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## Article

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Article

# A New Digital Value Chain Model with PLC in Biopharmaceutical Industry: The Implication for Open Innovation

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**Abstract:** The advancement of technology in the biopharmaceutical industry has spearheaded the speed and scale of digitalization in various aspects. New drug development is becoming more complex, costly, and challenging. This paper examines how the pharmaceutical value chain model could integrate with the product-life-cycle perspective to better explain the drug development process changes and how the digital transformation could be implemented at each stage of the drug development process. We suggest a new framework to capture digital value creation in the biopharmaceutical industry by focusing on the specific processes in new drug development and integrating the product life cycle management and value chain model. The new framework has operational implications for the biopharmaceutical industry, where digital transformation can simplify and increase the efficiency in each phase, from drug discovery, clinical trials, regulatory, manufacturing, commercialization, to monitoring processes.

**Keywords:** pharmaceutical industry; value chain; product life cycle management; drug development process; digital transformation; technology adoption; industry transformation; research and development; open innovation; innovation policy



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## 1. Introduction

There have been many changes in the healthcare and biopharmaceutical (H&BP) industries' business environment as new digital technologies have transformed the industry landscape in recent years. Moreover, the COVID-19 pandemic has spearheaded change at a revolutionary speed. The changes in the business environment and policy mechanisms enabled the H&BP industry to speed up drug development process for COVID-19 therapeutics and vaccines. The effects of the unprecedented change in the H&BP industry's operating environment are considerable within firms. In particular, digital transformation (DT) in the industry, operational business processes, therapeutic area portfolio shifts, and corresponding investment directions are the business areas and activities that were most impacted at the corporate level. These changes are linked to digital-technology-based pharmaceutical product development, digital therapeutics, diagnostics, patient monitoring, and telemedicine, among others. Inside pharmaceutical companies, internal management platforms have been transforming into integrated forecasting and revenue management models that incorporate new technologies.

With these changes taking place in various H&BP industry segments, the traditional pharmaceutical value chain operations need to be reconsidered and redesigned as a whole. In the past, the H&BP industry was characterized as single-handedly conducting all aspects from research and development (R&D), discovery, manufacturing, and investments to production under a single roof rather than through collaboration with other industries [1]. The traditional operating mode of the H&BP industry has been conservative in this respect [2].

Recent changes in the industry business environment have led to increasing collaboration and convergence both within the H&BP industry and with other sectors. Studies [3,4] show that increasing convergence through enhanced and speedier technological breakthroughs and innovations were taking place in the H&BP industries even before COVID-19. One of the most significant impacts of these changes on the H&BP industry is the new drug development process. The industry's new normal is taking shape through new and more efficient efforts, while many structural changes in the business environment impact the entire industry. These changes should ultimately benefit the patients [1].

To examine and address the changing paradigm in the H&BP industries, this paper focuses on the three areas that are critical to the H&BP industry's long-term prospects: (1) new drug development process, (2) digital initiatives, and (3) product life cycle (PLC) management. We propose a new framework for the H&BP industry value chain configuration under digital transformation and Industry 4.0. The new integrated framework provides a more comprehensive and extended perspective on the drug development process undergoing DT and industry convergence, leading to digital healthcare product development with digital initiatives. Overall, this paper suggests specific directions for the firms in the H&BP industry and draws strategic implications that are imperative for businesses to successfully transform and render sustainable and innovative growth in the digital era.

This research is organized as follows. Section 2 provides a review of the related literature and illustrates the latest industry trends and developments in the global H&BP industry. Section 2 further elaborates on how DT reshapes the sector and addresses the critical issues in the H&BP industry in terms of innovation and DT, among others. Section 3 proposes a new pharmaceutical value chain aligned with the PLC model to illustrate the new drug development process framework in the new digital era. The business transformation implications based on the new framework are discussed in Section 4. Section 5 concludes the paper by highlighting the strategic implications of the new value chain configuration framework and draws attention to the need for increased collaboration in the H&BP industry.

## 2. Theoretical Background and Earlier Research on H&BP Industry and DT

This section provides the theoretical background and a literature review in the pharmaceutical value chain and product life cycle (PLC) model for the drug development process. In addition, new initiatives with the technology adoption and what sectors changed under the digital healthcare environment compared to the traditional pharmaceutical business model will be investigated.

H&BP firms and related industries have been relatively conservative compared to other industries in terms of breakthrough innovation [2]. They were also latecomers to adapt to the changes related to Industry 4.0. The causes for this phenomenon vary. The healthcare sector and pharmaceutical industry lag behind in the implementation of digital initiatives. However, the importance of digital initiatives was recognized to accelerate the digitalization and solutions in the H&BP industry. A major hurdle was the nature of the pharmaceutical industry which tends to avoid risk. This is because the pharmaceutical industry, where people's lives and livelihoods are at stake, is a major regulatory target. This partially explains why the H&BP industry has taken a more conservative approach to changes and paid more attention to compliance and safety than faster innovation adoption. Hence, the regulatory changes were slow while scientific and digital technologies were developed rapidly [5]. An essential factor is the product's characteristics and the industry itself. This is because it is an industry that develops, produces, and supplies pharmaceutical drugs that treat patients. The procedures such as the approval, registration, and regulation related to these undergo strict monitoring and risk management. Nevertheless, there is now increased interest worldwide about how the H&BP industry and related industries are changing and how the internal and external environments surrounding the BP and healthcare industry are changing accordingly.

This paper suggests a new pharmaceutical value chain model that integrates the PLC perspective to explain the drug development process changes better and illustrates how the digital transformation could be implemented at each stage of the drug development process.

H&BP firms and industries are already changing their new drug development processes in line with the digital environment changes. In addition, due to the COVID-19 pandemic, they have started investing in the COVID-19 vaccines and treatments. This can be a change in a larger dimension than a change in a company's portfolio. Due to the nature of the H&BP industry, for example, it takes about ten to fifteen years to develop one pharmaceutical product, and it takes an average of USD 1 billion for development. This is because a considerable investment must be made before it is released. Therefore, investing in developing new drugs such as the COVID-19 vaccines and treatments may be challenging, but it is necessary for sustainable growth in the biopharmaceutical industry. However, significant changes in the H&BP sector are expected to continue as new drug development has been simplified with DT.

In addition, collaboration with technology companies is taking place in relevant healthcare-related industries as digital healthcare products are developed and released. There is also a trend toward convergence projects among such companies that are expected to continue in the future. In other words, these industries are moving within their ecosystem that creates results through collaboration between many firms rather than through a single firm. These changes are new to the industry as model innovations, focusing on "Open Innovation" systems. Following this background, this paper suggests a new framework for responding and finding solutions to these business transformation challenges.

Different groups or clusters will emerge during the digitalizing process, where one group or cluster will adapt relatively well and faster to the DT, whereas another group or cluster will make the changes rather slowly and mostly maintain previous business practices. H&BP firms that have difficulty or are unwilling to adopt DT to their businesses can predict that the future of those firms is less likely to show sustainable growth than the companies that take the digital initiatives aggressively and strategically plan the specific roadmap.

The next change is from the perspective of operating H&BP firms; the changes brought by DT can be said to be diverse. In particular, there are changes to the digital marketing platform and online-based sales/marketing activities of pharmaceutical companies so far. For example, it focuses on academic activities such as online academic seminars and symposia, reducing costs, and increasing efficiency from a corporate internal financial perspective. Therefore, studies on these changes will need to be conducted continuously, and as time passes and data are accumulated in the future, it will help establish further corporate strategies.

### *2.1. The H&BP Industry and DT in the 2020s*

#### *2.1.1. An Overview of the Global Healthcare&Biopharmaceutical (H&BP) Industry Trends*

Healthcare and biopharmaceutical industry sales are expected to reach almost USD 12 trillion in 2022 [6]. The medical and health services market accounts for the majority, followed by medicine and medical devices. The global healthcare and health services market is USD 7.2 trillion [6]. Furthermore, the H&BP industry is expected to grow rapidly, with an average of 5.9% annually, due to aging, increased interest in health, and digital convergence [7]. According to another industry forecast, the global biopharmaceutical market size is expected to reach USD 405 billion by 2024, showing a compound annual growth rate (CAGR) of 9.3% between 2016 and 2024. Furthermore, the global medical devices market size is forecasted to reach USD 522 billion by 2022 [8].

The Asia-Pacific area and Africa are the two fastest-growing regions. One of the main reasons for this high growth in the H&BP industry is the parallel economic development level that offsets technological capacity worldwide, triggering interest and investment. The H&BP sector advancement is a natural barometer to a nation's health and medical system welfare. With economies getting wealthier worldwide and technologies and capital

increasing globally, the H&BP sector growth is a natural step for human advancement as life expectancy increases, and quality of life improves.

Despite the H&BP industry's growing social role, new drug development has never been so challenging as in recent years. Firms are no longer able to develop as many novel products as before. The reason for this is that many blockbuster drugs have already been developed. Developing innovative products has become increasingly costly and more complex due to business environment challenges and tightening regulations. Hence, many global companies are focusing their investments on developing biological products (or biologics) and novel drugs developed from the existing chemical base products [9].

The past decade has seen increasing pressures undermining the H&BP industry's R&D productivity, leading to a decade of decline in return on investment [10]. The traditional business model in the H&BP industry is focused on generating profits first, which is established on an investment model rooted in R&D-based innovation. However, the past way of drug development results in reduced profit margins, increased selling costs, and higher general and administrative expenses. H&BP firms' net profit positions are likely to decrease due to a restricted environment with patent expiration, tightening new drug development processes, drug approval delay, generic launch, price cuts, strengthened regulations, and government policy changes. The need for a consistent approach for product approval in new therapeutic areas will put downward pressure on profits in the long term.

Despite this challenge, the R&D expenditures have not changed much in recent years, even though there has been a sharp decline in overall sales. As a result, it is challenging to make aggressive investments and develop new products as before [11]. Table 1 presents global prescription drug sales by industry-leading companies in 2019 and the industry outlook as of 2024.

**Table 1.** World Prescription Drug Sales (2019–2026): Top 10 Companies and Total Market.

Rank	Company	Prescription Sales (\$bn)			Market Share		
		2019	2026	CAGR	2019	2026	Change (+/–)
1	Roche	48.2	61.0	+3.4%	5.5%	4.4%	–1.1 pp
2	Johnson & Johnson	40.1	56.1	+4.9%	4.6%	4.0%	–0.6 pp
3	Novartis	46.1	54.8	+2.5%	5.3%	3.9%	–1.3 pp
4	Merck & Co.	40.9	53.2	+3.8%	4.7%	3.8%	–0.9 pp
5	AbbVie	32.4	52.7	+7.2%	3.7%	3.8%	+0.1 pp
6	Pfizer	43.8	51.1	+2.2%	5.0%	3.7%	–1.4 pp
7	Bristol-Myers Squibb	25.2	44.7	+8.6%	2.9%	3.2%	+0.3 pp
8	Sanofi	34.9	41.7	+2.6%	4.0%	3.0%	–1.0 pp
9	AstraZeneca	23.2	41.0	+8.5%	2.7%	2.9%	+0.3 pp
10	GlaxoSmithKline	31.3	40.8	+3.9%	3.6%	2.9%	–0.7 pp
Total Top 10		366.1	497.1	+4.5%	42.0%	35.8%	–6.2 pp
Other		505.8	893.1	+8.5%	58.0%	64.2%	
Total		871.8	1390.3	+6.9%	100.0%	100.0%	

Source: EvaluatePharma, 2020. The ranking is based on the projections for 2026 made in mid-2020.

As seen in Table 1, multinational companies (MNCs) have been leading the global pharmaceutical market sales growth, and the top ten companies account for 42.0% of the world's total market sales. The simple four-firm concentration ratio is 20.1%, with a Herfindahl–Hirschman Index (HHI) of 105.43. The industry outlook for 2026 suggests that competitive pressure is imminent as the top ten companies' concentration ratio is decreasing. In the future, the sales and net profits are expected to decline, and competition in the prescription drug market will intensify. The pharmaceutical industry is currently concerned about an increase in R&D costs and a decline in profitability compared to sales. However, the product pipeline has been changing due to digital transformation and investment shift in COVID-19 vaccines and treatments.



Despite these systemic challenges in the industry and the COVID-19 pandemic, the industry demand for innovative and effective therapies are the main drivers of long-term growth [12]. Medi-tech approval is an important index to measure the development of medical devices and innovative products in the biopharmaceutical industry. As a trend in medi-tech approvals from 2010 to 2019, the number of pre-market approvals (PMAs) and humanitarian device exemptions (HDEs) have increased since 2010 [13].

The fundamental changes in the H&BP industry that had undergone digital transformation (DT) are discussed in detail in Section 2.1.2. The research on the healthcare environment's DT focused on individual categories of digital healthcare competitiveness. Convergence trends in digital healthcare have only recently come to the fore. Another important healthcare management topic is the economic challenge of growth and aging. Hence, in the field of data-based precision medicine, hospitals, healthcare providers, and pharmaceutical companies now face a turning point in their traditional business models as a result of the changes in their business environment due to digitalization. Furthermore, healthcare payers such as governments, insurance companies, and patients are also included in this transformation.

Ultimately, there is a need to balance health provision and cost. Future healthcare costs, patient experience, treatment efficacy, healthcare capacity, and system efficiency depend on the health information exchange platforms and the use of electronic health records [14]. These challenges are connected to business environment changes that arise under the digital healthcare transformation. Healthcare providers, payers, and technology companies have started collaborating to increase and develop digital healthcare infrastructure. The WHO emphasizes the importance of efforts by grafting DT technologies to improve healthcare outcomes at a national level. DT technologies are also connected to the national healthcare competitiveness and policies under COVID-19 and the health ecosystem [15].

In view of the structural challenges the industry is facing, the top pharma companies are seeking strategies for increasing their R&D efficiencies through collaborative R&D with technology companies and by adopting AI technologies in the DT environment [12]. In recent years, R&D costs in top pharmaceutical companies have continued to increase. The top pharma companies may be investing heavily in R&D now to achieve a higher return on investment (ROI) in the longer term.

As a result of technological innovation, new investments and projects involving biomedical care companies are underway in developing new drugs. Pharmaceutical companies and big IT companies such as Google, Microsoft, Apple, Samsung, and research institutes collaborate with governments and other institutions in their countries. With the emergence of new technologies and regulation development, the focus areas of technology giants in the digital health sector have also changed over the years. Companies focusing on data management and analytics, imaging, and population health management platforms have received the most funding by the deal amount [16].

The pharmaceutical industry has generally made lower profit margins due to increased competitive pressures from environmental challenges such as generics and pricing policies. However, despite a low revenue range and declining sales in the pharmaceutical and biotechnology industries, R&D expenditures were not reduced substantially. As a result, it is more difficult to increase R&D expenditures further and develop new products than before [17].

#### 2.1.2. Digital Transformation (DT) Industry Trend

Although the change dynamics in the H&BP industry might be slow due to regulatory restrictions, many pharmaceutical companies have made significant digital transformation progress. The COVID-19 crisis has particularly impacted the H&BP industry's IT needs globally, especially in the software segment. The software segment has a 30% share in the global healthcare-related IT market [18]. With the availability of real-time information from clinical trials and patients, pharmaceutical drug manufacturers obtain insights on

how a drug affects a patient and how they can optimize its effects and minimize the side effects [19].

Independent and combinational use of AI, big data, and internet of things (IoT) technologies creates further innovations. The application of AI in the various sectors of H&BP industry reduces resource use and hence costs in a shorter period [20]. Although there are no specific estimates yet, AI technology has been found to improve cost effectiveness in the drug development process in 81% of biopharmaceutical companies in 2020 [21]. Other eminent technologies such as cloud computing, augmented reality (AR), virtual reality (VR), and blockchain are also being extensively used in the digital transformation process of the pharmaceutical industry [22]. According to industry predictions, the global market for AI medical diagnostics is projected to reach USD 4.0 billion by 2026, from USD 748 million in 2021, which is 39.8% CAGR [23].

The technologies with the traditional clinical development process are changing as DT enables new clinical trials processes. Significant changes that improve traditional processes' key issues are needed from drug discovery to the launch of a pharmaceutical drug. Digital technologies help transform H&BP firms with the new approaches taken by clinical research organizations and H&BP firms to discover and develop new drugs by integrating multiple data sources, increasing the productivity and quality of clinical trials [24].

The primary goal in innovation is to enhance efficiency, shorten the drug development process time, and reduce costs. The model developed in this paper reflects on the DT of the H&BP industry and integrates the current state of digital healthcare technology into the pharmaceutical value chain model.

Recent developments in digital and platform technologies have given rise to the bio-health industry's convergence concept and contribute mainly to this industry's recent changes. Biopharmaceutical platform technologies are integrated systems incorporating digital technology both from new drug development and from commercial operations points of view. Thus, platform technologies represent a wider view than digital technologies. The new drug development aspect is examined as a main topic in this article, and from the corporate commercial point of view, it is being developed to a non-face-to-face platform in conjunction with DT and due to COVID-19. Therefore, many traditional activities have been changed to online-based activities, such as online seminars, symposia, patient support programs, and supply chain management (SCM). Particularly, from an SCM point of view, pharmaceutical products are being managed under a digital technology platform from sourcing, production, demand, supply, and inventory management forecast. It is also utilized to develop an online platform of patient support programs to share the right and latest information for patients. Market-trend-based strategies for the healthcare market include increasing participation and collaboration across industries and companies and within the H&BP industry. This is a new normal in the H&BP industry following the fourth Industrial Revolution (Industry 4.0). For example, various companies participate in hospital-centered treatment, turning into an industrial ecosystem centered on healthcare and prevention. In other words, hospitals and health care services, IT, insurance, and fitness companies create various service markets.

In the case of medicines, personalized new drug development is a new area and an important goal:

- Applications in pharmaceutical product development: Digital transformation is utilized across the H&BP industry [25]. Major countries are investing heavily in developing customized medicines through big data analysis. The US invested USD 70 million in 2019 to develop customized anticancer drugs centered on the National Cancer Institute as part of the Precision Medicine Initiative. Global pharmaceutical companies and genome analysis companies have cooperated to develop customized new drugs, recommend (B2C), and clinical design (B2B).
- Applications in medical device development: In the case of medical devices, major countries are promoting the industrialization of the fourth industrial revolution technology, such as AI, 3D printing, and robots. In particular, as multinational companies

are centered on “Predictive, Preventive, Personalized, Participatory (4P)” based on the “Internet of Things, Cloud Computing, Big Data, Mobile (ICBM),” the core technology on the Industry 4.0 is shaping a new concept in the medical device technology development area.

In the rest of Section 2, the theoretical background and the literature on the traditional pharmaceutical product development process and value chain model are reviewed. We also elaborate on how digital transformation can effectively be incorporated into the processes in the bio-healthcare sector.

## 2.2. The Value Chain Concept in the Digital Era

The digital value chain has been a widespread practice in business and academic interest since the late 1990s. Various industries, particularly orienting from the content services and IT sectors, have recognized that successful DT requires new capabilities. For instance, Hansen and Birkinshaw (2007) had foreseen and incorporated innovation processes into the concept of value chain flow from idea generation to diffusion by raising key questions and performance indicators that could measure and spot innovation as a sequential activity within the organization [26].

This study connects to other works by showing how digital innovation can occur throughout the organizations’ value chain as a sequential innovative process flow. Berman (2012) suggested the following essential components: “business model innovation”, “business and community collaboration”, “cross-channel integration”, “insights from analytics”, “digitally enabled supply chain”, and “networked workforce” [27]. Novartis is exemplified as a good illustration of employees’ online collaboration with the patient groups in communities to develop new drugs. Similarly, Fichman, Dos Santos, and Zheng (2014) explored the “complexity of socio-material interactions in digital innovation”, the “specificities of digital technology”, and the “oscillation between the specific and the general” as the three links between digital innovation and value creation [28,29].

Just as the previous studies on digital value or supply chain focus on the growing importance of integration, a more recent study by Garay-Rondero et al. (2020) also emphasizes the functional role of interconnectivity between different digital supply chains in the era of Industry Revolution 4.0 [30]. However, on a different note, Buia, Heyning, and Lander (2018) highlight how firms could balance the advantage of outsourcing a part of their value chain activities with the potential risk of foreclosing their strategic options more carefully in the digital age since the more important segment of the business is now being outsourced, in other words, dependent [31]. The threat of the IT-oriented suppliers in the digital era is similar to start-ups as the new emerging stars in the H&BP industry. For instance, start-up firms could now threaten the mega-firms in the H&BP industry and eventually shake up the competition. This might occur if the start-ups transform drug discovery and development at greater speed and scale by combining genetic information and new therapies. Although this example focuses on biomolecular platforms around cellular, genetic, and other advanced therapies, experts say that it is a matter of time before this trend can expand into a range of diseases, including DNA and RNA decoding. This is a general example of how the previous models of value chains and platforms in the H&BP landscape might face.

## 2.3. Traditional Value Chain and Drug Development Process

The traditional drug development process mainly has the four major stages before commercialization begins in pharmaceutical product marketing. These four stages are: (1) drug discovery, (2) pre-clinical phase, (3) clinical development, and (4) Phase IV [32]. The process of new drug development involves many challenges, putting pressure on ROI. For example, for every 10,000~15,000 new compounds identified during the “drug discovery” phase, only one of these compounds is typically approved as a marketed drug. In particular, 10,000~15,000 new compounds are typically considered during the drug discovery step, and 250 of these compounds successfully move to stage two of the pre-



clinical step. Out of 250 compounds from the pre-clinical stage, about five compounds make it to the third stage of clinical trials. The clinical trials stage has three phases: Phase I to Phase III. In the end, only one new pharmaceutical product is approved by FDA. The post-approval process continues to the manufacturing and phase IV and commercialization in the market. There is still the possibility of withdrawing a newly developed drug due to unforeseen in vivo complications. The conventional drug development process has limitations, and even after the commercialization, the post-drug-discovery management process remains complex [33].

The conventional ecosystem of the H&BP industry includes healthcare providers, suppliers, professionals, various authorities, patient organizations, and insurers. Under the traditional value chain configuration, healthcare professionals and providers receive information from the consumers. Under digital transformation, however, information is generated throughout the value chain. In the digital transformation environment, information on each stage of new drug development and patient information is digitally managed. The main items of each stage are systematically and integratedly managed and began to form a circular structure. Product information, compliance, safety, and side effects data are accumulated and used again for new drug development through a reflection of data analysis. It can enhance the drug discovery process efficiency by improving patient care and management, which is related to the competitiveness of the national health industry. Information is then analyzed and sent back and forth, resulting in customized information to final users [34].

#### *2.4. New Initiatives and Digitalization in the Industry*

As DT progresses, the drug development process changes by incorporating digital initiatives in the pharmaceutical development stages. Today, vast amounts of biological and medical data are available, and machine learning algorithms are well-established, allowing the design of largely automated drug development pipelines to be conceived. These pipelines can induce or accelerate drug discovery, provide a better understanding of diseases and related biological phenomena, and help pre-clinical wet laboratory experimental plans and future clinical trial plans. The automation of these drug development processes could be critical to the current low production rates facing pharmaceutical companies [35].

As argued by [36], AI can lead to lower drug development costs, higher drug approval rates, faster access to medications by patients, and more effective and efficient compliance of patients with their treatments. DT leads to the revision of business models, improved production processes, and faster design and development of new drugs by using AI to screen compounds and increase responsiveness for customers [37].

Despite the importance of new drug development in the H&BP industry, there have been only a few academic studies on the effects of DT in new drug development and the pharmaceutical value chain in particular. A new concept in this context is the Internet of Medical Things (IoMT) [38]. IoMT contrasts the conventional approaches where evaluations are made retrospectively through large-scale clinical trials. Technologies such as IoMT allow real-time information sharing in clinical trials, and this starts to help for new drug development and various sectors in the H&BP industry. However, in terms of regulation, there are still areas to be updated and overcome in each country with standardized guidelines. WHS also recommends countries review the status of healthcare development and the biopharmaceutical industry. This subject is covered in more detail at the end of Section 2.4. The IoMT, for instance, can provide real-time outcome data and continuous assessments.

The pharmaceutical industry is currently facing challenges in the drug development process because of increased R&D costs and decreased efficiency. In this regard, AI is expected to improve the efficiency of the drug development process and reduce development costs. Therefore, the pharmaceutical industry started collaborating with the AI industry to overcome these challenges. These areas will ultimately help patients with treatment [39]. DT overall offers a mechanism to revise its business model, improve production processes, and design new drugs faster using AI. As a result, the drug development pipeline can

be largely performed automatically in a computational way, reducing and accelerating human-related technical errors [35].

As technology advances, clinical trials evolve with innovative capabilities, leading to novel study designs with patient empowerment [40]. The investment will make new designs for clinical trials feasible with more targeted interventions, lower costs, increased efficiency, and bring new therapeutic drugs to market faster than before. Major pharmaceutical companies have already begun exploring applications for digital technologies in their early-stage drug trials. The endpoints of digital technologies in clinical trials can drive innovation and opportunity in the pharmaceutical industry [38].

Digital technology adoption at the national level necessitates digital healthcare as a national policy objective. However, there is a current global interest in them. The regulations on digital healthcare should ease the setting of standards considering their practical utility, help create new models that are more specific, and work with patients' quality of life (QoL) and medical institutions such as hospitals, businesses, and associations.

The economic development level, the characteristics of health, and welfare policies differ by country. Hence, this is a situation where each country makes many trials and errors. Some countries are already using mobile digital healthcare applications, employing remote healthcare and disease management through apps, and are working on projects by quickly changing and renewing the regulations. Concerning policy aspects and objectives, the expected changes within the industrial group that these trends bring are expected to improve patients' quality of life and improve cost savings, efficiency, and convenience [41].

As digital health implementation guidelines, the World Health Organization (WHO) recommends that digital interventions for health systems focus on leadership and governance, strategy, infrastructure, government policies, regulations, and workforce. These aspects will become important in gaining an international competitive advantage. According to the WHO, global strategy on digital health should aim to support and respond to the growing needs of countries to implement appropriate digital technologies by their health priorities, its current digital health situation, the planned or aspirational future state of digital health, resource constraints, capacity limitations, risks, and other influential factors. With these goals, countries are encouraged to review their health development situation and to determine the most appropriate, strategic, cost-effective, and optimal policies and measures that will improve health and ensure universal health insurance coverage, sustainable development goals, and the greatest impact on national policy goal achievement [42].

### **3. A New Model for the Biopharma Industry's Drug Development Process**

#### *3.1. New Initiatives and Digitalization in the Industry*

This section introduces the new pharmaceutical value chain framework undergoing digital transformation. The framework consists of three elements. The first element covers the "new drug development process," which is the most essential part of the biopharmaceutical industry. Under the new drug development process, the target product to be developed changes as it is affected by the changes in the external environment and the therapeutic area. In particular, the product portfolios of H&BP firms begin to change. This affects the strategic orientation according to patents, generics, drug prices, biosimilars, and patient centricity, making the process more complex and delicate than in other industries.

The second element is related to the "digital initiatives" at each stage in the new drug development process. How technologies such as AI and machine learning are starting to be used in the drug development process and can be combined in the H&BP industry under DT environment and the phenomena in which BP and technology companies' convergence and collaborative projects are performed are key features of this element. Additionally, these technological advancements provide new strategies and Real-World Data (RWD) across new drug development processes [43].

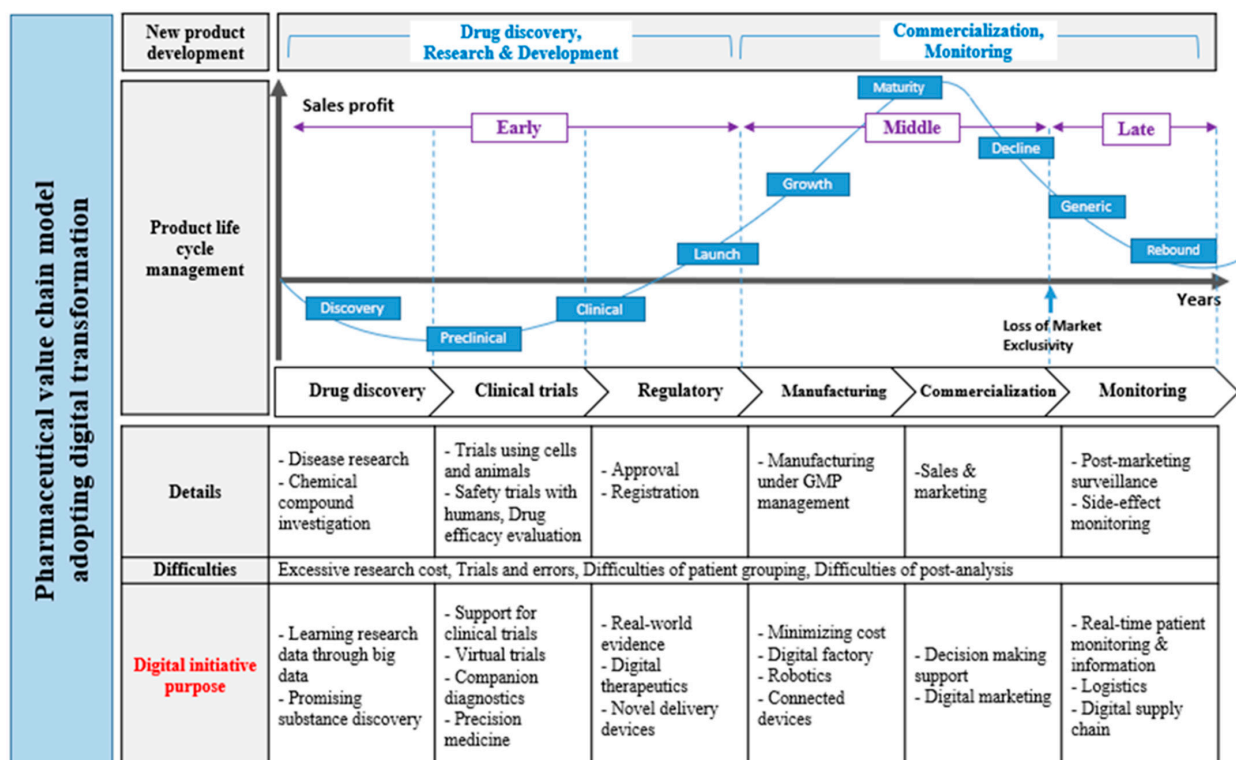
The third element focuses on "product life cycle (PLC) management." PLC management throughout the entire product process is an essential priority for pharmaceutical

companies, from the R&D stage of a product to the stage where the product expires after launch and patent expiration. This is linked to the pharmaceutical company's sales, cost, profit structure, and company strategies are established according to the characteristics of the products, competitors, and external environment. As discussed above, key changes in PLC management are linked to the new drug development process and digital initiatives in the DT environment.

Pharmaceutical PLC management is the process of managing the entire life cycle of a pharmaceutical product, from research, design, manufacturing, commercialization, and the product's end of life or withdrawal stages. Furthermore, pharmaceutical product's life cycle management, which pharmaceutical companies focus on, is a traditional and commercial operation tool to manage product investment, sales, and profit throughout the product's lifecycle. The PLC management process aims at gaining profitability and managing market share among competitors. If a patent expires, there will be competition from generics. It is essential to establish a pharmaceutical company's strategy at this stage. This is because it is a part that influences product sales, operation plans, profitability, and future development of new products. For example, pharmaceutical companies consider delivering different approaches with auto generic launch or combination product launch.

Based on the new pharmaceutical value chain elements and the effects of digital transformation on the drug discovery process stages, we now propose a new framework for sustainable value creation in the H&BP industry.

The new framework is illustrated in Figure 1. The framework displayed in Figure 1 integrates the new drug development process and PLC management of pharmaceutical drugs with digital initiatives undergoing the DT.



**Figure 1.** A New Digital Value Chain Framework for the Biopharmaceutical Industry. Source: Figure 1 is a modified and further developed model based on Korea Health Industry Development Institute (2020) [44], Das and Jadhav (2019) [45], and Kato (2018) [46].

As seen in Figure 1, new drug development and PLC management consist of two phases: (1) drug discovery and R&D, and (2) commercialization and monitoring. In more detail, the overall process is subdivided into a total of six stages: (1) drug discovery, (2)

clinical trials, (3) regulatory, (4) manufacturing, (5) commercialization, and (6) monitoring. As such, the pharmaceutical PLC management plan and strategy will stay as the key in addressing R&D productivity issues, in dealing with tighter reimbursement guidelines and repositioning against increasing generic and biologic product competition.

### 3.2. Key Features of the New Digital Pharmaceutical Value Chain and Business Transformation

This section discusses the role of *digital initiatives* in the pharmaceutical value chain model and how they affect pharmaceutical business transformation perspectives.

**Drug development process 1—Drug Discovery:** The first stage of drug discovery includes disease research and chemical compound investigation. The digital initiative perspective shortens the time for drug discovery by utilizing big data and AI. Substance discovery and candidate substance search are performed through more accurate prediction. Already in these processes, collaborations with many technology companies are taking place. Many companies span multiple drug life cycle stages, including drug discovery and data types, collaborating in the new drug development stages.

**Drug development process 2—Clinical Trials:** The second clinical trials stage involves conducting Phase I, II, and III studies after drug discovery. Clinical trials include safety testing in humans and validation of drug efficacy. This step helps to conduct clinical trials by incorporating digital initiatives efficiently. As argued in [47], big data and AI technologies are complementary. AI can help synthesize and analyze ever-expanding data employing data integration and interpretation, pattern recognition, and evolutionary modeling [47]. Even in the case of a generic drug, a one-size-fits-all approach may not be the best option anymore. Furthermore, the industry is in need of more well-trained data scientists. Industry-wide policies to fill this gap need to be put in place [48].

**Drug development process 3—Regulatory:** At the third regulatory stage, the approval and registration process for drugs that have been completed up to the Phase III clinical trials is in progress. Through the application of AI technologies, the Phase I and Phase II clinical trial results are better and more efficiently combined, patient-centered endpoints are developed, and real-world data (RWD) are collected and analyzed [47,49]. As argued in [50], RWD analysis serves several critical purposes for the biopharmaceutical industry, such as: “discovering or validating biomarkers,” “enabling a new understanding of a disease or disease associations,” “discovering new markers for patient stratification and targeted therapies,” finding “new markers for identifying persons with a disease,” and “pharmacovigilance.” AI will enable the collation and analysis of large data sets created through digital biomarkers, which will allow new clinical drug targets to be identified based on patients’ real-world data. The countries that have not been convinced of the use of digital technologies in the regulatory process can get and use appropriate regulatory information or refer to the experience from other countries that have adopted DT in their regulatory processes. In addition, matching or superseding the accuracy of manual processes at each regulatory stage could also be helpful to increase the efficiency of the regulatory frameworks.

**Drug development process 4—Manufacturing:** After the approval and registration of a pharmaceutical product, the process moves to the fourth manufacturing stage. This is handled based on good manufacturing practice (GMP) and the key stage in deciding the cost of goods sold (COGS) of pharmaceutical products. The objective of the digital initiative at this stage is to reduce production costs using digital factories robotics, and the production of healthcare products is also the main task involved. The pharmaceutical industries can employ predictive manufacturing approaches by reviewing the data and the information generated during the processes. The predictive manufacturing systems create new opportunities to increase the efficiency of manufacturing operations [48].

**Drug development process 5—Commercialization:** Pharmaceutical drugs are sold as finished products in the commercialization stage. In the market, prescriptions are made for patients, and procedures such as insurance benefits are made with related government ministries. Pharmaceutical companies put sales and investment through the sales and

marketing process and strive to maximize sales based on the attributes of product and marketing strategies. Digital initiatives will serve as a digital marketing tool and support decision-making in the promotion process. Due to COVID-19, digital marketing strategies have recently emerged in the pharmaceutical industry, and the importance of interactive activities based on online platforms and web symposia with physicians is increasing.

**Drug development process 6—Monitoring:** In this Monitoring stage, the side effects, commonly called post-marketing surveillance (PMS), are investigated. Since safety and efficacy are the most critical part of pharmaceutical products, safety information is continuously collected even after the product launch, and monitoring and response with the approved indications of product and labels are at the stage. The digital initiative at this stage would be real-time patient monitoring. As recently digital healthcare products have been developed and released under the digital healthcare environment, real-time observation of patient monitoring has emerged as an essential priority. Additionally, logistics and digital supply are major digital initiatives. Drug development and approvals are costly and lengthy, and much time is dedicated to preliminary research and clinical trials. According to [51], the median R&D cost for developing and marketing a new drug is nearly one billion US dollars (USD 985 million). A key strategic objective in the biopharmaceutical industry is to reduce the financial cost of new drug development and reduce the time-to-market. With AI integration and digital initiatives at every stage of the PLC, it might be possible to reduce the standard research time for a new novel drug from five years down to only one year [52].

These traditional drug development processes and PLC management strategies have changed dramatically due to digital transformation. First of all, the most significant change is the time and cost of developing a new drug. It is a secure system to prioritize the development of new drugs. In other words, to ensure its effectiveness and safety, it is necessary to go through a thorough step-by-step verification process. This is why it takes time for pharmaceutical companies to develop new drugs. However, as digital technology developed and AI, machine learning innovations have been applied to the biopharmaceutical industry, the time required for drug development has been reduced. In addition, as the technology for significant data management advances, many changes are being made to data, analysis, and patient enrollment necessary for clinical research.

#### 4. Discussion: New Pharmaceutical Value Chain Model with Digital Transformation and Open Innovation

The integrated value chain model in the H&BP industry under DT connects the new drug development with the PLC management processes rather than treating them separately. Conventionally, when product sales reach a mature stage and proliferate product promotion and sales, the patent expires, leading to development and release of generic products. Under our integrated value chain model, the big data analysis and AI tools prompted during digital transformation enable the continuous monitoring of the operational efficiency and the side effects of the product as early as R&D stage to the post-commercialization stage. The most crucial index to be monitored is the safety of pharmaceutical products, as it is the main issue in the H&BP industry.

R&D investment in the pharmaceutical industry is an investment in the future returns when products make success. However, this industry's ROI is relatively more uncertain due to higher failure rates, and it is more time-consuming than other industries. From the company's financial point of view, if the cost of R&D investment for drug development increases, internal ROI from R&D will likely decrease. This burdens the company financially leading to hesitations and tighter control for further new approvals. Since the digital approach will improve the efficiency and accuracy of the existing PLC management methods, new investment strategies need to be modified. Establishing the digital system and strategy will be the essential factors for the company's financial and sustainable management perspective.



As we mentioned, AI technology has begun to be applied to all stages in the drug development process. The new drug development process will save both time and expense. This stage is so crucial that the drug development and the industry's intrinsic goal form the basis of the H&BP industry. Digitally enhanced drug development using AI is still in its infancy. It is hard to predict precisely how the H&BP industry efficiency will develop in the future due to the complex and volatile nature of DT at this stage. It is highly likely that companies will undergo a certain period of trial-and-error stage through close observation and industry-wide collaboration.

Due to this current circumstance, experts are turning to open innovation as an essential proponent at this stage since it allows companies to utilize external knowledge and resources in the innovation process [53]. In recent years, extrinsic and intrinsic factors have led to more active invitations of external sources through open innovation such as partnerships and open sourcing for R&D virtualization in the pharmaceutical sector [54]. Open innovation has been adopted as an important indicator for collaboration across H&BP and related technology industries [35]. This has led to digital transformation application to pharmaceutical product development, digital therapeutics, and telemedicine technology advancement [25,39].

In particular, as more H&BP companies target R&D innovation that applies AI or machine learning, an effective partnership strategy that connects with other industries and companies at each level of the value chain will be paramount. The industry collaborations including partners in related industries will increase the probability and ROI from R&D and development.

The time spent on development can be reduced by incorporating digital technologies that are different from the existing drug development processes. One example is the development of various vaccines against COVID-19. The recent pandemic shows how collaboration that embed digital technology was significantly improved and activated with COVID-19 [3,4]. Open innovation particularly links to crowdsourcing process that expedite economic viability by reducing transaction costs compared to internal alternatives, although specific costs associated with rewarding unused ideas and codifications, to name a few, are still inconclusive and need further research [55].

Academic and clinical evidence remain to be solved, and studies on open innovation and other related topic are addressing specific scientific and economic impacts of open innovation [56]. Within open innovation, co-patenting is a possible solution that accelerates successful transformation of the new digital value chain in the biopharmaceutical industry [57]. The general mechanism is that open innovation allows more dynamic invite for and convergence with external intelligence as well as resources in each innovation process [53].

AI and digital initiatives discussed in this paper offers ways to attain cheaper, more efficient, and improved success of clinical trials [58]. In a survey of biopharmaceutical company managers and Industry 4.0 experts, Silva et al. (2020) found that the key benefits of implementing Industry 4.0 elements in the biopharmaceutical industry are expected to be mostly in the areas of increases in productivity, competitiveness, and product quality [59]. Overall, various collaborative strategies under open innovation strategies such as co-patenting leads to further value creation [28,29].

Table 2 shows some key changes in the pharmaceutical value chain undergoing digital transformation.

**Table 2.** Digital Value Chain for Drug Development and Business Transformation Indicators.

Index	Related Indicators (Sample)	Major Changes of Indicators (Business Transformation)	Reference
New Drug Development Process	AI application	<ul style="list-style-type: none"> <li>Digital and AI application changes</li> <li>pharmaceutical drug production from drug discovery to the monitoring process</li> </ul>	Chen and Decary (2020) [60]
	Novel drug development	<ul style="list-style-type: none"> <li>New drug development with digital technology adoption</li> </ul>	Drug Development and Delivery (2020) [17]
	Open innovation	<ul style="list-style-type: none"> <li>Collaboration between technology and biopharmaceutical industries</li> </ul>	Réda, Kaufmann and Delahaye-Duriez (2019) [35], Pinarello et al. (2021) [53], Schuhmacher et al. (2018) [54], Christensen and Karlsson (2019) [55], Yeung et al. (2021) [56], Maamari and Osta (2022) [57]
	Process simplification	<ul style="list-style-type: none"> <li>Simplify the drug approval and registration process</li> </ul>	Swissmedic (2019) [61]
	Digital healthcare products	<ul style="list-style-type: none"> <li>Focus on convenience and ‘Quality of Life’ for patients (ex. remote consultation and monitoring)</li> </ul>	Taylor (2020) [62], Phillips (2019) [41], WHO (2019) [42], Hill and Powell (2009) [63]
	Deregulation	<ul style="list-style-type: none"> <li>Deregulation of the product development process</li> </ul>	DITR (2019) [64]
	Company sustainability	<ul style="list-style-type: none"> <li>Reduce new drug development time and cost</li> <li>Sustainable growth of the pharmaceutical industry</li> </ul>	Pushpakom et al. (2019) [9], Tollman et al. (2016) [10], DiMasi et al. (2016) [11]

Source: Authors’ construction based on the literature reviewed.

## 5. Conclusions

The H&BP industry is undergoing important and revolutionary change. It is establishing new standards for the emerging new normal after COVID-19. New drug development is a crucial activity that needs to be managed and monitored for public health and safety worldwide. DT is a rapidly developing force that is reshaping the pharmaceutical industry. A digital initiative is now included in the product life cycle management and step-by-step processes, from drug discovery to candidates in the new drug development stage to product approval, launch, and eventual end-of-life or patent expiry stages. DT has drastic effects on each stage of the PLC, and it will transform the H&BP industry business models. Companies that are faster to adapt DT will develop more sustainable competitive advantages. Most importantly, open innovation can expedite this new wave when collaborations increase within the industry and with other related industries.

The pharmaceutical industry portfolios have started to change recently as investments in the development of new drugs and vaccines due to COVID-19 have been undertaken aided by the new resources and capabilities available under the digital transformation. A similar approach will likely help the development of new drugs in other areas. Therefore, as part of the efforts to redress the recent changes in the H&BP industry, this paper’s new value chain framework integrates the three existing and traditionally separate categories of the new drug development process, digital initiatives, and PLC management into a single framework. This approach embeds digital values created in each stage of the PLC to offer a strategic guideline for users as a continuum instead of the departmentalized approach common under the traditional pharmaceutical value chain model. This approach is novel in academic research as in the H&BP industry, which has been assumed as traditionally conservative due to health and life safety concerns. Our integrated model can contribute to optimize the drug development process by offering a systematic model to enhancing both safety and speed.

One of the solutions to improve the utility of the integrated model depends on the volume of data, and this is similar in other fields that undergo DT. As more data on the probability and speed of successful new drug development under the DT become available, it will be possible to conduct more accurate analyses and applicable results. Until now, the comparatively limited data and information are the areas to be improved. However, we

believe this is not a critical limitation because accumulated data and experiences in the H&BP industry worldwide would gradually improve the condition.

Despite the current challenges in the data volume, the opportunities to be foreseen through our integrated model is immense. For instance, it would be possible to examine what categories of new drugs can further develop through this approach and what features these new drugs have in terms of their efficacy and safety compared to existing new drugs. From the standpoint of pharmaceutical biotechnology companies, research on financial and product portfolios is also expected to be a good research topic in the future to validate how the new drugs launch through these processes and how it contributes to the overall growth and profit of the company.

Industries such as the pharmaceutical and bio-health sectors are looking for appropriate strategies and standardized platforms for new drug development and new business structures that can combine digital healthcare as solutions to adopt, explore, and find opportunities in the new post-COVID environment. Our industrial convergence model shows the importance of pursuing collaboration amongst industries, and this is an important element in the digitalizing landscape. This paper also suggests that increased collaboration with other related industries could help the pharmaceutical industry and companies to achieve sustainable growth by linking to other industries, companies, and technologies.

Creating new values by integrating different resources and entities through DT will be a key priority to enable optimized speed and safety in the H&BP industry at multiple levels. The new conceptualized model introduced in this paper has made a meaningful initiation to guide this trend. However, sequential studies that apply and empirically test the models will be the important next step in finding more specific guidelines, conditions, and company or drug-specific implications during and after operationalization to enhance the model's applicability.

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