regarding the adoption of new digital technologies. An example item is: "The organization has effectively communicated its strategic goals concerning the new technology to stakeholders." Cognitive Readiness is composed of three items focused on the individual capabilities within the organization, specifically the knowledge, skills, and adaptability required for successful technology deployment. An example item was: "The organization owns the necessary know-how to effectively implement the new technology". Items were rated on a 7-point Likert-type answering scale ranging from 1 (not at all) to 7 (a great deal).

3.4.2 AI Adoption

Individual behaviors have been recognized as critical influential factors in technology adoption literature (Venkatesh, 2022; Venkatesh et al., 2003, 2012), and there is a growing discussion among scholars to address this issue in the context of AI (Ho et al., 2023; Venkatesh, 2022). To assess the adoption of new technologies within an organization, We used to measure the following constructs: *Performance Expectancy, Behavioral Intention, Social influence and Effort Expectancy* (Venkatesh, 2022; Venkatesh et al., 2003, 2012). Each of these constructs is measured using specific items rated on a 7-point Likert scale, ranging from "strongly disagree" (1) to "strongly agree" (7). Using this measurement scale allowed for a comprehensive understanding of how employees perceive, intend to use and are influenced by adopting AI. In particular, Effort Expectancy refers to the degree of AI easiness to learn and use. This construct captures perceptions related to the simplicity and intuitiveness of the technology. Behavioral Intention measures the likelihood that employees will adopt and use AI in the future, assessing their willingness and plans regarding the adoption of AI. Performance Expectancy examines the perceived benefits of AI in enhancing job performance and efficiency. This construct focuses on how employees believe AI will help them to complete tasks more quickly, improve the quality of their work, and increase their overall productivity. Finally, Social Influence evaluates the extent to which employees perceive that the adoption of the AI is supported and encouraged by their managers and peers, therefore considering the role of leaders and other organizational members to support and sustain adoption.

3.4.3 SDG performance

Given that research on the linkage between AI and SDG in the pharma industry is scant, and hence that lack of validated measures[6], we drew on our field interviews to develop our survey items. Specifically, we developed a set of items to capture sustainability performance covering SDGs #3, #9, #12, and #17, as emerged from this analysis. We paid particular attention to discussing these

[6] A notable exception is represented by the Overview Report on “Embedding Environmental Sustainability into Pharma’s DNA Contents, year 2022”, which we carefully considered to finalize our questionnaire.

items with experts and key opinion leaders during the pilot testing of the questionnaires. Particularly, for SDG #3"Good Health and Well Being" we gained a detailed perspective on how PI companies are addressing global health challenges, improving, and getting more efficient drug development phases through the adoption of AI technologies. Regarding SDG #9 “Responsible Consumption and Production", we understood that responsible production is central in the pharma industry to ensure that drug production occurs sustainably, reducing environmental impacts and promoting ethical practices. Interviewees provided AI relevant information on sustainable initiatives, such as proposing new activities for responsible waste management and green production principles. For SDG #12 we learned that "Industry, innovation and infrastructure” are also relevant in the field, as AI helps organizations to innovation across the whole value chain. Finally, for SDG #17 our interviews revealed that “Partnerships for the Goals” are of particular importance because the capability to deploy AI technologies and consequently address global issues such as access to medicines, shared research, and the promotion of sustainable solutions, happens mostly through alliances and partnerships.

3.4.4 Economic Performance

Economic performance is a widely used dependent variable in management research. Accordingly, in the context of our research, we operationalized economic performance in terms of the following self-reported financial indicators (Latifi et al., 2021): (i) Profits, reflecting the organization's ability to generate profit from its operations; (ii) Revenue Streams, assessing the stability and diversity of the firm's revenue sources (iii) Market Share, evaluating the firm's market presence relative to its competitors. We asked respondents to report on a 7-point Likert scale their firm’s economic performance.

3.4.5 Moderating Variable: Organizational Size

To test the hypothesized role of organizational size as a moderator in our model, we considered the size of the organizations in which respondents were employed. Specifically, we used a binary variable that took the value of 1 if the respondent was employed in a small-medium organization and 0 if he/she was employed in a large organization instead. The threshold of 250 employees, routinely used in existing research (Kotey & Folker, 2007), was used to distinguish between small-medium and large firms.

Table 3 represents descriptive statistics of our variables.

TABLE 3 ABOUT HERE

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4. Analysis and Results

Our analysis was conducted in several stages. We began by validating our measurement scales through Exploratory Factor Analysis (EFA) and Confirmatory Factor Analysis (CFA). Then, we employed Structural Equation Modeling (SEM) to test our research hypotheses regarding the relationships between organizational readiness, AI adoption, Sustainable Development Goals (SDG) performance, and economic performance. SPSS was utilized for the EFA, while Lisrel was used for both the CFA and SEM analyses. Mediation effects were tested using the Prodclin software package, following the methodological approached outlined by Churchill Jr. (1979) and Steenkamp & Van Trijp (1991).

4.1 Measurement Model

We began by testing the reliability of our scale to ensure that the selected items accurately represent the hypothesized constructs. Internal consistency was assessed using Cronbach's α (Churchill Jr, 1979; Steenkamp & Van Trijp, 1991). As shown in Table 4, the criteria for proceeding with

Exploratory Factor Analysis (EFA) were satisfied, with most constructs achieving Cronbach's α coefficients greater than 0.8 (Churchill Jr, 1979; Steenkamp & Van Trijp, 1991).

We then conducted an EFA to identify the smallest number of factors that effectively summarize the original set of items, ensuring that m > n (Churchill Jr, 1979; Steenkamp & Van Trijp, 1991). Typically, EFA can result in some loss of variance; therefore, retaining as much variance as possible is crucial. In our analysis, this condition was successfully met. Using Maximum Likelihood Analysis with PROMAX rotation, we achieved a variance of 72.62%, accounting for 8 factors out of 22, with no significant cross-loadings (greater than 0.4) (Churchill Jr, 1979; Steenkamp & Van Trijp, 1991).

Following this step, we aimed at understanding the degree of consistency between repeated measures of the same construct by testing convergent and discriminant validity conditions through a CFA (Churchill Jr, 1979; Steenkamp & Van Trijp, 1991). The correlation matrix reported in Table 5 shows high levels of correlation (ϕ_{12}) between the different constructs. Despite such correlation values, all of them exceed the conditions of convergent and discriminant validity provided by Fornell and Larcker (Fornell & Larcker, 1981), which entails $AVE\xi_1 > \phi_{12}^2$; $AVE\xi_2 > \phi_{12}^2$ verified in all cases:

- $\begin{cases} \text{AVE (Behavioral Intention)} = 0.686 \\ \text{AVE (Performance Expectancy)} = 0.630 \end{cases} > (\phi_{12}^2 = (0.743)^2 = 0.552)$
- $\begin{cases} \text{AVE (Social Influence)} = 0.716 \\ \text{AVE (Performance Expectancy)} = 0.630 \end{cases} > (\phi_{12}^2 = (0.641)^2 = 0.410)$
- $\begin{cases} \text{AVE (Cognitive Readiness)} = 0.704 \\ \text{AVE (SDG Performance)} = 0.524 \end{cases} > (\phi_{12}^2 = (0.626)^2 = 0.391)$
- $\begin{cases} \text{AVE (Strategic Readiness)} = 0.610 \\ \text{AVE (SDG Performance)} = 0.524 \end{cases} > (\phi_{12}^2 = (0.687)^2 = 0.471)$
- $\begin{cases} \text{AVE (Cognitive Readiness)} = 0.704 \\ \text{AVE (Strategic Readiness)} = 0.610 \end{cases} > (\phi_{12}^2 = (0.719)^2 = 0.568)$

This allowed us to claim that the scale was reliable, valid, and ready to be tested for SEM analysis (Churchill Jr, 1979; Steenkamp & Van Trijp, 1991).

TABLES 4 AND 5 ABOUT HERE

4.2 Structural model

In the final step we aimed to evaluate the structural equation model by testing the significance of the paths, examining the effects of the hypothesized relationships, and assessing the explanatory power of our research model. The specified model was found to fit the data well, as all relevant indicators satisfy the SEM conditions (Churchill Jr, 1979; Steenkamp & Van Trijp, 1991): $\chi 2$ (degrees of freedom) = 347.051 (183); *Global Fit Index* (GFI)= 0.942; *Adjusted Goodness of Fit Index* (AGFI) = 0.920; *Comparative Fit Index* (CFI) = 0.992; *Root Mean Square Error Of Approximation* (RMSEA) = 0.0415, *P-Value for Test of Close Fit* (RMSEA < 0.05) = 0.982, *Standardized RMR* = 0.0375.

Tables 6 and 7 present the results of the Structural Equation Modeling (SEM) analysis. Specifically, Table 6 details the direct hypothesized effects, while Table 7 illustrates the mediation effects tested using the asymmetric confidence interval technique available in Prodclin Software (MacKinnon, 2012). Tables 8 and 9 provide the results for the moderating effect of organizational size on the relationship between SDG performance and economic performance (Byrne et al., 2005). The moderation analysis compares nested models: an unconstrained model, where the moderation parameter is freely estimated across groups (Small and Large Companies), and a constrained model, where the moderation effect parameters are set to be equal across these groups. As shown in the invariance analysis (Table 8), the model adheres to Scalar Invariance principles ($p < 0.01$), allowing for a valid comparison of the constructs' basic structure, structural relationships, covariances, and latent variable means across the two groups. This ensures that the hypothesized moderation effects can be meaningfully compared. In evaluating the nested models to confirm the moderation effects (Table 9), the model with the lower chi-square value is favored, indicating a significant difference between the groups and confirming the presence of moderation.

Finally, Table 10 compares the significance of moderating effects between small-medium and large-sized organizations. The results indicate that small-sized firms serve as a statistically significant moderator (H7: $\beta = 0.327$, $p < 0.01$).

TABLE 5 ABOUT HERE

The results overall address strategic and cognitive readiness as antecedent dimensions for AI Adoption and, in turn, achieving higher SDG performance. In particular, we find that the strategic (H1) and cognitive (H2) readiness variables are positively and significantly associated with AI Adoption (H1.a.I γ=0.392, p<0.01), (H1.a.II γ=0.419, p<0.01), (H1.a.III γ=0.148, p<0.05), (H1.a.4 γ=0.348, p<0.01), (H1.b.II γ=0.219, p<0.01), (H1.b.III γ=0.386, p<0.01), (H1.b.IV γ=0.109, p<0.05). An exception is the relationship between cognitive readiness and the "Behavioral intention" component of adopt AI, which although positive is not statistically significant. In addition, as hypothesized, strategic and cognitive readiness are positively and significantly related to SDG performance (H3.a.I β=0.558, p<0.01) (H3.b.I β=0.303, p<0.01).

Our findings also show that, while the relationship between AI Adoption components and SDG Performance hypotheses (H2) is not supported (except for the Social Influence component H2.b, β=0.174, p<0.05), AI Adoption mediates the relationship between strategic readiness and cognitive readiness and SDG performance (H3.a. II, β=0.051, p<0.01), (H3.a.III, β=0.073, p<0.01), (H3.a.IV: β=0.018, p<0.01), (H3.a.V: β=-0.062, p<0.01), (H3.b.II: β=0.011, p<0.01), (H3.b.III: β=0.038, p<0.01), (H3.b.IV: β=0.046, p<0.01), (H3.b.V β=-0.020 p<0.01). Moreover, our results confirm that – although only for the two components "Social Influence" (H5.b β=0.196, p<0.01) and "Performance Expectancy" (H5.d β=0.260, p=p<0.05) – there is a positive relationship between AI Adoption and economic performance, and that SDG performance mediates the relationship between AI Adoption and economic performance (H6.a: β=0.034,

p<0.01), (H6.b β=0.025, p<0.01), (H6.c: β=0.023, p<0.01) in all its components. Overall, this confirms that a positive AI Adoption, facilitated by a greater strategic and cognitive readiness, is related to higher levels of SDGs attainment, which in turn is associated with greater economic performance.

Finally, our results show that SDG is related to ECP significantly and positively (H4 β=0.194, p<0.01), and that organizational size moderates this relationship such that it is stronger for small-medium firms, rather than large companies (H7: β=0.327, p<0.01).

TABLES 7-8-9-10 ABOUT HERE

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5. Discussions

This study provides significant advancements by elucidating the conditions under which AI adoption drives sustainability and economic success. Following we will discuss the theoretical and managerial contributions.

First, the hypothesized model empirically demonstrates that organizational readiness is not merely a precursor to AI adoption but a determining factor for successful, full-scale deployment within organizations, confirming prior literature elaborations that encompass both strategic foresight (e.g., clear long-term objectives) and cognitive preparedness (e.g., employees' ability to understand and work with AI technologies) (Belhadi et al., 2024; Cao et al., 2021; Lokuge et al., 2019; Venkatesh, 2022). The analysis, indeed, highlights that both Strategic (H1.a) and Cognitive (H1.b) readiness are critical factors underlying AI Adoption, as well as for achieving higher performance in terms of SDGs (H3). This alignment emerges as a fundamental cornerstone, where organizational strategies, policies, and structures are pivotal in fostering an environment conducive to embracing AI, coherently with current discussions in the academic Technology Adoption (Cao et al., 2021; Dwivedi et al., 2021; Sykes et al., 2009; Venkatesh, 2022; Venkatesh et al., 2003,

2012) and Sustainability (Brevini, 2020; Floridi et al., 2021; Hao, 2019; Lin, 2021; Strubell et al., 2019; Yu et al., 2022). It is worth mentioning that while the positive relationship between Social Influence, Effort Expectancy, and Performance Expectancy is validated, Behavioral Intention to Use AI and Cognitive Readiness are not statistically significant (H1.b.I). These relations may be influenced by different factors and operate independently of each other, as indicated by various perspectives in the literature, characterizing AI as ambiguous, challenging to understand the reasoning behind decision-making, and worrying in terms of job replacement (Anderson, 2003; Cao et al., 2021; Dwivedi et al., 2021; Schneider & Leyer, 2019; Tversky & Shafir, 1992).

However, providing relevance to our hypothesized model, all individual components of AI Adoption (H3) have emerged as mediators in the relationship between Strategic and Cognitive Readiness and to achieve enhanced SDG performance. These findings are interesting for two main reasons. First, results underscore the intricate interplay between Strategic and Cognitive Readiness and the realization of enhanced SDG performance, which previous research has largely disregarded. Second, the results show, unlike other authors (Courtland, 2018; Gupta et al., 2021), the significance of AI Adoption in achieving SDG performance and the consequent increased economic performance impacts. This is in line with the increasingly relevant academic debate considering AI as beneficial in terms of Sustainability (Berente et al., 2021; Brevini, 2020; Floridi et al., 2021; Hao, 2019; Lin, 2021; Sjödin et al., 2023; Strubell et al., 2019; Yu et al., 2022), suggesting that the organizational landscape and its readiness profoundly shape the organization's ability to leverage AI technologies effectively, subsequently driving progress toward SDG objectives (Vinuesa et al., 2020).

Third, our findings shed new light on the influence of AI Adoption on Economic Performance (ECP) (H5), particularly in conjunction with SDG as the underlying mediating factor (H6). This is a fascinating insight as previous technology adoption literature is limited in understanding performance in terms of deployment not to create economically viable competitive advantage (Cao et al., 2021; Sykes et al., 2009; Venkatesh, 2022; Venkatesh et al., 2003, 2012). This theoretical

contribution adds nuance to the debate on AI's impact on organizational performance, demonstrating that SDG achievements can serve as a bridge between AI investments and long-term economic gains (Anderson, 2003; Dwivedi et al., 2021; Schneider & Leyer, 2019; Tversky & Shafir, 1992; Venkatesh, 2022). It is noteworthy that only Social Influence and Performance Expectancy to use AI exhibit a positive relation with ECP in the hypothesized model, while effort expectancy and behavioral intention do not. This suggests that, on the one hand, the social context and the perceived performance benefits of AI contribute positively to a firm's economic outcomes (H5.b, H5.d). On the other hand, further investigation into the underlying mechanisms driving perceived performance benefits and behavioral intention of AI would benefit a comprehensive understanding of the relation.

However, as a fourth theoretical contribution, our analysis highlights a significant and positive relationship between SDG and Economic Performance. This finding further emphasizes the pivotal role of SDGs in driving superior outcomes such as increased revenues, market share, and profits within organizations. This finding, which has not been demonstrated in the literature so far, resonates with the growing recognition of AI and sustainability as key drivers of business success in today's global landscape (Berente et al., 2021; Brevini, 2020; Floridi et al., 2021; Hao, 2019; Lin, 2021; Sjödin et al., 2023; Strubell et al., 2019; Yu et al., 2022), suggesting again that organizations that prioritize SDG initiatives and integrate them into their core digital AI strategies are better positioned to achieve not only financial prosperity but also long-term resilience and competitiveness.

Fifth, we contribute to the existing literature by demonstrating that within the pharmaceutical industry, small and medium-sized organizations are particularly well placed to exploit the benefits of AI adoption to improve their overall performance (Corvello et al., 2024; Cubric & Li, 2024; Mariani et al., 2023; Nishant et al., 2020; Toniolo et al., 2020). This implies that, according to the conceptualized model, companies that are strategically and cognitively oriented towards digital innovation are typically smaller, making it less burdensome and more accessible for them to

initiate more effective Adoption of AI, consequently leading to an improvement in SDG performance. (Corvello et al., 2024; Cubric & Li, 2024). This contribution is particularly relevant as it suggests how small organizational size can impact the effects of AI adoption on both SDG and economic outcomes, with smaller organizations standing to gain more economic viability through sustainable practices.

6. Limitations and Future Research

Our study is not without limitations. First, it is limited by the narrow scope of the sampled data, which was derived exclusively from the pharmaceutical industry. We recommend that future research broaden data collection efforts to include diverse sectors, thereby enhancing the validity and generalizability of the findings. A second limitation of our study pertains to the use of cross-sectional data, which is inherently more susceptible to common method bias. To address this, we encourage the use of longitudinal data collection methods to provide a more comprehensive and nuanced understanding. Additionally, future research could explore qualitative investigations into how factors such as individual capabilities, competencies, and expertise in AI adoption influence SDG performance. Finally, our analyses are based on primary data collected from a sample of managers, which may reflect their individual perceptions of the research constructs – we suggest that future studies incorporate secondary data to assess the robustness and replicability of our findings.

7. Conclusion

What is the relationship between AI, SDGs, and organizational performance? This paper takes a first step in addressing this important question, shedding new light on the enablers of AI adoption and its consequences. Our conceptual model and empirical investigation jointly suggest that AI adoption, supported by organizational readiness, is conducive to the achievement of the SDGs and, in turn, to economic performance. We show that strategic and cognitive readiness are essential for

AI adoption, as they enable effective integration of this technology into the operational framework, thus predicting SDGs and economic performance. Our paper contributes to the emerging debate on the conditions under which AI positively supports sustainability and economic performance in organizations.

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Figure 1. Conceptual Model

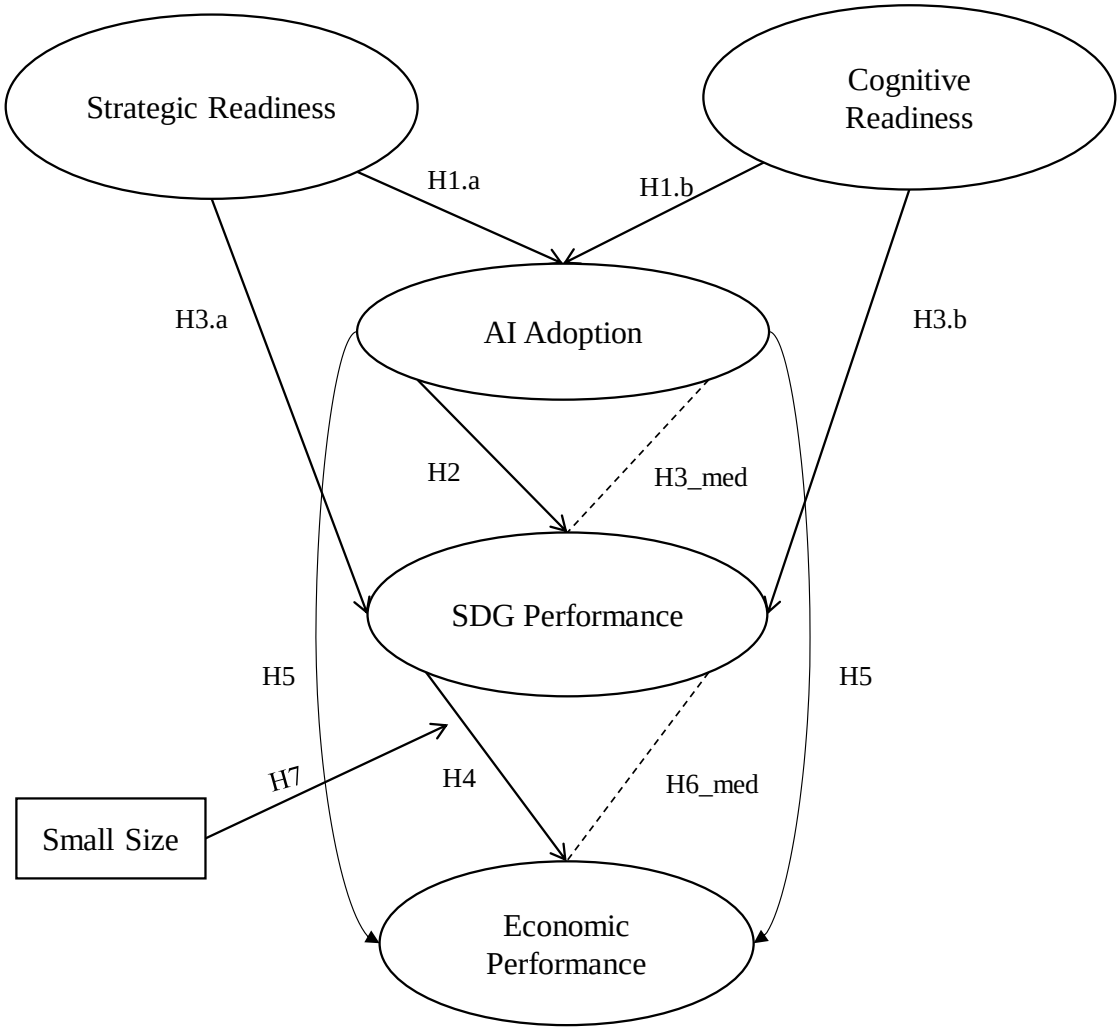

Figure 2 – Sample Representation Size/Turnover

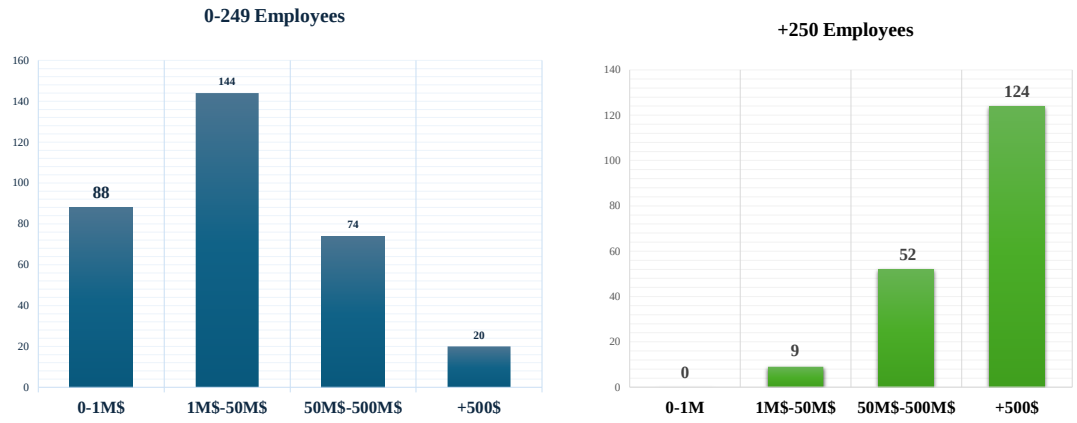

Table 1. AI Relevance within Pharmaceutical Industry and SDG Framework

Value Chain Phase	AI Benefits	SDG Related	Source
Drug Development and Research	• Facilitating the discovery of novel drug candidates • Enhanced support to discover new treatments for rare diseases • Potentially substituting initial clinical trial phases • Supporting in the evaluation and matching of Patient-Site for Trials • Minimizing delays related to trial activities • Disincentivize individual transfer	SDG 3 - Good Health and Well-being SDG 9 - Industry, Innovation, and Infrastructure SDG 17 - Partnerships for the Goals	*Archival Material:* (Hariry et al., 2022a; Miozza et al., 2024; Wojtara et al., 2023; Zhang et al., 2023) Deloitte Report 2018, European Federation of Pharmaceutical industries and Associations Report 2024, Deloitte Report 2022, Deloitte Report 2024, Mckinsey Report 2025 *+ Interviews*
Manufacturing	• Predicting equipment breakdowns and Maintenance • Enhancing drug quality Assurance • Minimizing Resource Waste • Supporting in Energy efficiency practices • Fine-tuning production volumes through real-time demand insights	SDG 3 - Good Health and Well-being SDG 9 - Industry, Innovation, and Infrastructure SDG 12 - Responsible Consumption and Production	*Archival Material:* (Kulkov, 2021; Miozza et al., 2024; Reinhardt et al., 2020; Sharma et al., 2020; Trenfield et al., 2022) Deloitte Report 2018, European Federation of Pharmaceutical industries and Associations Report 2024, Deloitte Report 2022, Deloitte Report 2024, Mckinsey Report 2025 *+ Interviews*

Patient Access	• Optimize warehouse Management • Detect counterfeited drugs • Automating Procurement Management • Supporting staff and material shortages Management • Personalized Medicine	SDG 3 - Good Health and Well-being SDG 9 - Industry, Innovation, and Infrastructure SDG 12 - Responsible Consumption and Production SDG 17 - Partnerships for the Goals	*Archival Material:* (Chamekh et al., 2017; Kulkov, 2021; Miozza et al., 2024; Trenfield et al., 2022) Deloitte Report 2018, European Federation of Pharmaceutical industries and Associations Report 2024, Deloitte Report 2022, Deloitte Report 2024, Mckinsey Report 2025 *+ Interviews*

Table 2. Demographics of the sample

Firm Size		
N. of Employees	Frequency	Percentage
0-249 Employees	326	63.8
+250 Employees	185	36.2
Total	511	100

Pharmaceutical Value Chain Area		
Value Chain Areas	Frequency	Percentage
Drug Development and Research	110	21.53
Manufacturing	177	34.64
Customer and Patient Access	224	43.83
Total	511	100

Turnover		
Range	Frequency	Percentage
0 - 1M$	88	17.22
1M$ - 50M$	154	30.14
50M$ - 500M$	126	24.65
+500M$	143	27.99
Total	511	100

Table 3. Descriptive Statistics

Constructs	Mean	S.D.	Skewness	Kurtosis
Effort Expectancy (E_Exp)	5.34	1.32	-0.78	0.33
Behavioral Intention (B_Int)	5.88	1.17	-1.13	1.16
Performance Expectancy (P_Exp)	5.94	1.10	-1.28	1.98
Social Influence (Si)	5.40	1.24	-0.81	0.67
Cognitive Readiness (Cog_Read)	5.07	1.38	-0.68	0.03
Strategic Readiness (S_Read)	5.22	1.42	-0.81	0.23
SDG Performance (SDG)	4.89	1.57	-0.66	-0.15
Economic Performance (ECP)	5.10	1.36	-0.76	0.57

Table 4. Validity and Reliability Items

Constructs	Items	Questionnaire item	EFA Loadings	Cronbach's α	Composite Reliability	AVE
Effort Expectancy (E_Exp)	E_Exp 1	I find AI Easy to learn	0.868	0.831	0.788	0.654
	E_Exp 2	I find AI Easy to use	0.845			
Behavioural Intention (B_Int)	B_Int 1	I intend to adopt AI in the next year	0.724	0.896	0.867	0.686
	B_Int 2	I predict I would use AI in the next year	0.876			
	B_Int 3	I plan to adopt AI in the next year	1.001			
Performance Expectancy (P_exp)	P_exp 1	I find AI useful in my job	0.482	0.828	0.773	0.630
	P_exp 2	I find AI useful to accomplish tasks more quickly	1.043			
Social Influence (Si)	Si_1	Adoption of AI is supported by management	0.643	0.869	0.834	0.716
	Si_2	Adoption of AI is supported by the organization	1.079			
Cognitive Readiness (Cog_Read)	Cog_Read 1	Members of my organization have the appropriate knowledge for new technology deployment	0.864	0.903	0.876	0.704
	Cog_Read 2	Members of my organization have the appropriate skills for new technology deployment	0.912			
	Cog_Read 3	Members of my organization have the appropriate digital adaptability for new technology deployment	0.768			
Strategic Readiness (S_Read)	S_Read 1	My company has clear long-term objectives for new technology deployment	0.928	0.869	0.824	0.610
	S_Read 2	My company has coherent strategic goals for new technology deployment	0.788			
	S_Read 3	My company communicates clearly its strategic goals for new technology deployment	0.687			
Economic Performance (ECP)	ECP 1	In the last years, my company increased Profits	0.912	0.849	0.801	0.581
	ECP 2	In the last years, my company increased Revenues	0.848			
	ECP 3	In the last years, my company increased Market Share	0.677			
SDG Performance (SDG)	SDG 1	My company adopts new equipment aimed at reducing the environmental footprint	0.842	0.872	0.813	0.524
	SDG 2	My company adopts continuous manufacturing and green chemistry principles	0.911			
	SDG 3	My company established new collaborations to ensure fair and equitable treatment accessibility	0.718			

	SDG 4	My company is committed to ensuring equal access to treatments across the world	0.594			

Table 5. Correlation Matrix

	Variable	1	2	3	4	5	6	7	8
1	Ecp	1.000							
2	Sdg	0.497	1.000						
3	B_Int	0.510	0.457	1.000					
4	Si	0.528	0.554	0.607	1.000				
5	E_Exp	0.413	0.446	0.444	0.458	1.000			
6	P_Exp	0.548	0.435	**0.743**	**0.641**	0.547	1.000		
7	S_Read	0.481	**0.687**	0.548	0.641	0.467	0.571	1.000	
8	Cog_Read	0.430	**0.626**	0.446	0.581	0.543	0.483	**0.719**	1.000

Table 6. Direct Effects

Hypothesis	Loadings	Standard Deviation	T Statistics	*p*-value	Interpretation
H1.a.I: S_read → B_Int	γ=0.392	0.060	6.549	***	Accepted
H1.a.II: S_read →Si	γ=0.419	0.062	6.810	***	Accepted
H1.a.III: S_read →E_Exp	γ=0.148	0.066	2.234	**	Accepted
H1.a.IV: S_read → P_Exp	γ=0.348	0.056	6.255	***	Accepted
H1.b.I: Cog_read → B_Int	γ=0.086	0.055	1.558	---	Rejected
H1.b.II: Cog_read →Si	γ=0.219	0.057	3.812	***	Accepted
H1.b.III: Cog_read →E_Exp	γ=0.386	0.066	5.827	***	Accepted
H1.b.IV: Cog_read → P_Exp	γ=0.109	0.052	2.104	**	Accepted
H2.a: B_Int →SDG	β=0.131	0.092	1.433	---	Rejected
H2.b: Si→SDG	β=0.174	0.080	2.177	**	Accepted
H2.c: E_Exp →SDG	β=0.119	0.066	1.807	---	Rejected
H2.d: P_Exp→SDG	β=-0.179	0.120	-1.493	---	Rejected
H3.a.I: S_Read→SDG	γ =0.558	0.075	7.986	***	Accepted
H3.b.I: Cog_Read→SDG	γ =0.303	0.069	4.442	***	Accepted
H4: SDG → ECP	β=0.194	0.046	4.183	***	Accepted
H5.a: B_Int → ECP	β=0.151	0.084	1.799	---	Rejected
H5.b: Si→ECP	β=0.196	0.068	2.870	***	Accepted
H5.c: E_Exp → ECP	β=0.088	0.057	1.557	---	Rejected
H5.d: P_Exp→ECP	β=0.260	0.109	2.384	**	Accepted

*Note: p<0.001=***; p<0.005=***

Hypothesis	Loadings	Standard Deviation	*p*-value	Lower Limit	Upper Limit	Interpretation
H3.a.II: S_read → B_Int→SDG	β=0.051	0.037	***	-0.06906	0.18951	Accepted
H3.a.III: S_read → Si →SDG	β=0.073	0.035	***	-0.03651	0.20821	Accepted
H3.a.IV: S_read →E_Exp→SDG	β=0.018	0.013	***	-0.01626	0.07706	Accepted
H3.a.IV: S_read → P_Exp → SDG	β=-0.062	0.043	***	-0.22486	0.07702	Accepted
H3.b.II: Cog_read → B_Int → SDG	β=0.011	0.011	***	-0.01981	0.06716	Accepted
H3.b.III: Cog_read →Si →SDG	β=0.038	0.020	***	-0.01879	0.12513	Accepted
H3.b.IV: Cog_read → E_Exp → SDG	β=0.046	0.027	***	-0.03791	0.15008	Accepted

H3.b.IV: Cog_read → P_Exp → SDG	β=-0.020	0.016	***	-0.09576	0.02837	Accepted
H6.a: B_Int → SDG →ECP	β=0.034	0.017	***	-0.01676	0.10743	Accepted
H6.b: Si → SDG →ECP	β=0.025	0.019	***	-0.03519	0.10287	Accepted
H6.c: E_Exp → SDG →ECP	β=0.023	0.014	***	-0.01938	0.08112	Accepted
H6.d: P_Exp → SDG →ECP	β=-0.035	0.025	***	-0.13645	0.04401	Accepted

Table 7. Mediation Effects

*Note: p<0.001=****

Table 8. Invariance Analysis

Model	χ^2	df	$\Delta\chi^2$	Delta df	*p*-value	CFI	ΔCFI	RMSEA	p close-fit
Configural Invariance	596.105	366	---	---	---	0.989	---	0.046	0.811
Metric Invariance	618.218	380	22.113	14	0.07	0.989	0	0.0459	0.820
Scalar Invariance	638.553	402	20.335	22	0.56	0.989	0	0.0438	0.921

Table 9. Comparing Free and Constrained Models for Moderation

Model	χ^2	df	$\Delta\chi^2$	Delta df	*p*-value	CFI	ΔCFI	RMSEA
Free	639	402	---	---	---	0.989	---	0.0438
Constrained	828	413	189.225	11	***	0.981	-0,007	0.0543

*Note: p<0.001=****

Table 10. Moderating Effects - Small versus Big Sized Firms effect

Hypothesis	Loadings	Standard Deviation	T Statistics	*p*-value	Interpretation
H7: SDG → Mo: Small Size →ECP	β= 0.327	0.059	5.508	***	Accepted
H7: SDG → Mo: Big Size →ECP	β= -0.026	0.059	-0.443	---	Rejected

*Note: p<0.001=****

Paper 5: Bridging the Digital Divide in Pharmaceutical Industry: a Future Research Agenda

Abstract

This paper delves into the evolving landscape of Digital Transformation (DT) in the Pharmaceutical Industry (PI), identifying both the opportunities and challenges it presents. Using a sample of 70 PI-DT papers, this study develops a systematic literature review (SLR) and the probabilistic topic modeling technique called latent Dirichlet allocation (LDA) in order to (i) identify relevant emerging challenges and opportunities and (ii) propose a future research agenda to bridge the digital divide. By highlighting current applications and deployment, this study provides a pathway for future research to adopt a more sustainable and forward-thinking approach to PI-DT. Moreover, the study explores the transformative impact of integrating digital technologies in (i) Advancing Drug Discovery Research, (ii) Reinventing Strategies and Organizational Frameworks, (iii) Manufacturing Optimization (iv) Supply Chain and Logistics Optimization and (v) Developing Patient Centric Models. Overall, this study contributes to a more profound comprehension of PI-DT and establishes a foundation for further exploration and discourse in this swiftly evolving field.

Keywords: *Digital Transformation, Pharmaceutical Industry, Systematic Literature Review, Topic Modeling, LDA (Latent Dirichlet Allocation), Future Research Agenda*

1. INTRODUCTION

Digital Transformation (DT) has emerged from the convergence of automation, the internet, digital technologies, and services and it represents a pivotal stride in improving productivity and quality, expanding product portfolios, comprehending customer behavior, and achieving cost-effectiveness leading to a disruptive impact on both society and businesses (Sunmola & Javahernia, 2021; Verhoef et al., 2021; Vial, 2019). The pharmaceutical Industry (PI) stands as a compelling domain for exploration (e.g. Kordestani, Oghazi, & Mostaghel, 2023; Kulkov, 2021; Miozza, Brunetta, & Appio, 2024; Zakari et al., 2022) however, the uncertainty surrounding the legal framework between PI-DT and stringent quality controls on final products creates structural barriers that slow the digital transition process for organizational and industrial restructuring (Satwekar, Miozza, Abbattista, Palumbo, & Rossi, 2024; Satwekar, Volpentesta, Spagnoletti, & Rossi, 2022). Overall, the existing literature on the PI-DT phenomenon appears fragmented, for three primary reasons. First, most PI-DT relevant papers adopt a scientific or technical perspective, failing to adequately capture the organizational and industry-level implications of digital technology's deployment. For instance, multiple authors have demonstrated AI techniques as facilitators for accelerating the drug discovery phase (Patel & Shah, 2022; Raschka & Kaufman, 2020; Zhavoronkov et al., 2019) or digital twins for optimizing manufacturing processes (Chen et al., 2020a); however, while these articles are valuable for advancing scientific knowledge, they primarily emphasize technical and practical insights rather than laying the foundations for a comprehensive implementation of DT paradigms at both organizational and industry levels.

Second, much of the relevant literature positions PI-DT within the broader healthcare context (Kraus, Schiavone, Pluzhnikova, & Invernizzi, 2021; Raghupathi & Raghupathi, 2014; Trenfield et al., 2022a), often blending its focus with adjacent sectors such as hospitals and pharmacies. For example, studies have examined cloud-based and AI applications for pharmacies business model (Anil Kumar Ratnala, Sahana Ramesh, & Bhavani Krothapalli, 2022) or deployment in Hospitals (Lian, Yen, & Wang, 2014). Although these studies provide valuable insights into DT at an

industrial and organizational level, they fail to address and effectively represent DT across the entire PI value chain.

Third, the scant existing PI-DT literature tends to study single digital technology implications within single Value Chain Phases, limiting the breadth and generalizability of DT applicability. For instance, authors described how 3D printing is reshaping Drug Discovery phase (Awad, Trenfield, Goyanes, Gaisford, & Basit, 2018; Norman, Madurawe, Moore, Khan, & Khairuzzaman, 2017), other authors investigated potential Blockchain solutions for PI supply Chains (Abdallah & Nizamuddin, 2023; Anil Kumar Ratnala et al., 2022; Shi, Yi, & Kuang, 2019). While these studies underscore the importance of PI-DT at both organizational and industry levels, they only partially represent the broader implications involved with this phenomenon.

Overall, to shed light on these matters, there is the need for more elaborations, (i) untangling from pure technical dynamics, (ii) preventing isolated contributions and (iii) including a more holistic perspective on the whole Value Chain, consequently substantially addressing PI-DT as a subject of active discussion for effective deployment.

To shed comprehensive light on these gaps, this study aims to answer the following Research Questions:

- *RQ1: "What are the Major Challenges and Opportunities to Bridge the Pharmaceutical Industry Digital Divide?"*
- *RQ2: "What are the future Practice Research Avenues to Bridge the Pharmaceutical Industry Digital Divide?"*

Accordingly, we conducted an in-depth analysis of the literature by employing two methods: a systematic literature review and topic modeling using latent Dirichlet allocation (LDA). First, the SLR process consisted of defining our research question and creating a review procedure to select relevant materials based on replicable criteria (Delbufalo, 2012; Sivarajah, Kamal, Irani, & Weerakkody, 2017; Tranfield, Denyer, & Smart, 2003) with the ultimate goal of understanding the PI-DT phenomenon in detail, narrowing relevant Challenges and Opportunities (RQ1). The

Rayyan Software was used to gather and extract the selected articles, ensuring that the exclusion criteria and quality control were followed. Afterward, the topic modeling with LDA technique (Blei et al., 2003; Blei, 2012) was deployed to further eviscerate the review framework, enabling the development of a future research agenda to bridge the PI digital divide (RQ2). *KNIME Analytics* was used to preprocess the text of the papers' titles, abstracts, keywords, and introductions, to run the LDA and perform the subsequent analysis.

Overall, by carefully examining and elucidating the PI-DT across diverse Value Chain Phases, this article paves the way for a more comprehensive discourse in: (i) Advancing Drug Discovery Research, (ii) Reinventing Strategies and Organizational Frameworks, (iii) Manufacturing Optimization (iv) Supply Chain and Logistics Optimization and (v) Developing Patient Centric Models as main future avenues for PI-DT practitioner's research. In the following sections, we will outline: (i) the Methodology, which is divided into two parts: a description of the systematic literature review and the topic modeling technique, (ii) a descriptive representation of the review framework, (iii) an interpretation of the relevant challenges and opportunities associated with PI-DT, and (iv) an in-depth discussion about the 16 topics selected in LDA and (v) representation of the future research agenda.

2. Methodology

In order to cover the above-cited research gaps, we have elaborated the existing literature based on a two-stage process. First, we employed a Systematic Literature Review (SLR), following established guidelines in the literature (Tranfield et al., 2003), aiming to develop a framework of relevant papers that encapsulates and synthesizes the subject matter to address our research question. Second, we employed a LDA topic analysis (Blei et al., 2003; Blei, 2012) to further refine the review framework, identifying the key emerging themes of this paper future research agenda.

2.1 Systematic Literature Review

2.1.1 Setting the SLR Procedural Conditions

SLR is a replicable research methodology designed to analyze the state-of-the-art of a specific research theme, supporting a specific research question (Sivarajah et al., 2017; Tranfield et al., 2003). This section outlines the systematic approach to emerge the review framework, ensuring a comprehensive and rigorous process.

The initial step involved clearly defining and establishing the research question, aiming to thoroughly examine the existing body of knowledge on the subject and provide reliable and robust results (Kitchenham & Charters, 2007; Tranfield et al., 2003). This methodological section aims to contribute to the understanding of PI-DT by focusing on the following research question:

- *RQ1: "What are the Major Challenges and Opportunities to Bridge the Pharmaceutical Industry Digital Divide?"*

To thoroughly analyze the existing body of knowledge on the subject and provide reliable and robust results, we applied the following procedural conditions (Delbufalo, 2012; Kitchenham & Charters, 2007; Sivarajah et al., 2017; Tranfield et al., 2003) :

- *Condition I* – We utilized three of the most widely recognized academic search engines: *Scopus, Science Direct, Google Scholar and PubMed*. These databases contain a vast collection of international journals, providing a reliable and comprehensive source of published information in our field of interest (Delbufalo, 2012; Sivarajah et al., 2017; Tranfield et al., 2003). The review was conducted from September 2022 until December 2024 through comprehensive searches of reputable academic search engines applying the following keywords: *"#Technology AND Pharma OR Pharmaceutical Industry AND Digital Transformation OR Industry 4.0 AND Literature Review OR #ValueChainPhase"*
- *Condition II* – To ensure relevance, we selected articles with pertinent keywords and reviewed only sections that explicitly referred to this article's objectives (David & Han, 2004; Sivarajah et al., 2017), considering only articles written in English and published

after 2009. The year 2009 was selected as a cut-off as preceding works were unlikely to yield relevant PI-DT perspectives;

- *Condition III* –Through an exploratory title, abstract, and keyword analysis, we excluded Outdated Papers, and un-peer-reviewed articles such as Book Chapters, Industry Reports, and not yet published materials such as Conference Papers, Proceedings Papers, and Recommendations.
- *Condition IV* – A wide range of studies encompassing qualitative, quantitative, surveys, mixed methods, and literature reviews with a specific emphasis on the PI-DT practitioner's perspective were included in the selection process. Therefore, Non-Pharma Papers and Technical and Scientific related papers dealing with topics such as Chemistry, Biochemistry, Biology, and Bioinformatics were disregarded among the selected peer-reviewed articles.
- *Condition V* – A rigorous quality control check was conducted via full-text reading to ensure a reproducible and effective searching process (Delbufalo, 2012; Sivarajah et al., 2017; Tranfield et al., 2003); which will be discussed in the following sub-section.

2.1.2 Conducting the SLR

By applying the above-mentioned conditions, we came out with 404 relevant articles. Initially, duplicate papers (n=45) were removed. In alignment with our research objectives, the exclusion criteria further involved non-pharma Industry relevant papers (n=11), Pharma Industry papers not addressing DT (n=79), Healthcare Papers (n=92) that lacked references to implications with PI *(Condition II).* Additionally, unpublished articles such as Book Chapters and Industry Reports (n=60), Conference Papers, Proceedings Papers, and Recommendations (n=76), Outdated Papers (n=23) *(Condition III)*, PI-Scientific studies (n=113), PI-DT practioner's studies (n=80): were omitted from our analysis as they did not contribute substantial information upon full-text review. Subsequently, an exploratory analysis of titles, abstracts, and keywords was undertaken to

eliminate non pertinent studies. After removing irrelevant articles, 70 papers were comprehensively analyzed and integrated into our research framework. Figure 1 summarizes the identification, screening, and inclusion of relevant articles in the review framework.

Figure 1

2.2 Text preprocessing and LDA topic modeling

The papers extracted from the review framework were analyzed and categorized within the Value Chain Phases (VCP). Subsequently, to identify and describe future research avenues to bridge the pharmaceutical industry digital divide (RQ2), this paper employs the latent Dirichlet allocation (LDA) topic modelling technique (Blei et al., 2003; Blei, 2012). The literature on innovation and technology includes several examples of the application of topic modelling (Arsenyan & Piepenbrink, 2023). For instance, LDA has been employed in literature reviews on Artificial Intelligence (Arsenyan & Piepenbrink, 2023), Energy Transition (Trivedi et al., 2023), and Disruptive Innovation (Hopp et al., 2018). Our literature review applies text preprocessing phases (Hickman et al., 2022), LDA, and the subsequent analysis of topic clusters using *KNIME Analytics* on specific sections of the 70 papers: the concatenation of titles, keywords, abstracts, and introductions. The following paragraphs describe this process.

2.1.1 Text preprocessing

The preprocessing is a common step in text mining techniques that prepares and transforms raw text extracted from the sources into a format suitable for subsequent analyses. In our paper, this phase encompasses all operations performed on the text to reduce the noise created by words or

symbols that do not add content and to minimize the vocabulary analyzed by topic modeling algorithms (Hickman et al., 2022).

Firstly, the text was cleaned of stop words such as "there", "are", "some", and so on, and stripped of punctuation. These words and symbols were removed because they do not contribute to the formation of topics. Secondly, the terms were stemmed using the Kuhlen stemming algorithm, which reduces words to their root form so that singular and plural variations, as well as different conjugations and declensions, yield the same term. Thirdly, all numeric terms were removed, the entire text was converted to lowercase, and words with fewer than four occurrences were eliminated. Fourthly, the authors performed a manual check on the remaining words. Through this process, words that had slipped through the automated stop-word removal (e.g., “sometimes” or “moreover”), common scientific-publication jargon not considered useful for topic modeling (e.g., “et al.”, “conclu*”, authors’ names), and other words representing, for instance, verbs were deleted. Finally, bi grams were created through an automated process that identifies repeated word pairs in the text. These were considered in the subsequent analyses as single terms, separated by a hyphen. The resulting bag of words was then deemed suitable for the next LDA phase.

2.2.2 LDA

Probabilistic topic models (e.g., LDA) are statistical methods that analyze words from preprocessed documents to uncover hidden thematic structures and their interconnections (Blei, 2012). LDA, the most well-known topic modelling technique, is a three-level hierarchical Bayesian model (Egger & Yu, 2022) based on the idea that documents contain multiple topics, each represented as a distribution over a fixed vocabulary. Firstly, the LDA estimator randomly selects a distribution over topics. Secondly, for each word in the documents (i) a topic is randomly chosen from the distribution over topics assigned in the first step, and (ii) a word is then randomly selected from the corresponding distribution over the vocabulary (Blei, 2012; Maier et al., 2021).

In our analysis, we employed a parallel LDA with approximation of Gibbs sampling (Newman et al. 2009). The LDA process requires the selection of three parameters. The α and β parameters were chosen according to the standard values accepted in top business journals (α = 0.1, β = 0.01) (Huang et al., 2018). Specifically, a higher β results in topics consisting of a larger number of words, whereas a higher α leads to greater topic diversity (Egger & Yu, 2022). The third parameter, the number of topics (k), was determined the analysis of the perplexity and, consequently, through direct observation of the LDA outputs for values ranging from k = 1 to k = 25. The final decision was to set k at 16, as this number of topics best represents the topics encapsulated within the sample of papers. These topics will be examined in the subsequent section dedicated to the future research agenda.

3. Systematic Literature Review results

This section presents a thorough analysis of the review framework, which includes 70 papers, focusing on the main PI-DT applications in each phase of the Value Chain, as well as the associated opportunities and challenges (RQ1).

3.1 Drug Discovery

The first drug's Value Chain Phase is *Drug Discovery (DD),* in which scientists conduct tests on molecular compounds to create new potential treatments (Mignani, Huber, Tomas, Rodrigues, & Majoral, 2016). This phase usually takes at least one year to be validated; once the promising drugs are identified, scientists collect information about potential effectiveness through experiments[7]. This phase also includes Preclinical Research activities, in which, before human testing, scientists check for potential side effects, following *Good Laboratory Practices* (Macleod et al., 2009). These guidelines set the requirements to achieve consistent information about dosage and toxicity levels and, on average, 1-2 years[8]. Undertaking DT in DD means creating an interrelated ecosystem based on data analyzed via advanced analytical tools, allowing scientists to cooperate across

[7] *https://www.fda.gov/*
[8] *https://www.fda.gov/*

different countries. One of the most disrupting digital technologies in DD is Artificial Intelligence (AI) (Hariry, Barenji, & Paradkar, 2022a; Patel & Shah, 2022; Raschka & Kaufman, 2020; Trenfield et al., 2022a). The review framework indicates AI as an enabler for DD process efficiency providing more accurate outcomes compared to conventional techniques (Lusci, Pollastri, & Baldi, 2013) and most importantly to potentially substitute CT empowering scientists to analyze millions of molecules with quicker and richer insights (Margulis et al., 2021; Raschka, 2019; Raschka & Kaufman, 2020; Turki & Taguchi, 2019). Nevertheless, AI deployment requires complex, highly skilled talent and high-quality data to train and develop accurate models (Hariry, Barenji, & Paradkar, 2022b). One of the most influential factors for PI-DT, indeed, is the ever-increasing availability of *"Big Data Analytics"*. Before DT, PI-organizations used to collect data as a result of self-made individual campaigns; while nowadays, thanks to the wide range of sources from which is possible to extract relevant information (e.g. health apps, genomic records, social media, medical imaging, wearables and more) the use of Big Data Analytics techniques promises substantial improvements for DD (Raghupathi & Raghupathi, 2014). However, issues linked to data privacy and fragmented formats, and varying levels of quality and consistency (Banner et al., 2021) challenge Big Data Analytics deployment. These problems might be partially solved by hiring Big Data Analytics Experts and shifting towards *Cloud Computing* (Al-Shura, Zabadi, Abughazaleh, & Alhadi, 2018; Schadt, Linderman, Sorenson, Lee, & Nolan, 2010; Sommer, 2013) as it offers a shortcut to achieve higher computational power and space at lower costs, and most of all, allows data to be collected, supported, and processed on third parties cyber-secured servers rather than personal servers (Yang & Tate, 2012). Cloud, under this perspective, is pivotal to implementing AI, as in terms of volume and variety, algorithms will be more likely to produce valuable information and facilitate drug scientists to cooperate in experiments, even across different locations worldwide (Hariry et al., 2022b). However, every system generally comes with its own protocols and formats, which can pose challenges of interoperability and data exchange. To ensure efficient collaboration and communication between these systems, data standardization

and interoperability must be established. Unfortunately, the absence of universally accepted standards and the presence of legacy systems create obstacles to integration and compatibility of information. Additionally, implementing these technologies necessitates substantial investments in infrastructure, equipment, reliable and secure internet connectivity, and, most of all, issues related to data protection. An interesting technology that retains significant potential for data protection is Blockchain (Trenfield et al., 2022a). Owned to its capability to secure information, together with AI applications, by gathering relevant knowledge such as Scientific Literature, patented industry applications or patient's data, can be a significant driver to new and counterintuitive experiment outcomes. However, since the PI is highly regulated, the use of Blockchain technology introduces new complexities and uncertainties regarding health authority alignment. Thus, there is a need for clarity and guidance on how it can be deployed. As for other technologies, Blockchain requires significant investments in cost infrastructures, such as high computing power, storage capabilities, and ongoing maintenance and support (Ertz, Centobelli, & Cerchione, 2022; Lima Jr, Novaes, Santos Jr, & Arias, 2021). This constitutes an important barrier for deployment. Authors (Trenfield et al., 2022a) emphasize IoT and Robots as one of the most critical DT technologies to enhance the DD Phase. These technologies are revolutionary because they can create an interoperable and proactive lab ecosystem by replacing manual, repetitive actions such as preparing samples for laboratory testing (Miozza et al., 2024), increasing worker's safety, as they would otherwise be engaged with toxic substances in person (Hariry et al., 2022b). The last fundamental technologies involved in the DD phase are 3D printing, AR and VR. On the one hand, 3D printing technologies enable researchers exploring new drug delivery methods and iterate on designs more efficiently through rapid prototyping of tissues and to-be drugs (Awad et al., 2018; Wu & He, 2020), on the other hand, AR and VR increase communication and collaborations around the world, by real-time sharing of information sharing and virtual-models (Miozza et al., 2024). This can lead to the discovery of breakthrough drug delivery systems and therapeutic approaches. However, being these technologies at early stage of development they

present several issues, such as meeting regulatory standards, cost infrastructures, and lack of skilled talent. Table 1 and 2 summarizes the above discussion addressing Opportunities and Barriers for PI-DT.

3.2 Clinical Trials

If a drug complies with preclinical trials, it goes to the second drug's Value Chain step (2) *Clinical trials (CT),* involving human testing. This phase is the most critical phase, accounting for average investments from 1.5 to 2.0 billion USD, 10 to 15 years to be completed, and usually low success rates (Banner et al., 2021; DiMasi, Grabowski, & Hansen, 2016; Paul et al., 2010). One of the most significant failures is the massive delays in finding eligible patients, such that 86% of trials do not adhere to enrolment deadlines (Harrer et al. 2019). AI and Big Data Analytics come at help, as patient suitability assessments can now be conducted by integrating analytics methods on patient-specific genomics, electronic medical records, and other sources of information such as handwritten documents, digital medical imagery, or socioeconomic data. Again, a crucial barrier is maintaining time-consistent data; a possible solution could be to engage patients as longitudinal partners, to achieve higher levels of data reliability (Harrer, Shah, Antony, & Hu, 2019b). In such a way, AI solutions can be adapted to read and classify this information, segmenting patients for trials opportunities based on their characteristics or eliminating those likely to be dropped out before even starting the trials (Denicolai & Previtali, 2020; Dowden & Munro, 2019; Harrer et al., 2019b; Willetts, Hollowell, Aslett, Holmes, & Doherty, 2018). Remote monitoring is becoming a common approach in CT thanks to the exponential usage of wearable devices (IoT), AR and VR (Harrer et al. 2019; Hariry, Barenji, and Paradkar 2022a). Several types of IoT devices can be adopted such as electroceuticals and smart contact lenses, tattoo sensors molecular sensors, smart pills, nano biosensors, and functionalized nanoparticles (Ahmed et al., 2019; Hadjinicolaou, Meffin, Maturana, Cloherty, & Ibbotson, 2021; Hariry et al., 2022a; Norton, Lee, Lee, & Lee, 2015; Shandilya et al., 2019) . These tools can be deployed together with AR and VR by clinicians to monitor and patient's outcomes to treatments in real-time (Miozza et al., 2024). Despite the

many beneficial areas that have been demonstrated in the Practitioner's Literature, the integration of Big Data Analytics with AI algorithms in CT is still hindered by some crucial challenges, such as companies relying on local servers and consequently decreasing their overall computing power or tool's capability to learn limited to a restricted amount of information, and data retaining different formats needing to be polished before deployment (Hariry et al., 2022b). By integrating Cloud Computing and IoT information, AI may enhance the accuracy and efficiency of CT results, upgrading data accessibility and enlarging analytical, learning, and training power (Al-Shura et al., 2018; Argiyantari, Simatupang, & Basri, 2020; Hariry et al., 2022b) However, the critical challenge remains that of data privacy and sharing concerns. Since 2007, FDA has required that all CT be registered in a public database called ClinicalTrials.gov[9]. However, a recent study found that over half of the registered trials did not disclose their results (Barenji, Akdag, Yet, & Oner, 2019). CT frequently faces issues related to the exchange, integration, and acquisition of data disclosure (Hariry et al., 2022b), this can be due to different geographies, operating systems, or security-related issues. Utilizing Blockchain technology to manage this information may support ensuring data traceability, empowering trust in regulatory adherence, data integrity, transparency, and secure sharing (Hariry et al., 2022b; Omar, Jayaraman, Salah, Yaqoob, & Ellahham, 2021). Additionally, Blockchain and AI can support ensuring the Patient recruitment process by anonymously matching registered patients with trial sites validating their eligibility to the protocol's criteria (Denicolai & Previtali, 2020; Horng et al., 2017; Omar et al., 2021). Furthermore, smart contracts can be designed to verify the legitimacy of sponsors and clinical sites (Omar et al., 2021). As for the DD phase, Blockchain deployment is hindered by high Infrastructure costs, storage capabilities, ongoing maintenance and support, and alignment to Regulatory Requirements. DT in CT can also involve the use of 3D printing technology. This new methodology has become increasingly popular recently (Norman et al., 2017). As for the DD phase, this technology can be used to create tissue models for drug testing, allowing scientists to

[9] *https://www.fda.gov/*

understand better how drugs interact with human tissues and potentially reducing the need for in vivo (animals and humans) testing. Table 1 and 2 summarizes the above discussion addressing Opportunities and Barriers for PI-DT.

3.3 Manufacturing

Once scientists have enough evidence that a potential treatment is safe and effective, they apply for the approval of the reference Regulatory Institution (e.g. FDA), which is responsible for validating the new drug within a certain period and deciding whether to approve it for market distribution. Most drugs currently available on the market should be harmless and applicable to large groups of people (Satwekar, …, & 2022, n.d.), therefore, ensuring the effectiveness of MK is of vital interest as it safeguards people's health and well-being (Sharma, Kaur, and Singh 2020). The industrial *Manufacturing* (3) of drugs is divided into the following activities*: Processing Raw Materials, Manufacturing, Extraction, Purification, and Packaging of The Final Product* (Sharma, Kaur, & Singh, 2020a) Each phase is subject to strict regulation and control, ensuring the drug's consistency and reliability. Drug production differs significantly from consumer goods; thus, strict *Quality-by-Design principles* apply (Satwekar et al., 2022; Yu et al., 2014) to achieve significant drug quality specifications. Accordingly, the critical question for PI-organizations is to identify how to leverage advanced technologies with the concepts of *Quality-by-Design* to ensure consistent and reproducible quality of drug products. In this context, Blockchain has the potential to support in complying with regulatory requirements by creating a permanent record of transactions and activities, complying with Good Manufacturing Practices (GMP), and enabling faster validation and control by health authorities (R. Y. Garankina, Zakharochkina, Samoshchenkova, Lebedeva, & Lebedev, n.d.). While undertaking DT in the context of MK, an important mention goes to the concept Smart Manufacturing, which aims to substitute manual, repetitive actions with automated systems linking plant equipment into an integrated digital environment, self-validating, self-improving, and even self-correcting production processes (Festa, Safraou, Cuomo, & Solima, 2018; Sharma et al., 2020a; Silva, Resende, Amorim, &

Borges, 2020a). The first DT technology involved is IoT as, through sensors, it empowers transmission and data integration across the different MK phases. By closely monitoring operations, IoT can regulate environmental conditions such as humidity, light, temperature, or radiation exposure (Argiyantari et al., 2020; Sharma, Kaur, & Singh, 2020b). The main challenge with IoT being widely deployed is the need for a uniform architecture to manage sensor-based data into valuable information. Again, a potential solution could be shifting towards Cloud Computing, as it ensures a large and continuous exchange of information, with AI-based predictions for the equipment load, machinery maintenance, or enhanced production quality control (Kulkov, 2021b; Saha, Rathore, Parida, & Rana, 2022). In addition, by using AR and VR employees can access training tutorials in real-time to better understand a procedure or even engage a remote expert across the globe to solve problems quickly and cost-effectively (Arief, Gustomo, Roestan, Putri, & Islamiaty, 2022; Burrichter, Chen, & Marco, 2022; Reinhardt, Oliveira, & Ring, 2020; Mahak Sharma, Sehrawat, Giannakis, & Dwivedi, 2023; Silva, Resende, Amorim, & Borges, 2020b). By combining these technologies with Robots, PI plants may account for different benefits, such as manual labor reduction, work safety increase, real-time visibility of materials, energy efficiency, and production workflow. However, as for many other DT technologies, Robots, AR and VR need high investments in infrastructure, specific talent and reliable and secure internet connectivity to be deployed (Miozza et al., 2024). Another crucial DT technology is Digital Twins (Chen et al., 2020b; Coito et al., 2022; Trenfield et al., 2022b). A Digital Twin represents a physical system in a virtual environment and the fundamental challenge is determining the link between the MK plant and a digitally designed space (Chen et al., 2020b). As stated above, IoT devices source large amounts of data. This information can be integrated in real-time with the virtual component and used to predict the operation's loads or material properties. To achieve such conditions, a pivotal role is again played by Cloud Computing as a storeroom and as a training platform backing operators to simulate tasks such as material tracking, serialization, or product quality assurance (Chen et al., 2020b). PI is on the verge of Digital Twins adoption, however, it is still in the infant

stages as current software and tools cannot build an exact digital copy of the MK plant (Sharma, Sehrawat, Luthra, Daim, & Bakry, 2022). Most of the current digital twin's applications in PI, indeed, can only transfer data from the physical plant to the virtual component, not returning the flow of information the other way around (Chen et al., 2020b; Sharma et al., 2022). Another interesting trend being experienced in PI-MK is the production of finished drugs from active ingredients and excipients through computer-controlled 3D printings (Norman et al., 2017). Compared to traditional PI processes, 3D printing retains distinctive benefits regarding product complexity, flexibility, and throughput. However, the adoption of 3D printing deployment is hindered by several barriers, such as Regulatory requirements specific to ensure the quality of products, intellectual property concerns to allow for easy replication, and limitations regarding the materials that can be used (Wu & He, 2020). Overall, adopting 3D printing technology in the PI requires significant investment and expertise to overcome these challenges and realize their full potential benefits. Table 1 and 2 summarizes the above discussion addressing Opportunities and Barriers for PI-DT.

3.4 Supply Chain

The PI-SC comprises Manufacturers, Retailers, Hospitals, Logistics companies, Pharmacies, and Consumers. It is common in PI-SC to encounter problems such as a lack of transparency, difficulty in tracking products, lack of trust, and shipment of expired products (Zakari et al., 2022) therefore it is vital to maintain accurate information (R. Garankina, …, & 2018, n.d.; Kordestani et al., 2023; Sharma et al., 2020a; Zakari et al., 2022). One of the most impactful technologies in the digitalization of PI-SC is Blockchain (Ghadge, Bourlakis, Kamble, & Seuring, 2022; Hosseini Bamakan, Ghasemzadeh Moghaddam, & Dehghan Manshadi, 2021; Zulfiqar, Lakho, Nizam, & Fayyaz, 2022), as it allows secure and quick transactions among different stakeholders, which can disclose and revise detailed and accurate data. The literature has addressed Blockchain to enhance Counterfeit drug prevention, Product Distribution, Safety and security of drugs, Traceability, Data Governance, and Data Quality (Alharthi, Cerotti, & Far, 2020; Junaid, Zhang, Cao, & Luqman,

2023; Zakari et al., 2022). A crucial challenge for PI-SC is managing and monitoring the Cold Chain effectively to ensure that drugs are transported at the appropriate temperature maintaining high product quality standards (Nguyen, Lamouri, Pellerin, Tamayo, & Lekens, 2022; Saha et al., 2022; Sharma et al., 2022). Given the unique biological conditions required for handling drugs, monitoring environmental conditions during transportation is crucial. This is where IoT and blockchain technologies come in. Integrating IoT and blockchain technologies can significantly improve coordination and communication in the PI cold chain (Hosseini Bamakan et al., 2021)(Nguyen et al., 2022). IoT devices can detect environmental parameters such as temperature and humidity during transportation by leveraging sensors and automatically regulating them to ensure a safe and secure cold chain. This real-time information can then be transmitted and shared across the SC using IoT and AI, ultimately leading to better decision-making and improved overall efficiency in terms of DT. In addition, Blockchain technology can address the issue of counterfeit medicines and minimize PI waste, ensuring that all stakeholders involved in the cold chain are aware of the products' condition and the progress of the SC (Ding et al., 2020; Kordestani et al., 2023; Shamsuzzoha, Ndzibah, & Kettunen, 2020; Shetty et al., 2022; Zoughalian, Marchang, & Ghita, 2022) This transparency can help to build trust between the parties involved and promote better decision-making. In summary, integrating IoT, AR, VR and Blockchain technologies in the cold chain can provide transparency, improve coordination and communication, and ultimately lead to better decision-making, efficiency, virtual visualization of logistics processes and effectiveness in the PI-SC. Another critical area where DT impacts SC is Warehousing and Inventory Management (Shamsuzzoha et al., 2020; Sharma et al., 2022). Pharma companies have storage and warehouses worldwide, and this activity is one of the most expensive in the PI-SC. IoT, AR, VR, Robots and AI enhance the effectiveness and accuracy of warehouse processes by adjusting inventory quantities, proposing strategic decisions, automating tasks reducing manual labor and increasing safety of workers. SC’s decision-makers can be further supported for operations from raw material procurement to end-patient delivery by AI (Kumar Detwal et al.,

2023). Generally, Large Manufacturers have been increasingly using AI for Raw Materials Procurement; these kinds of software can assist decision-makers in allocating manual labor and shortcomings in the SCs and searching for suppliers, but a more successful application is needed (Kulkov, 2021b; Rathi, Majumdar, & Chatterjee, 2024) owned to the lack of consistent data able to feed and train more consistent algorithms. Table 1 and 2 summarizes the above discussion addressing Opportunities and Barriers for PI-DT.

3.5 Market Access

The next step of the Pharma drug's Value Chain Phase is (5) Market Access (MA). The DT of this phase aims to deliver personalized information to segmented groups of patients built on their behavioral and health features (Ginsburg & Willard, 2009; Sigman, 2018; Trenfield et al., 2022a). Undoubtedly, the development and expansion of the Internet play a crucial role in this Value Chain Phase. Based on the study of data such as click-on-ads, social media engagement, smartphone apps, or personal health information such as genomics, PI-organizations can reconstruct an insightful patient journey and user persona to be exploited to engage with Personalized Medicine. In a few words, Personalized Medicine involves considering an individual's distinct genetic, environmental, and lifestyle factors to establish customized strategies for prevention, diagnosis, and treatment (Ginsburg & Willard, 2009; Sigman, 2018; Trenfield et al., 2022a). In this context, the first technology worth to be mentioned is Blockchain as it can be used as a decentralized storage of genomic data and for Intellectual Property rights usage. In this way, scientists can access trustable and transparent and trustable data to pursue new Drug Discovery Projects, while patent owners can easily license and track their self-developed knowledge. Moreover, since the ever-increasing availability of data, by collecting relevant information onto Cloud to train algorithms, the use of AI can bring numerous benefits and opportunities (Kulkov, 2021a; R. Liu et al., 2021): (1) *Market forecasting*, to predict the demand for a particular drug, which allows companies to adjust their production quantities accordingly; (2) *Marketing Channels assessment*, to help companies understand which channels are most effective in reaching their target audience; (3)

Individual patient plans, to develop personalized plans for patient retention, which can lead to patient loyalty and reduce the risk of patients switching to competitor products; and finally (4) *Sales forces empowerment*, as AI together with AR and VR (Miozza et al., 2024) can provide sales teams with insights, real-time functioning demonstrations and recommendations, which can help them to create more targeted and personalized campaigns. Another interesting technology facilitating MA phase is 3D printing. 3D printing can produce on-demand optimal drug treatments and dosages for patients based on their unique genetic profiles (Aquino, Barile, Grasso, & Saviano, 2018; Norman et al., 2017; Ramos, Daim, Gaats, Hutmacher, & Hackenberger, 2022). This could reduce adverse drug reactions, waste, costs and increase treatment efficacy. Although many companies are currently aware of 3D printing's benefits, its impact is still limited as health agencies have not yet comprehensively regulated 3D printing. Concerns about the safety and responsibility for adverse event, printer defects or MK malfunctions still a remain. Another interesting technology that retains a significant impact in MA is Cybersecurity, which is at the core of Big Data Analytics Management, preventing and protecting the system's integration and sharing. The information treated by PI-organizations is very sensitive (Del & Solfa, 2022; Raghupathi & Raghupathi, 2014) and if threatened or altered, they can be used for medical or financial frauds or hack attacks. Potential defense may rise from cooperation of multiple actors involved (Mantle et al., 2019) in the Value Chain such as Regulators, organizations both from PI and Big Tech giants converging their effort toward unified cybersecurity principles and practices, still there's seem difficulty to project forces to this joint effort (Del & Solfa, 2022). Table 1 and 2 summarizes the above discussion addressing Opportunities and Barriers for PI-DT.

Table 1

Table 2

4.LDA results

After a thorough analysis and review of our Framework, we applied the LDA topic modeling technique to identify the major themes for a future research agenda in the context of the Digital Transformation of the Pharmaceutical Industry (PI-DT). In general, the word cloud (Figure 4) provides a visual representation of the highest-weight content words extracted from our sample of papers, processed, and used in the topic modeling algorithm. In particular, the size of each word's font reflects its weight. We segmented our review framework into 16 topics with their respective keywords to answer the RQ2: *"What are the future Practice Research Avenues to Bridge the Pharmaceutical Industry Digital Divide?"*. Accordingly, these topics were carefully examined and subsequently clustered into relevant themes to develop a research agenda bridging the digital divide in the pharmaceutical industry in practice looking at single digital technologies to create a relevant future research agenda. In the context of our analysis, the integration of digital technologies emerged to transform the existence and physical co-presence of patients, researchers, and PI operators, considering five major clusters: (i) Advancing Drug Discovery Research, (ii) Reinventing Strategies and Organizational Frameworks, (iii) Manufacturing Optimization (iv) Supply Chain and Logistics Optimization and (v) Developing Patient Centric Models. Subsequently, we will present the interpretation of the clustered emerged topics, along with the underlying logic of their grouping in the context of the PI-DT phenomenon.

Figure 2

4.1 Advancing Drug Discovery Research

The first cluster to emerge from the Topic Modeling analysis focuses on Advancing Drug Discovery Research. Central to this transformation is the growing reliance on AI computational tools and large-scale data analysis, which empower scientists to support the identification of potential novel drug candidates and optimizing discovery workflows. Furthermore, advancements in deep learning and molecular modeling are enhancing the predictive accuracy of molecular properties, such as solubility, by employing sophisticated neural networks. These technological innovations are complemented by refined research methodologies that continue to drive scientific progress, reinforcing the critical role of interdisciplinary approaches in advancing patient treatment. Within their managerial strategies, interdisciplinary collaboration between life sciences, computer sciences and engineering should also be a focal point. This not only enhances the rate at which scientific exploration moves forward but also allows for the creation of solid models based on diverse views. In addition, integrating cloud computing tools enables data to be shared and high-performance computing to be conducted in real time, which is essential for the training of intricate algorithms. Table 3 presents the keywords identified through Topic Modeling analysis, along with the relevant papers included in each topic and a brief description of the underlying rationale for grouping the topics within the same cluster.

Table 3

4.2 Reinventing Strategies and Organizational Frameworks

The second cluster to emerge from the Topic Modeling analysis focuses on reinventing Strategies and organizational Frameworks. The analyzed topics highlight the transformative impact of digital technologies and innovative strategies on organizational structures and PI practices. These advancements span various dimensions, including the adoption of digital frameworks, fostering innovation and sustainable development through novel business models, and leveraging technology for effective management and collaboration. One key theme is to engage the workforce in driving acceptance and adoption of the integration of cutting-edge DT technologies. Innovations in this field can be supported by augmented and virtual reality, showcasing the potential of digital solutions to optimize organizational processes and overall engagement. In conclusion, these advancements not only redefine organizational and operational paradigms but also highlight the potential for greater efficiency, flexibility, and innovation in organizational settings. Table 4 presents the keywords identified through Topic Modeling analysis, along with the relevant papers included in each topic and a brief description of the underlying rationale for grouping the topics within the same cluster.

Table 4

4.3 Manufacturing Optimization

The third cluster to emerge from the Topic Modeling analysis focuses on Manufacturing Optimization. Central to this transformation is the adoption of tools such as cloud computing, lean principles, and Industry 4.0 technologies, including 3D printing, automation, and data analytics leading to smart manufacturing paradigms. These digital technologies are reshaping manufacturing processes by streamlining production, reducing costs, and enabling data-driven decision-making. The implementation of 3D printing, for instance, plays a pivotal role in

prototyping during drug development, facilitating faster and more efficient testing phases. Together, these technologies are poised to accelerate the entire lifecycle of drug development and quality production, from initial design to market delivery. Beyond efficiency, these advancements also enhance precision and safety within manufacturing operations, crucial in the Pharmaceutical industry. Table 5 presents the keywords identified through Topic Modeling analysis, along with the relevant papers included in each topic and a brief description of the underlying rationale for grouping the topics within the same cluster.

Table 5

4.4 Supply Chain Optimization

The fourth cluster to emerge from the Topic Modeling analysis focuses on Supply Chain Optimization. This cluster focuses on efficienting processes, emphasizing real time control, transparency, and sustainability as core elements. In particular, this topic highlights that technologies and strategies that enhance supply chain logistics, address disruptions, and build resilience in response to challenges related to global supply chains. This cluster emphasizes the adoption of advanced technologies such as Blockchain to address vulnerabilities in digital networks, Data-driven solutions leveraging computational tools to optimize resilience, sustainability, and cold chain performance. Table 6 presents the keywords identified through Topic Modeling analysis, along with the relevant papers included in each topic and a brief description of the underlying rationale for grouping the topics within the same cluster.

Table 6

4.5 Developing Patient Centric Models

The first cluster to emerge from the Topic Modeling analysis focuses on Advancing Drug Discovery Research. Central to this shift is the integration of personalized medicine, where genetic and clinical data inform precision therapies and risk assessments tailored to individual patients. This approach emphasizes not only the customization of treatments but also the broader role of genomics and data-driven insights in enhancing clinical care. The underlying concept of this cluster is treating each patient as a unique individual who utilizes their genetic characteristics along with medical history and ailments to formulate a customized treatment plan. Data analytics, together with machine learning, should be implemented to provide each patient with tailored therapies and assign them risk. A significant driver of this transformation is the application of data analytics and machine learning, which enable more accurate and timely clinical decision-making. Another key strategy is improving patient engagement through the use of AR and VR technologies. Such tools are immersive, enabling patients to understand their treatment better and make decisions right from the start. Finally, the need to protect patient information remains the most unavoidable. Cyber security need to be stringent in guarding against illegal access and data leakage. There should be public-private actors working together in a certain joint approach towards basic cybersecurity standards and protocols. Having professionals from pharmaceutical and other big tech companies would help fill knowledge divides and strengthen the digital boundaries. Security measures have to be checked and changed routinely as new threats continue to emerge. Table 7 presents the keywords identified through Topic Modeling analysis, along with the relevant papers included in each topic and a brief description of the underlying rationale for grouping the topics within the same cluster.

Table 7

5.PI-DT Research Agenda

Our study has shed light on the intricate dynamics of Digital Transformation (DT) in the Pharmaceutical Industry (PI), unveiling a landscape teeming with opportunities yet fraught with challenges. Moving forward, concerted efforts from various stakeholders—regulators, pharmaceutical companies, technology providers, and healthcare professionals—will be imperative to cultivate an ecosystem conducive to innovation and substantial advancements in patient outcomes. Table 8 summarizes the future practice avenues we have identified to enhance the deployment of PI-DT, based on the above analysis.

Table 8

Our research dives into the gaps that seems to emerge from the research what has been published so far. It extends the understanding of the diverse aspects of PI DT in very practical terms. The use of digital technologies suggests the application of different disciplines and holistic frameworks that include all parts of the pharmaceutical value chain. In practice, this research agenda is instrumental for managers to establish business priorities, pursuing the technological changes that are required to overcome existing gaps and harness digital transformation effectively. As we stand at the threshold of a new era in PI, the insights gleaned from this paper serve as a guiding light and a clarion call to action for all those vested in the trajectory of healthcare. Our research

agenda offers a window into the real-world applications of digital technologies and their efficacy in addressing the dynamic needs of the PI, revealing strong literature-based evidence on the strategic relevance of digital solutions. Multiple digital technologies were lauded for their potential to streamline operations, enhance decision-making, and foster innovation. However, despite the recognized potential, the review framework highlighted notable gaps in the current practice landscape emeriging different research gaps with respect of individual digital technologies. These gaps underscore the industry's efforts in harnessing the full power of digital transformation. In particular, our research agenda evidences the need for more sophisticated, tailored, and personalized approaches to be seamlessly integrated into existing workflows, allowing for actionable insights to accelerate the development of new drugs and therapies. It involves creating immersive, interactive environments that can facilitate remote collaboration, hands-on training, and real-time monitoring of drug effects on patients. The insights from our analysis not only validate the theoretical underpinnings of our study but also highlight the practical challenges and opportunities that lie ahead. As the PI continues to navigate the complex journey of DT, a balanced approach is needed—one that embraces the disruptive potential of emerging technologies while addressing the practical considerations of implementation, user adoption, and regulatory compliance. This research underscores the critical importance of adopting a holistic and forward-thinking approach to PI-DT, leveraging insights from current applications, opportunities, and obstacles of DT technologies. Furthermore, by exploring the transformative potential of integrating digital technologies, we underscore the pivotal role of DT in laying the foundation for further scholarly exploration and discourse in this swiftly evolving domain within academia and practice.

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Table 1. Opportunities

Technology	Drug Discovery	Clinical Trials	Manufacturing	Supply Chain	Market Access
AI	• Support discovering new drug candidates • Rare Disease Treatment • Potentially substitute clinical trials phase	• Predict patient and site's suitability for trials • Reduce delay of trials • Reduce individual transportations for participating at trials	• Predict equipment failures • Enhanced Product Quality Control • Predict Production quantities • Optimize and Adjust Production Quantities through real time demand forecasting	• Predict risks linked to suppliers • Increase the accuracy of warehouse processes by adjusting inventory quantities, proposing strategic decisions, and automating material Procurement • Assist decision makers in allocating manual labor and shortcomings	• Personalized Medicine • Enhance patient outcomes by analyzing patient's genomics • Market forecasting • Salesmen enforcement
Cloud computing	• Real-Time Information sharing between Stakeholders, across and within a firm's systems • Cross Geography Activities • Facilitate data standardization • High computing power to train and deploy AI algorithms • Enhanced Cybersecurity	• Real-Time Information sharing between Stakeholders, across and within a firm's systems • Cross Geography Activities • Facilitate data standardization • High computing power to train and deploy AI algorithms • Enhanced Cybersecurity	• Real-Time Information sharing between Stakeholders, across and within a firm's systems • Cross Geography Activities • Facilitate data standardization • High computing power to train and deploy AI algorithms • Enhanced Cybersecurity	• Real-Time Information sharing between Stakeholders, across and within a firm's systems • Cross Geography Activities • Facilitate data standardization • High computing power to train and deploy AI algorithms • Enhanced Cybersecurity	• Personalized Medicine • Real-Time Information sharing between Stakeholders, across and within a firm's systems • Cross Geography Activities • Facilitate data standardization • High computing power to train and deploy AI algorithms • Enhanced Cybersecurity
Blockchain	• Enhance Data mining and Data Analysis by securing information • Ensure trustable Data Exchange between stakeholders • Ensure Data Privacy • Facilitate deployment of AI by ensuring a transparent collection of relevant Literature and patented applications	• Trustable information exchange with health authorities • Trial's candidate validation • Smart Contracts to validate the site's reliability • Enhance Data mining and Data Analysis by securing information • Ensure trustable Data Exchange between stakeholders • Ensure Data Privacy • Facilitate deployment of AI by ensuring a transparent collection of relevant Literature and patented applications	• Compliance with Good Manufacturing Practices • Ensure trustable Data Exchange between stakeholders in material's procurement phase • Facilitate deployment of AI	• Improve transparency, tracking products, trust, and shipment of expired products • Prevent Counterfeited Drugs circulation • Enhance Environmental footprint tracking • Cold Chain Monitoring • Smart Contracts to validate stakeholder's reliability • Enhance Data mining and Data Analysis securing information	• Decentralized storage of genomic and marketing data • Intellectual Property rights Protection • Personalized Medicine
IoT	• Interactive Lab Ecosystems across different geographies • Reduction of manual labor and repetitive activities in labs, such as preparing samples	• Remote monitoring of candidate's reactions to treatments	• Real Time Monitoring • Transmission and integration of data • regulate and control environmental conditions during production • Energy Efficiency Control	• Cold Chain Monitoring • Real time monitoring • Product's Quality • Enhanced Warehousing and Inventory Management	• Personalized Medicine • Patient Monitoring through wearables and health apps
3D printings	• Create tissue models for drug testing, reducing the need for animal testing • Rapid prototyping of drug candidates	• Create tissue models for drug testing, reducing the need for human testing • Rapid prototyping of drug candidates	• Rapid Prototyping • On-demand production • Lean and Flexible Production lines	Not deployed	• Personalized Medicine • on-demand optimal drug treatments and dosages • improve accessibility to drugs • timesaving, space-saving, and patient-friendly alternative to conventional PI compounding
Big Data Analytics	• Support discovering new drug candidates • Interactive ecosystems across different geographies • Analyze different sources of data	• Support discovering new drug candidates • Interactive ecosystems across different geographies Analyze different sources of data	• Interactive ecosystems across different geographies • Analyze different sources of data	• Interactive ecosystems across different geographies • Analyze different sources of data	• Personalized Medicine • Develop User Persona buying patterns • Empowerment Salesforce • Interactive ecosystems across different geographies • Analyze different sources of data
AR and VR	• Real-time sharing of information with scientists around the world	• Real-time monitoring of drug's effects on patients • Reduce Manual Work	• Real-Time Monitoring • Manual labor reduction	• Virtual Visualization of logistics • Reduce Manual Work	• Empower salesforce with real time demonstrations and descriptions of drug's insights

	• Reduce Manual Work • Increase the Safety of workers	• Increase the Safety of workers	• Real-world objects interaction • displaying information and knowledge to support the assembly process • Virtual training • On the field Simulation and Prototypings	• Increase the Safety of workers	
Cybersecurity	• Protect Genomics and Research Data	• Protect CT data	• Protect MK and Process data	• Protect SC data	• Protect Genomics and Patient Data
Digital Twins	Not deployed	Not deployed	• Predict equipment loads and failures • Real-time Simulation and Prototyping to reduce costs • to simulate tasks such as material tracking, serialization, or product quality assurance; • Hands-on Training	Not deployed	Not deployed
Robots	• Reduce Manual Work • Increase the Safety of workers	• Reduce Manual Work • Increase the Safety of workers	• Reduce Manual Work • Increase the Safety of workers	• Inventory and Warehousing Management enhancement • Reduce Manual Work • Increase the Safety of workers	Not deployed

Table 2. Challenges

Technology	**Drug Discovery**	**Clinical Trials**	**Manufacturing**	**Supply Chain**	**Market Access**
AI	• Data Privacy • Different variety of data sources • Need of high Computing Power to train Algorithms • Highly skilled talent for data mining • Need for multidisciplinary figures	• Keeping Time consistent data • Local servers • Data Access and Privacy Issues • Data Privacy • Different variety of data sources • Need of high Computing Power to train Algorithms • Highly skilled talent for data mining • Need for multidisciplinary figures	• Different formats of data • Interoperability across systems • Keeping Time consistent data • Local servers • Data Privacy • Different variety of data sources • Need of high Computing Power to train Algorithms • Highly skilled talent for data mining • Need for multidisciplinary figures	• Different formats of data • Interoperability across systems • Keeping Time consistent data • Local servers • Data Privacy • Different variety of data sources • Need of high Computing Power to train Algorithms • Highly skilled talent for data mining • Need for multidisciplinary figures	• Data Privacy • Different variety of data sources • Need of high Computing Power to train Algorithms • Highly skilled talent for data mining • Need for multidisciplinary figures
Cloud computing	• Legacy Storage systems • Need to create interoperable data formats • Infrastructure costs • Reliable and secure Internet connectivity	• Different formats of data • Interoperability across systems • Keeping Time consistent data • Local servers • Data Privacy • Different variety of data sources • Need of high Computing Power to train Algorithms • Highly skilled talent for data mining • Need for multidisciplinary figures	• Different formats of data • Interoperability across systems • Keeping Time consistent data • Local servers • Data Privacy • Different variety of data sources • Need of high Computing Power to train Algorithms • Highly skilled talent for data mining Need for multidisciplinary figures	• Different formats of data • Interoperability across systems • Keeping Time consistent data • Local servers • Data Privacy • Different variety of data sources • Need of high Computing Power to train Algorithms • Highly skilled talent for data mining Need for multidisciplinary figures	• Different formats of data • Interoperability across systems • Keeping Time consistent data • Local servers • Data Privacy • Different variety of data sources • Need of high Computing Power to train Algorithms • Highly skilled talent for data mining • Need for multidisciplinary figures
Blockchain	• Infrastructure costs	• Infrastructure costs	• Infrastructure costs	• Infrastructure costs	• Infrastructure costs

	• Stakeholder's acceptance and adoption • Storage capabilities • Aligning to Regulatory Requirements • Require greater computational capabilities to provide better security, immutability, and increased transparency • Lack of Blockchain expertise • Data formats alignment • Interoperability across different Blockchain systems	• Stakeholder's acceptance and adoption • Storage capabilities • Aligning to Regulatory Requirements • Require greater computational capabilities to provide better security, immutability, and increased transparency • Lack of Blockchain expertise • Data formats alignment • Interoperability across different Blockchain systems	• Stakeholder's acceptance and adoption • Storage capabilities • Aligning to Regulatory Requirements • Require greater computational capabilities to provide better security, immutability, and increased transparency • Lack of Blockchain expertise • Data formats alignment • Interoperability across different Blockchain systems	• Stakeholder's acceptance and adoption • Storage capabilities • Aligning to Regulatory Requirements • Require greater computational capabilities to provide better security, immutability, and increased transparency • Lack of Blockchain expertise • Data formats alignment • Interoperability across different Blockchain systems	• Stakeholder's acceptance and adoption • Storage capabilities • Aligning to Regulatory Requirements • Require greater computational capabilities to provide better security, immutability, and increased transparency • Lack of Blockchain expertise • Data formats alignment • Interoperability across different Blockchain systems
IoT	• Ensuring Data security • Different formats of data sources • Reliable and secure Internet Connectivity • Need for a uniform architecture to manage sensor-based data into valuable information	• Ensuring Data security • Different formats of data sources • Reliable and secure Internet Connectivity • Need for a uniform architecture to manage sensor-based data into valuable information	• Ensuring Data security • Different formats of data sources • Reliable and secure Internet Connectivity • Need for a uniform architecture to manage sensor-based data into valuable information	• Ensuring Data security • Different formats of data sources • Reliable and secure Internet Connectivity • Need for a uniform architecture to manage sensor-based data into valuable information	• Ensuring Data security • Different formats of data sources • Reliable and secure Internet Connectivity • Need for a uniform architecture to manage sensor-based data into valuable information
3D printings	• Need for specific talent • Regulatory acceptance • Cost infrastructures	• Need for specific talent • Regulatory acceptance • Cost infrastructures	• Regulatory Standards and Protocols • Lack of expertise • Intellectual property • Material's limitations • Need for specific talent • Regulatory acceptance • Cost infrastructures	Not Deployed	• Regulatory Standards and Protocols • Lack of expertise • Intellectual property • Material's limitations • Need for specific talent • Regulatory acceptance • Cost infrastructures
Big Data Analytics	• Different variety of data sources • Lack of consistent data • Need of high Computing Power to train Algorithms • Highly skilled talent for data mining • Need for multidisciplinary figures • Infrastructure costs • Regulatory alignment for data disclosure and privacy • Data acquirement	• Different variety of data sources • Lack of consistent data • Need of high Computing Power to train Algorithms • Highly skilled talent for data mining • Need for multidisciplinary figures • Infrastructure costs • Regulatory alignment for data disclosure and privacy • Data acquirement	• Different variety of data sources • Lack of consistent data • Need of high Computing Power to train Algorithms • Highly skilled talent for data mining • Need for multidisciplinary figures • Infrastructure costs • Regulatory alignment for data disclosure and privacy • Data acquirement	• Different variety of data sources • Lack of consistent data • Need of high Computing Power to train Algorithms • Highly skilled talent for data mining • Need for multidisciplinary figures • Infrastructure costs • Regulatory alignment for data disclosure and privacy • Data acquirement	• Different variety of data sources • Lack of consistent data • Need of high Computing Power to train Algorithms • Highly skilled talent for data mining • Need for multidisciplinary figures • Infrastructure costs • Regulatory alignment for data disclosure and privacy • Data acquirement
AR and VR	• Need for specific talent • Cost infrastructures • Reliable and secure Internet Connectivity • Different variety of data sources • Need for a uniform architecture to manage sensor-based data into valuable information	• Need for specific talent • Cost infrastructures • Reliable and secure Internet Connectivity • Different variety of data sources • Need for a uniform architecture to manage sensor-based data into valuable information	• Need for specific talent • Cost infrastructures • Reliable and secure Internet Connectivity • Different variety of data sources • Need for a uniform architecture to manage sensor-based data into valuable information	• Need for specific talent • Cost infrastructures • Reliable and secure Internet Connectivity • Different variety of data sources • Need for a uniform architecture to manage sensor-based data into valuable information	• Patient's and Salesforce acceptance • Need for specific talent • Cost infrastructures • Reliable and secure Internet Connectivity • Different variety of data sources • Need for a uniform architecture to manage sensor-based data into valuable information
Cybersecurity	• Lack of uniform effort and engagement	• Lack of uniform effort and engagement from multiple	• (Lack of uniform effort and engagement from	• Lack of uniform effort and engagement from multiple	• Lack of uniform effort and engagement from multiple

	from multiple stakeholders to protect patient data • Hack attacks	stakeholders to protect patient data • Hack attacks	multiple stakeholders to protect patient data • Hack attacks	stakeholders to protect patient data • Hack attacks	stakeholders to protect patient data • Hack attacks
Digital Twins	Not Deployed	Not Deployed	• Difficulty in exchanging data across systems • Linking the plant and a digitally designed space	Not Deployed	Not Deployed
Robots	• Need for specific talent • Cost infrastructures • Reliable and secure Internet Connectivity • Different variety of data sources • Need for a uniform architecture to manage sensor-based data into valuable information	• Need for specific talent • Cost infrastructures • Reliable and secure Internet Connectivity • Different variety of data sources • Need for a uniform architecture to manage sensor-based data into valuable information	• Need for specific talent • Cost infrastructures • Reliable and secure Internet Connectivity • Different variety of data sources • Need for a uniform architecture to manage sensor-based data into valuable information	• Need for specific talent • Cost infrastructures • Reliable and secure Internet Connectivity • Different variety of data sources • Need for a uniform architecture to manage sensor-based data into valuable information	Not Deployed

Table 3 – Topic Clustering for Advancing Drug Discovery Research

Topic_ID	Papers Included	Keywords	Description
Topic_11	(Horng et al., 2017)(Willetts et al., 2018)(Manvinder Sharma, Sharma, Gupta, & Pandey, 2023)	data, method, patient, clinical, decision, health, set, activity, support, model, system, detection, sign, vital, text, machine-learn, trigger, physical, collect, detect	These topics highlight the application of AI tools such as machine learning in drug discovery research, particularly for identifying new potential drug candidates, examining the use of deep learning and molecular modeling in predicting the properties of molecules for therapeutic purposes.
Topic_2	(Rathi et al., 2024)(DiMasi et al., 2016)(Dowden & Munro, 2019)(Harrer et al., 2019b)(Mignani et al., 2016)(Paul et al., 2010)	cost, rd, drug, increase, industry, data, pharmaceutical, development, result, innovation, patent, productivity, medicines, pharmaceutical-industry, product, time, estimate, innovative, approval, market	
Topic_4	(Lusci et al., 2013)(Margulis et al., 2021)(Raschka & Kaufman, 2020)(Turki & Taguchi, 2019)	drug, approach, learn, machine-learn, method, prediction, deep, drug-discovery, data, predict, compound, molecular, apply, molecules, chemical, discovery, result, candidates, ml, propose	

Table 4 – Topic Clustering for Reinventing Strategies and Organizational Frameworks

Topic_ID	Papers Included	Keywords	Description
Topic_0	(Burrichter et al., 2022)(Kulkov, 2021b)(Mak & Pichika, 2019)(Trenfield et al., 2022b)	management, technology, ai, development, resource, pharma, process, human, company, data, reality, artificial-intelligence, virtual, industry, sustainable, use, research, augment, proces, efficiency	These topics focus on digital transformation frameworks and novel organizational strategies for sustainable development. Multiple technologies are highlighted, particularly AI, Data analytics, virtual reality and cloud computing, which can be deployed in different contexts such as for HRM or Market forecasting, allowing for successful deployment and streamlining of processes.
Topic_1	(Banner et al., 2021)(Raghupathi & Raghupathi, 2014)(Schadt et al., 2010)	data, analytic, application, algorithm, set, sector, current, computational, result, analysis, technology, biopharmaceutical, generate, identify, challenges, life, increase, paper, future, environment	
Topic_13	(Satwekar et al., 2024)(Festa et al., 2018)(Satwekar et al., 2022)	dt, proces, digital, research, management, busines, technology, innovation, digital-transformation, theoretical, framework, people, organization, design, study, practical, approach, biopharmaceutical-company, successful, understand	
Topic_8	(Al-Shura et al., 2018)(Arief et al., 2022)(Q. Liu, Zhao, Kamioka, & Nakamura, 2021)(Ramos et al., 2022)(R. Garankina et al., n.d.)	pharmaceutical-industry, busines, research, company, study, industry, cloud-compute, market, technology, pharma, model, implementation, level, core, current, result, cost, factor, conduct, significant	

Table 5 – Topic Clustering for Manufacturing Optimization

Topic_ID	Papers Included	Keywords	Description
Topic_14	(Coito et al., 2022)(Del & Solfa, 2022)(Mantle et al., 2019)	digital, manufacture, risk, system, security, operation, cyber, production, laboratory, physical, biological, automation, impact, emerg, information, product, process, model, threat, workflow	These topics highlight key drivers related to technological advancements in pharmaceutical manufacturing operations. Particularly, this cluster highlights the significance of

Topic_7	(Awad et al., 2018)(Norman et al., 2017)(Patel & Shah, 2022)(Yu et al., 2014)	drug, product, technology, 3d, quality, manufacture, print, proces, pharmaceutical, design, recent, control, paper, process, review, development, create, pharmaceutical-industry, potential, tool	ensuring drug quality through smart manufacturing processes which involve deploying technologies such as cybersecurity, 3D printings, IoT.
Topic_9	(Chen et al., 2020a)(Reinhardt et al., 2020)(Sharma et al., 2020b)(Silva et al., 2020b)(Barenji et al., 2019)(Sharma et al., 2022)	industry, technology, adoption, sector, pharmaceutical, manufacture, production, smart, framework, system, internet, industrial, concept, firm, pharmaceutical-manufacture, benefit, application, revolution, implementation, iot	

Table 6 – Topic Clustering for Supply Chain and Logistics Optimization

Topic_ID	Papers Included	Keywords	Description
Topic_3	(Kumar Detwal et al., 2023)(Lima Jr et al., 2021)(Junaid et al., 2023)(Shamsuzzoha et al., 2020)	supp-chain, system, pharma, pharmaceutical, sustainable, product, logistic, research, information, improve, services, impact, company, health, performance, customer, operation, centralize, relate, country	These topics focus on supply chain processes, challenges, and future directions, such as sustainability. An important emerges is the significance of Cold Chain Management via real-time monitoring of drug characteristics, such as temperature during transportation via IoT and the adoption of blockchain technology for enhancing transparency, security, and counterfeit prevention.
Topic_5	(Alharthi et al., 2020)(Ghadge et al., 2022)(Kordestani et al., 2023)(Zakari, Al-Razgan, Alsaadi, …, & 2022, n.d.)(Zulfiqar et al., 2022)(Haq & Esuka, 2018)(Omar et al., 2021)(Shetty et al., 2022)(Zoughalian et al., 2022)	blockchain, drug, blockchain-technology, counterfeit, data, system, pharmaceutical-industry, pharmaceutical, transaction, pharmaceutical-supp-chain, solution, sector, paper, transparency, study, distribution, health, security, implementation, contract	
Topic_6	(Argiyantari et al., 2020)(Ding, 2018)(Ertz et al., 2022)(Miozza et al., 2024)(Nguyen et al., 2022)(Saha et al., 2022)(Yang & Tate, 2012)	research, psc, study, industry, literature-review, pharmaceutical-supp-chain, process, literature, lean, barrier, identify, emerg, systematic, future-research, lack, researcher, exist, review, issues, supp-chain	
Topic_15	(Aquino et al., 2018)(Hosseini Bamakan et al., 2021)(Ahmed et al., 2019)(Hariry et al., 2022a)	healthcare, chain, patient, cold, sustainability, technology, management, potential, medical, medication, challenges, effectivenes, capability, hospital, healthcare-system, information, monitore, cost, pharmaceutical, temperature	

Table 7 – Topic Clustering for Developing Patient Centric Models

Topic_ID	Papers Included	Keywords	Description
Topic_12	(Denicolai & Previtali, 2020)(Wu & He, 2020)(Macleod et al., 2009)	research, laboratory, study, model, innovation, pharmaceutical, busines, ecosystem, finding, science, firm, framework, animal, rd, field, human, network,	These topics highlight a key trend in healthcare: Personalized Medicine. In particular, this cluster emphasizes the role of technology and sustainable practices in improving patient

		development, organization, prevent	care and healthcare management, underscoring the importance of data-driven decision-making through machine learning and clinical models for individual treatment.
Topic_10	(Ginsburg & Willard, 2009)(Harrer et al., 2015)	medicine, health, personalize, care, genomic, information, individual, precision, tool, risk, genome, sens, development, disease, treatment, patient, medical, inform, field, technology	

Table 8 – Future Research Agenda

Technology	Future Research Avenues	Research Themes
Artificial Intelligence	• Investigate methods to optimize patient recruitment • Explore AI-driven approaches to reduce trial delays • Research how to minimize the need for individual transportation of participants • Investigate how to exploit predictive analytics and molecular modeling • Explore how to potentially substitute Humans in Trials • Explore new market forecasting techniques • Research models Predicting Risks Associated with Suppliers • Explore models Forecasting Optimal Inventory and Production Quantities • Investigate how to Automate Material Procurement	• Advancing Drug Discovery Research, • Reinventing Strategies and Organizational Frameworks, • Manufacturing Optimization • Supply Chain and Logistics Optimization • Developing Patient Centric Models
Cloud Computing	• Explore how the use of Cloud enhances cross geography activities and Real-Time Information sharing • Explore potential usage of Cloud to deploy higher computing power to train algorithms • Develop standardized data formats and interoperability frameworks • Develop advanced techniques and compliance frameworks to address data privacy concerns and regulatory requirements	• Advancing Drug Discovery Research, • Reinventing Strategies and Organizational Frameworks • Manufacturing Optimization • Supply Chain and Logistics Optimization • Developing Patient Centric Models
Blockchain	• Explore potential usage of smart contracts to validate the reliability of clinical trial sites and improve organizational frameworks in drug development • Elaborate on the role that blockchain play in optimizing supply chain and logistics by preventing counterfeit drugs and ensuring product transparency • Research on how decentralized storage solutions enabled by blockchain support genomic data sharing and personalized medicine development • Investigate whether blockchain enhance compliance with Good Manufacturing Practices (GMP) and improve the environmental footprint tracking in pharmaceutical manufacturing • Explore whether blockchain-based cold chain monitoring systems improve the quality and safety of pharmaceutical logistics and supply chain operations	• Advancing Drug Discovery Research, • Reinventing Strategies and Organizational Frameworks • Manufacturing Optimization • Supply Chain and Logistics Optimization • Developing Patient Centric Models
Internet of things (IoT)	• Investigate how to integrate different data formats • Explore encryption, authentication, and access control mechanisms to safeguard IoT-related information • Develop IoT-based platforms for remote monitoring of patients' reactions to treatments • Investigate IoT-enabled solutions for enhanced warehousing and inventory management	• Advancing Drug Discovery Research, • Reinventing Strategies and Organizational Frameworks • Manufacturing Optimization • Supply Chain and Logistics Optimization • Developing Patient Centric Models

3D Printings	• Conduct tests to validate how 3D printing of tissue models for drug testing accelerates drug discovery while reducing reliance on animal and human testing • Investigate what is the role of 3D printing in improving the accessibility of drugs through personalized medicine • Understand the economic and regulatory challenges of implementing 3D printing technologies in pharmaceutical manufacturing	• Advancing Drug Discovery Research, • Reinventing Strategies and Organizational Frameworks • Manufacturing Optimization • Supply Chain and Logistics Optimization • Developing Patient Centric Models
AR and VR	• Research uniform architectures to seamlessly integrate and manage data from diverse sources • Explore methods to encourage final users to accept the use of AR and VR technologies • Explore user experience design, education, and communication strategies to foster trust and adoption among final users • Explore 5G deployment Case Studies to demonstrate Enhanced reliable and secure internet connectivity • Develop AR and VR solutions for real-time monitoring of drug effects on patients or real time information sharing among scientists worldwide • Explore the potential of AR and VR technologies to increase worker safety	• Advancing Drug Discovery Research, • Reinventing Strategies and Organizational Frameworks • Manufacturing Optimization • Supply Chain and Logistics Optimization • Developing Patient Centric Models
Cybersecurity	• Elaborate on the strategies that can be implemented to protect clinical trial data from cyberattacks, ensuring data integrity and participant privacy • Explore effective methods to secure supply chain data and ensure trustable information exchange among stakeholders • Validate the cybersecurity awareness and training significance to safeguard sensitive data • Explore what are the regulatory frameworks and policies to ensure robust cybersecurity practices across the pharmaceutical industry	• Advancing Drug Discovery Research, • Reinventing Strategies and Organizational Frameworks • Manufacturing Optimization • Supply Chain and Logistics Optimization • Developing Patient Centric Models
Digital Twins	• Investigate how to improve Data Exchange and Integration across different sources • Explore methods to effectively link physical manufacturing plants with digitally designed spaces • Develop real-time Simulation and Prototyping methodologies to optimize resource allocation, costs and efficiency • Develop methodologies to effectively link physical manufacturing plants with digitally designed spaces	• Advancing Drug Discovery Research, • Reinventing Strategies and Organizational Frameworks • Manufacturing Optimization • Supply Chain and Logistics Optimization • Developing Patient Centric Models
Big Data Analytics	• Explore new strategies to streamline data acquisition processes and integrate different formats • Develop robust methodologies to aggregate and harmonize unrelated datasets to extract valuable information • Develop User Persona to understand different Buying Patterns • Investigate how Salesforce is empowered through personalized recommendations for customer engagement • Forster collaboration with experts coming from Customer's industry to create a more fitted Patient approach • Investigate more innovative approaches to efficient Resource deployment during Algorithm Trainings	• Advancing Drug Discovery Research, • Reinventing Strategies and Organizational Frameworks • Manufacturing Optimization • Supply Chain and Logistics Optimization • Developing Patient Centric Models

Robots	• Design infrastructure to facilitate the adoption of robotics in manufacturing processes • Investigate the best practices for ensuring reliable and secure internet connectivity to enable the integration of robotics within operations • Investigate how can robotics be utilized to standardize and optimize quality assurance and regulatory compliance in pharmaceutical manufacturing and logistics	• Advancing Drug Discovery Research, • Reinventing Strategies and Organizational Frameworks • Manufacturing Optimization • Supply Chain and Logistics Optimization • Developing Patient Centric Models

Figure 1 – SLR Process [10]

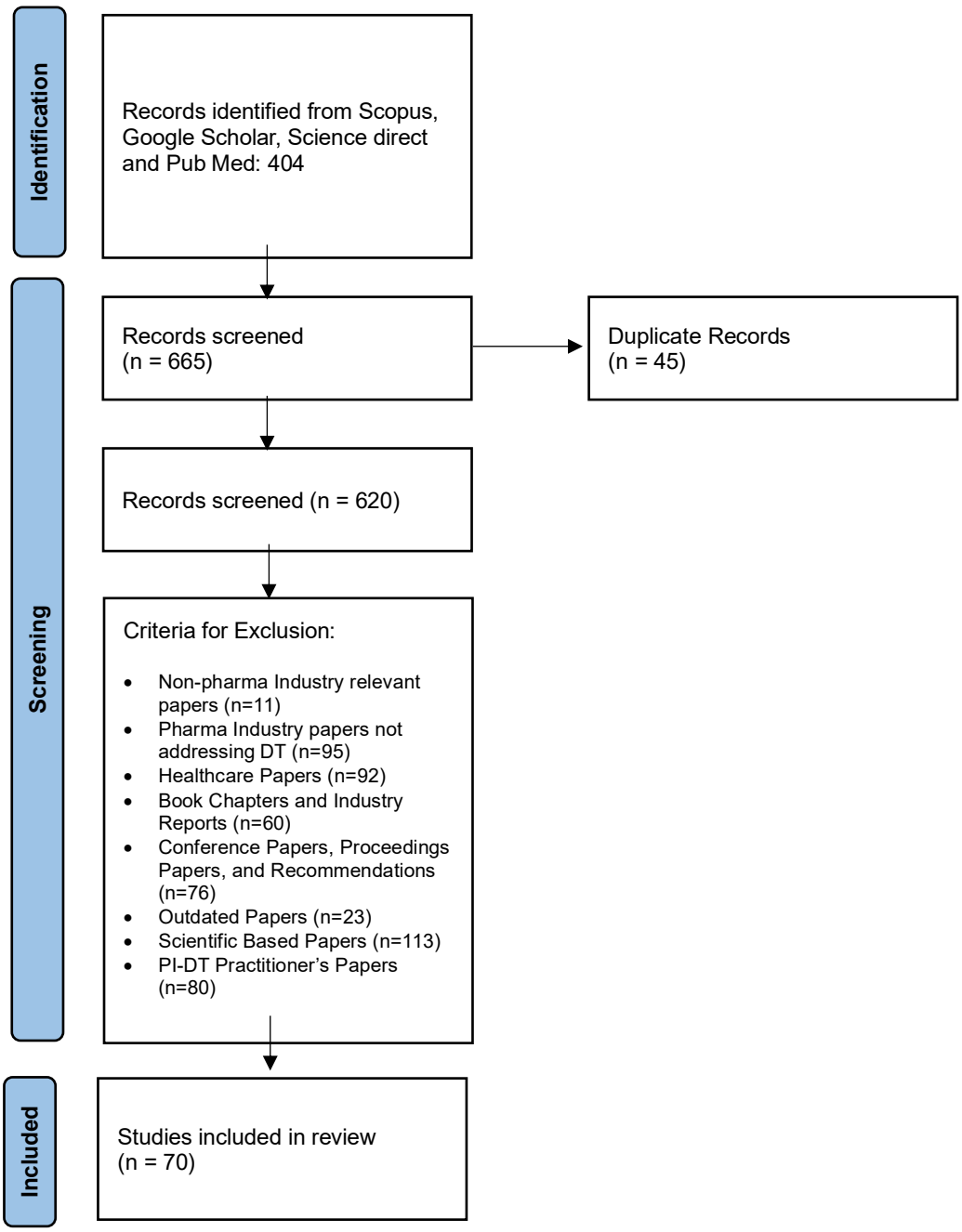

Figure 2 – Word Cloud

[10] Source: Page MJ, et al. BMJ 2021;372:n71. doi: 10.1136/bmj.n71.This work is licensed under CC BY 4.0. To view a copy of this license, visit https://creativecommons.org/licenses/by/4.0/

pharmaceutical
technology
research
development
system
industry
management
data
study
information
innovation
laboratory
paper
increase
challenges
busines
machine-learn
pharmaceutical-supp-chain
supp-chain
production
market
human
cost
patient
approach
digital
potential
proces
model
method
process
implementation
sustainable
sector
pharma
result
review
identify
risk
tool
design
set
impact
firm
rdf
medical
physical
company
current
field
health
security
operation
manufacture
product
drug
application
organization
pharmaceutical-industry
framework
emerg