Pharma 4.0: Revealing Drivers of the Digital Transformation in the Pharma Sector

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Abstract. The primary goal of this paper was to uncover the drivers of digital transformation (DT) in the pharmaceutical industry. The Covid-19 pandemic and tightening regulatory standards in the global pharma industry necessitated pharma executives need to understand the most critical drivers of digitalizing the sector and charting a new path that improves production processes and streamlines these companies' overall supply chain. This research aims to identify the drivers for DT in the pharmaceutical industry. The Web of Science Core Collection and Scopus gathered relevant data for the research study. The research employs objective analysis to ensure that more reliable conclusions were drawn following the study. The study also proposed that external and internal factors, such as supply chain difficulties and data silos, impact DT adoption in the pharmaceutical sector.

Keywords: Digital transformation · Industry 4.0 · Pharma 4.0 · Pharmaceutical industry · Supply chain complexities

1 Introduction

This section clarifies the pharmaceutical sector during the pandemic and how it influences its activities. Pharmaceuticals were one of the most rapidly changing industries in 2020, with the adoption of new digital technologies becoming more common throughout the pandemic. Covid - 19 prompted a rise in the use of technology to halt the rapid spread and death of millions of people worldwide. These DTs ranged from big data analytics to aid in research and development (R&D) and clinical trials. Artificial Intelligence (AI) surveillance cameras and drone-borne cameras, among others, can not only collect real-time data on people's locations but also track and restrict their mobility inside a monitored/locked-down area [1].

The pharmaceutical business is anticipated to spend more than $4.5 billion on DT by 2030 [2, 3]. Pharmaceutical companies believe that implementing digital processes will result in savings of 20% or more, including a 17% reduction in expenses associated with poor product quality and a 14% reduction in delivery reliability. Lee et al. [4] predicted that Pharma 4.0 might increase output by 200% compared to current capabilities. They further underlined that digital changes and automation have resulted in more than 65% overall deviation reductions and 60–90% testing time reductions.

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At the very least, the Covid-19 outbreak heightened global awareness of the need to accelerate the implementation of cutting-edge DT procedures [5, 6]. As a result, scientists worldwide reacted quickly, emphasizing the critical role those digital technologies play in mitigating the effects of new challenges like Ebola and the Covid Pandemic and assisting manufacturing companies in scaling up and improving the entire process from product development to market sales [7]. As a result, companies have been motivated to further progress on their DT journeys [8].

In this context, this paper will review pertinent literature, reveal the key drivers to a digitalized pharmaceutical space, identify relevant gaps and challenges, and highlight the benefits of adopting digitalization and its impact on operations in the pharma sector.

2 Literature Review

This section defines and gives clarity on what DT is with examples. DT is defined by researchers as a cultural development or construction of a business model, redefining firm capabilities, processes, and linkages to fundamentally disrupt established (traditional) business practices [7]. Furthermore, Carcary et al. [9] state that effective digitalization needs to develop diverse skills, which would change depending on the business climate and the company's need to remain competitive. As a result, digital technology must be integrated into how businesses process and companies must effectively rethink and perhaps redesign their business models. Thoben et al. [10] described DT as "changes that digital technology causes or effects on all aspects of human existence"; however, this definition confounds the concept with its impact. Various DT definitions are accessible as scholars have sought to strengthen the DT concept by broadening the definition and terminology outside the sphere of usage [11]. It then makes some definitions overlap or mislead others, such as emerging digital technologies such as social networking, mobile analytics, and embedded devices. It enables significant commercial benefits such as improved customer experience, improved processes, or the creation of new business models [12].

The Internet of things (IoT), 3D printing, the Industrial Internet of things (IIOT), Enterprise Resource Planning (ERP) Systems, Artificial Intelligence (AI), Machine Learning (ML), Big data (BD), and the convergence of physical manufacturing and digital technologies have all resulted from this revolution [13]. DT is inextricably linked to Industry 4.0, whether in the services or industrial sectors; it is the transformation that propels Industry 4.0 forward. Businesses are now ensuring that digitalization and automation eliminate mistakes that have the potential to harm their brand and result in massive financial losses. On the other hand, the pharmaceutical industry has a history of resistance to new technologies and digital solutions. Nonetheless, with the Covid-19 outbreak causing widespread concern and posing a continuing threat, digitalization appears to be the best way to ensure everyone has access to safe medication [2]. Environmental changes because of the growing population and pollution cause contention and disruption. Therefore, digitalization was required to address these environmental challenges while simultaneously increasing competition, and improving customer relations, productivity, profitability, effective planning, problem-solving, and decision-making to continue delivering medical items [14].

The pharmaceutical industries are extremely sophisticated in terms of technological use. However, in terms of operations, the sector has been quite conservative in embracing new technology thus far, relying on a long-established supply chain and manufacturing models [15]. The highly regulated environment in which pharmaceutical companies operate is an important factor. Digitalization has enormous potential to assist pharmaceutical businesses in addressing these difficulties of lack of integrated planning throughout the network. Companies across all industries are boosting operations through a collection of developing technologies known as Industry 4.0 [12].

3 Methodology

This section describes the nature of the data obtained and selected to achieve the research purpose. The approach used to select and analyse articles is the Systematic Literature Network Analysis (SLNA) [16]. In addition, the web of science, Google scholar and Scopus were considered for literature analysis (2004 to 2022) [9]. Out of the 63 articles, 14 were irrelevant abstracts, 16 were irrelevant to objectives, and 19 were used for the review.

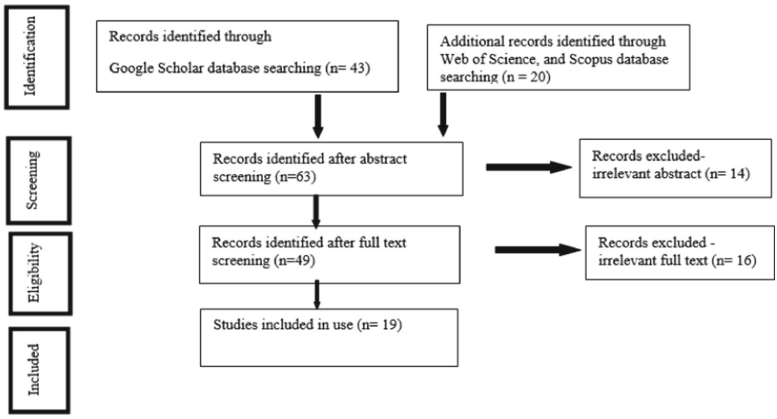


Fig. 1. Systematic Literature Review.

Figure 1 shows a structure crucial in performing a secondary investigation, such as a systematic literature review (SLR), to minimize bias in the study. The structure embodies the detailed plan for the review, specifying the process to be followed to achieve results and facts as findings [17].

4 Results and Findings

The research findings and results displayed seven important motives for DT and its benefits in the pharmaceutical sector, as well as the influences of digitalization. There are several reasons why the pharmaceutical industry needs to be digitalized. Some of the key motivations for digital enablement adoption in pharma are as follows [18]:

- The need for effective data management practices,
- Harnessing the expert knowledge of other industry players worldwide,
- Improving the frontiers of research related to the manufacturing of safe and quality pharma products,
- Supply chain complexities,
- The ever-changing needs of customers,
- Reducing production costs and increasing profitability, and
- The need for effective teamwork.

Developing clear data management strategies is essential to avoid running out of data centre space and financial resources in the pharmaceutical industry due to the day-to-day creation of data. This data is valuable to pharma sector researchers for many reasons, including improving clinical trials, developing personalized medicines, and advancing new product research [7]. Digitalization improves supply chain visibility and speeds decision-making. As a result of digitalization, companies are more adaptable and responsive and improve planning accuracy, manufacturing efficiency, inventory, and service levels [18]. A digital supply chain ecosystem with virtual supply chain control tools, cloud-based information architecture, and a digitally enabled physical supply chain is required to capitalize on this opportunity. People, machines, and resources communicate as a cyber-physical system, improving all stages of the operations value chain: plan, source, and make. In addition, it allows manufacturers and distributors to reach previously inaccessible customers [3].

According to the findings, internal and external factors significantly impact the adoption of DTs in the pharmaceutical industry. The development of new drugs is too expensive, and clinical approval times are too long; this is one of many internal factors influencing DT. However, technology such as AI can help with data science tools for smart experimental design, data-driven decision-making, and process optimization [19]. People with the necessary skills are scarce, making them expensive and limited in their time. Also, IoT, an enabler of CPS, interconnects real and digital components via embedded chips, sensors, and networks to create algorithms and replace judgments that rely on manual data analysis [20].

Given the time and money spent on drug R&D, medication discovery, clinical trials, product quality evaluation, pharma supply networks, and marketing, the pharmaceutical industry is unquestionably a large and complex ecosystem. As a result, understanding these forces will aid in developing appropriate structures or technologies to address the SWOT Pharma analysis (Fig. 2).

Figure 2 illustrates the four main quadrants that drive pharma digitalization transformation. Large capital investments are required to transform an organization's operations digitally. Pharmaceutical companies with larger financial cashflows have an advantage in adopting and implementing newer technologies. Brand image is critical to those in the pharmaceutical industry who are quickly adopting new technologies. Pharma executives at these companies are more likely to adopt and implement technologies that will further strengthen their market position. A deeper understanding of these technologies and more efficient ways of doing things, combined with structural flexibility, all contribute to the early adoption and implementation of digital enablers.



Fig. 2. SWOT Pharma Analysis, the four quadrants that identify pharma company strengths, weaknesses, opportunities for digitalization, and threats for adoption and implementation

Regardless of the propellers to digital enabler adaptation, low quality and production capacity, data silos, broken audit trails, and a lack of optimization for equipment and processes all impede the drive towards 4.0 pharma activities. Covid-19 Pandemic presented and accelerated the adoption of advanced technologies, hastening the development of vaccines [3]. This, along with other external factors such as customer demand, regulatory requirements from standard authorities, and conflicts such as the one between Russia and Ukraine, present opportunities to further enhance and expand the frontiers of digitalization in the pharmaceutical sector. However, there are some perceived barriers to DT adoption. These may include industry competition, supply chain complexities, the risk of reputational damage, data losses, and a variety of other unknowns.

Digitalizing the processes that support the pharmaceutical industry can significantly improve the quality of some critical industrial processes such as documentation and materials management, and logistical challenges, making them safer, more efficient, and more consistent. This considerably reduces the barrier of supply chain complexity, which is a big lure to the digitalization agenda. Furthermore, the study discovered that it has a higher impact when digitalization is applied to all aspects of a business. As a result, it is critical to determine whether there are any project dependencies or possible synergies. The digitalization of a process may affect other developments consistent with the work of [21]. As a result, to properly digitalize processes, it is important to identify cross-divisional activities and establish their ownership.

Finally, the study discovered that supply chain difficulties, worldwide pandemics such as Covid -19, demand shifts, and regulatory requirements all positively influenced the adoption of DT in the pharmaceutical sectors.

5 Conclusions and Further Research

Digitalization is unquestionably playing a key role in catalysing a paradigm change in the pharmaceutical sector. It can also be concluded that, despite significant efforts in digitalization over the past three years since Covid's initial strike, the pharmaceutical

industry has been resistant to digital implementation. It resulted in very slow progress in the sector's digitalization. As a result, production costs, employee skills, efficiency, customer satisfaction, breaking new ground and discovering cutting-edge quality products, enhanced digital platforms through data acquisition and protection, tracking various aspects of production, and many other factors are impacted. The push for a fully digitalized pharmaceutical industry is more pressing than ever primarily because digital platform enablers improve processes such as data collection, real-time information sharing of trial results, and the ability to track various aspects of productions. However, it also aids in reducing the complexities that have plagued the pharma industry over the years.

As with any other type of change, industry participants should expect challenges in managing these initiatives, as outlined above, employee resistance to the proposed change, flaws in the adoption process, and overall implementation lag. However, this can be effectively managed by engaging employees and providing training on new and innovative working methods while also committing to their job security and benefit.

The pharmaceutical sector must implement digital standards that ensure partner compatibility to address cybersecurity concerns. Pharmaceutical companies must also have the necessary resources, such as a multidisciplinary team of specialists and the funds to make the required investments. Technological advances will have an impact on the pharmaceutical industry. Industrial productions are linked with modern information and communication technology as part of the digitalization process, allowing for a self-organized manufacturing process and capturing important, usable data [21]. Further researchers are encouraged to broaden the scope of this research by investigating all other aspects of the pharmaceutical supply.

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