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Faculty of Business Economics

Master of Management

Master's thesis

Exploration of Biopharmaceutical Ecosystems

Tram Anh Doan

Thesis presented in fulfillment of the requirements for the degree of Master of Management, specialization Strategy and Innovation Management

SUPERVISOR :

Prof. dr. Jean-Pierre SEGERS

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www.uhasselt.be
Universiteit Hasselt
Campus Hasselt:
Martelarenlaan 42 | 3500 Hasselt
Campus Diepenbeek:
Agoralaan Gebouw D | 3590 Diepenbeek

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I. Problem statement

The global pharmaceutical industry is a crucial player in economic growth and a healthier world, with its value reaching USD 1.5 trillion in 2023.

Within this sector, biopharma is gaining public attention due to its therapeutic innovation focused on advanced treatments like vaccines, genetic modification, and antibodies. Despite its innovative contribution to social wellness, biopharma companies are facing growing global issues, such as the aging population, rising healthcare costs, and sustainability pressure, that push companies to rethink their operation and value creation.

Key trends, particularly artificial intelligence (AI), digitalization, and sustainability, are changing the way value is created, how companies engage with patients, and how they stay competitive. AI is accelerating drug discovery, digital tools are transforming care delivery and patient interaction, and sustainability efforts are pushing companies to align with global goals like the UN's 17 Sustainable Development Goals.

Despite growing interest, there's still limited understanding of how these trends work together to shape business model transformation in the biopharmaceutical industry. Differences between company sizes and across regions are particularly underexplored. This study addresses that gap by examining how biopharma companies, from early-stage startups to large multinationals, are adapting their models in Asia, Europe, and the United States.

II.Research Methodology

The Quadruple Helix framework was employed to explore together perspectives from industry, government, academia, and patient communities, providing a more complete picture of the sector's evolution. This study used a qualitative approach using semi-structured interviews with 10 experts selected through purposeful sampling. Participants were required to have significant experience in biopharma or healthcare and represent perspectives across the Quadruple Helix—industry, academia, government, and patients. The sample included startups, SMEs, and large firms across Asia (Vietnam, Singapore), Europe (Belgium, France), and the U.S. Interviews lasted 60–75 minutes and were conducted online or in person. All participants gave informed consent. The methodology enabled exploration of how business model transformation differs by firm size and region in response to emerging trends like AI, digitalization, and sustainability.

III. Findings

The biopharmaceutical industry is undergoing a fundamental transformation, largely driven by the convergence of technological innovation, shifting societal needs, and sustainability. Insights from ten expert interviews across Asia, Europe, and the United States reveal how companies are adapting their business models in response to three major trends: artificial intelligence (AI), digitalization, and

sustainability. These changes are not occurring uniformly but are instead shaped by firm size, geography, and the broader innovation ecosystem.

A. The impacts of emerging trends on the biopharmaceutical industry

Artificial intelligence is speeding up early drug discovery, what once took years can now happen in months. It's taking over routine lab work and market research, and even supporting new tools like digital twins. But the benefits come with trade-offs. Poor-quality data can lead to bad results, and in the rush to move fast, companies risk skipping important validation steps. There's also workforce impact, as many routine jobs are being replaced with roles that focus on overseeing AI.

Digital technology is also changing healthcare by providing more real-world health data. This helps with earlier diagnosis and supports a shift toward preventive care instead of only treating illness. Platforms that link hospitals, pharmacies, insurers, and patients show promise, but uneven insurance policies and patient concerns about remote care still slow adoption.

Sustainability, while less developed, is starting to gain ground. Support from government policies, joint public-private projects, and pressure to protect brand reputation are pushing firms to act. Practical steps like drug repurposing and leaner clinical trials show how companies are trying to meet sustainability goals without overhauling their entire system.

B. Business Model Types in response to these emerging trends

1. Patient-Centric Models

Companies are now bringing patients into the process much earlier, sometimes as early as when new molecules are being considered. They co-design clinical trials to focus on real-world quality-of-life improvements, not just clinical metrics. Many also offer added services, like free transport to clinics, to help patients stick with treatment.

2. Platform-Based Models

- **Product platforms** use a core scientific tool or method—like mRNA technology or a library of compounds—to develop multiple treatment options more efficiently.
- **Transaction platforms** manage the flow of data and payments across the healthcare system, often built on freemium or subscription models.

3. Drug Repurposing

Thanks to AI, companies are revisiting older or failed drug compounds to find new uses, speeding up R&D and cutting costs. This approach also fits with sustainability goals. One example: Paxlovid, originally developed for a different purpose, was successfully redirected to treat COVID-19.

4. Telemedicine Ecosystems

Combining wearable tech with remote doctor visits, this model helps reach people in rural areas or those with limited mobility. It lightens the load on healthcare systems and creates new revenue streams, though legal and insurance issues are still being worked out.

5. Technology-Transfer Spin-Offs

Universities are licensing out patents or launching startups through their tech-transfer offices. This brings new innovations to the market and creates local jobs. But in some places, it's still hard to find people who understand both science and business well enough to make these ventures succeed.

6. Virtual Biotech Firms

These are small, agile companies that don't run their own labs. Instead, they outsource lab work to contractors and use AI tools to manage research projects remotely. This lets them operate with lower costs and more flexibility.

Table A: The level of emerging trend influence in business model evolution

Business model	AI	Digitalization	Sustainability
Patient-centric model	Moderate	High	High
Platform-based model	High	High	Moderate
Telemedicine model	Low	High	High
Drug repurposing model	High	Moderate	High
Technology transfer	Low	Low	High
Virtual firm	High	High	Moderate

C. Different business transformations in regions

- **Asia (Singapore & Vietnam):**
  - ***Patients*** are highly mobile-first, yet healthcare use of apps trails social media and e-commerce.
  - ***Firms*** in Singapore deploy AI across R&D; Vietnamese firms use digital tools mainly for marketing or biosimilar tech-transfer, constrained by price-sensitive consumers and talent shortages.
  - ***Governments*** offer tax breaks for "high-tech" status, but research commercialization is hampered when the state claims the bulk of licensing revenue.
  - **Business model:** The potential of emerging biopharma business models in this region will be *platform, telehealth and drug repurposing*

- **United States:**
    - ***Ecosystem maturity*** supports end-to-end AI integration, thriving virtual biotechs and vibrant drug-repurposing ventures.
    - ***Government funding*** for basic science is tightening, but orphan drug credits and state programs still focus innovation on rare diseases.
    - ***Academia–industry coupling*** is strongest globally, with tech-transfer offices pushing patents and spin-offs as standard career paths.
    - **Business model:** *tech transfer, AI-driven model, virtual biotech structures, and drug repurposing*

- **Europe (Belgium & France):**
    - ***Scientific depth*** remains world-class, and Horizon funding underwrites early innovation.
    - ***Regulatory caution***—GDPR and tight reimbursement rules—slows data-sharing and telemedicine uptake; patients still value in-person consultations.
    - ***Corporate strategy*** trends toward partnering with specialist AI/bio-informatics firms rather than building capabilities internally, while university incubators are closing the commercialization gap.
    - **Business model:** *AI-powered drug discovery, platform model, and technology transfer model*

D. Business model differences by firm size

Dimension	Start-ups	SMEs	Big Pharma
Adaptation speed	Very high—AI, digital and virtual models integral from day one	Moderate—selective, ROI-driven	Slow—legacy processes, and dominant logic hinder rapid scaling
Favored BMs	Virtual biotech, AI platforms, drug repurposing, spin-offs	Bio-informatics services, targeted platform plays, niche repurposing	Patient-centric orchestration, integrated data platforms, personalized therapies

The study proposes a clear, evidence-based insights that traces how new technologies shape business models across different company sizes and regions. It helps leadership teams test investment decisions against real-world patterns and points regulators to the specific data-sharing and reimbursement hurdles that slow promising therapies. By providing comparative findings, the work also gives researchers a richer empirical base for refining current theory. In this way, the study adds a grounded, actionable perspective to the conversation about future predictions of the biopharmaceutical industry.

IV. Critical Considerations and Recommendations

This study shows how new technologies are changing business models in biopharma, but it has a few important limitations.

First, the analysis doesn't include China - the world's largest market for both pharmaceuticals and AI. That leaves a major gap in understanding how these trends are playing out across Asia.

Second, insights from the U.S. are based on a single interview. Although collected insights are valuable, one person's view cannot represent such a large and complex industry. Therefore, any conclusions about the U.S. should be seen as initial signals, not firm findings.

Third, the study takes a wide-angle, global view. While that gives a broad picture, it lacks a deep look into country-specific factors like policy, infrastructure, or cultural norms, all of which influence how fast and how well new models are adopted.

Future research should include China, bring in more voices from the U.S., and dig deeper into individual countries to better capture how biopharma business models are evolving in specific local contexts. Moreover, scholars should deepen understandings of biopharma business-model shifts in two ways: (1) investigate how biopharma companies create adaptive business models that withstand political and economic shocks—such as tariffs or cuts in U.S. federal funding—by leveraging digital infrastructure, flexible operations and strategic alliances; and (2) study start-ups in depth, assessing how they scale their innovations despite limited funding, partner trust issues and competition from larger firms. Comparing start-ups that thrive with those that struggle can reveal how stronger links with universities, big-pharma partners or investor networks help them keep their unique strengths while remaining competitive in a tightly regulated industry.

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1. INTRODUCTION

The pharmaceutical sector remains one of the most critical industries in terms of global health and economic stability. In 2023, the global pharma market exceeded USD 1.5 trillion in value (Statista, 2025b), underlining its size and significance. Within this field, the biopharmaceutical sector plays a uniquely strategic role by advancing targeted therapies, vaccines, and regenerative treatments. Despite biopharma's contribution to medical innovations that have helped people live longer and healthier lives, it is well known as one of the most heavily regulated and complex sectors. Developing a single drug can take more than ten years, cost billions, and demand strict adherence to clinical, regulatory, and ethical standards.

Today, the biopharmaceutical industry is at a turning point. Social concerns such as aging populations, rising healthcare costs, and growing sustainability concerns, together with rapid change in technology, are forcing companies to rethink how they run their business. Artificial intelligence (AI), digitalization, and sustainability are reshaping how biopharmaceutical companies create value, engage with patients, and build competitive advantage. AI is accelerating drug discovery, streamlining repetitive workflows, and enabling the development of precision medicines. Meanwhile, digital platforms are transforming patient engagement and introducing new transactional models within healthcare delivery. At the same time, increasing pressure to meet environmental and social expectations is prompting firms to align with global sustainability frameworks, such as the United Nations' 17 Sustainable Development Goals (SDGs) and the 2030 Agenda.

While much of the existing literature focuses on discrete aspects of technological innovation or regulatory change (Gaynor et al., 2024b; Langione et al., 2019; Smuha, 2021), there are still few studies that look at how all these factors work together to reshape the core structure of biopharmaceutical companies. Even fewer compare how these transformations vary by company size or across different regional ecosystems. This study aims to explore how these major trends are driving change in the biopharmaceutical industry. It focuses on three main goals:

1. To identify the emerging business models shaped by these trends - AI, digital technologies, and sustainability.
2. To understand how business model changes differ among startups, small and medium-sized enterprises (SMEs), and large companies.
3. To compare regional differences by analyzing expert’s insights from Asia (specifically Singapore and Vietnam), the United States, and Europe.

By drawing on qualitative insights from industry experts and applying the Quadruple Helix framework which examines the interplay between academia, industry, government, and civil society, this study offers a well-rounded perspective on emerging business paradigm shifts in the biopharmaceutical sector. It contributes to a deeper understanding of how biopharmaceutical firms strategically adapt to emerging

trends and provides practical implications for organizations seeking to navigate and shape the future of healthcare innovation.

This thesis is structured as follows. In the Literature Review (Chapter 2), we introduce the biopharmaceutical industry landscape (Section 2.1), the key actors shaping its innovation ecosystem (Section 2.1.2), and the theoretical foundation of business model innovation (Section 2.2). We then explore the impact of emerging trends—namely artificial intelligence, digital technologies, and sustainability—on biopharmaceutical transformation (Sections 2.3.1 to 2.3.3). In Chapter 3, we present the research methodology, including the study's qualitative design (Section 3.1), data collection and coding framework (Section 3.2), and thematic analysis approach (Section 3.3). Chapter 4 outlines the empirical findings, with a focus on business model evolution (Section 4.1) and comparative transformation across firm sizes and regions (Section 4.2). In Chapter 5, we analyze the broader implications of these findings (Section 5.1), contrast organizational and regional dynamics (Sections 5.2.1 and 5.2.2), and discuss practical implications (Section 5.2.3). Finally, in Chapter 6, we conclude the study with key takeaways and summarize its contributions, followed by a discussion on research limitations and recommendations for future inquiry (Chapter 7).

2. LITERATURE REVIEW

2.1 Setting the scene

2.1.1 The landscape of Biopharmaceuticals

The biopharmaceutical industry is an emerging industry that has recently drawn significant public interest thanks to its profound impact on the healthcare revolution. Although biopharmaceutical products have been on the market for over 40 years, there is still no clear, standardized definition for the industry *(Pande et al., 2025; Rader, 2008; Sekhon, 2010).* The term "biopharmaceuticals" first appeared in the 1980s and typically refers to drugs whose active ingredients are derived from natural biological sources and manufactured using biotechnology (Kesik-Brodacka, 2018; Rader, 2008). In simpler terms, biopharmaceuticals are where biotechnology meets pharmaceuticals.

Unlike traditional pharmaceutical drugs or also known as chempharmaceuticals, synthesized from chemical processes, biopharmaceuticals rely on biological substances such as tissues, cells, and living organisms in the development of therapeutic proteins, vaccines, antibodies, and gene therapies *(Haider, 2023; Sekhon, 2010)*. Table 1 outlines different categories of biopharmaceuticals and their related therapeutic uses.

This study will focus on red biotechnology, which is a sub-sector that includes drug discovery, vaccines, diagnostics, genetic therapies, and regenerative medicines (Segers, 2015). Red biotechnology innovation is transforming the biopharmaceutical industry by enabling precision treatments that reduce

side effects and offer new therapeutic options for rare or previously untreatable diseases. A central component of this field is the development of Advanced Therapy Medicinal Products (ATMPs). ATMPs are a specialized category, in which medicines are based on gene therapy, cell therapy, and tissue-engineered therapy. ATMPs use gene-modified donor cells or biologically identical tissues to target diseases at a molecular level, offering patients a safer and more effective treatment (Deloitte, 2024; McKenzie et al., 2022). These advanced therapies highlight the growing potential of red biotechnology to drive personalized medicine and represent a significant shift toward more targeted, effective healthcare solutions.

Era	Description	Examples	Therapeutic indications
19th Century – Present	"Conventional" biotech products Isolated from animals or humans	Blood and blood components e.g. blood plasma	Blood transfusions
		Stem cell therapies e.g. bone marrow transplants	Leukaemia
		Immunoglobulins	Inducing immunity for diseases such as tetanus following exposure or in high-risk individuals
19th Century – Present	Vaccines Provides immunity to certain diseases	Inactivated	Measles
		Attenuated	Influenza
		Toxoid	Tetanus
		Subunit	Human papilloma virus
		Conjugate	Hepatitis
1982 – Present	Recombinant biopharmaceuticals Produced using recombinant DNA technologies	Blood factors e.g. Factor VIII and Factor IX	Haemophilia
		Growth factors e.g. human growth hormone, gonadotrophins	Growth hormone deficiencies
			Breast cancer
			Prostate cancer
			Endometriosis
		Cytokines e.g. interferons, interleukins, erythropoietin	Anaemia
			Bone cancer
			Hepatitis
			Multiple sclerosis
		Enzyme replacement therapies	Lysosomal storage disorders e.g. mucopolysaccharidosis
		Monoclonal antibodies	Cancers
			Autoimmune disorders
2017 – Present	Gene Therapies Introduction of foreign nucleic acid into cells to induce therapeutic effects	Somatic cell gene therapy	Haemophilia
			Congenital blindness
			Leukaemia

Table 1: Example of biologically sourced pharmaceutical products (Lalor et al., 2019)

Biopharmaceuticals are becoming increasingly important in the pharma industry owing their rapid growth. Impressively, its global market size was valued at USD 448.1 billion in 2023 and is expected to reach USD 745.1 billion by 2030. The United States accounts for more than half of the global market share, followed by Europe at 34.4%, and the Asia-Pacific region at roughly 10% *(P&S Intelligence Research, 2024)*.

In fact, the biopharmaceutical industry has undergone significant shifts in the last decade. Gautam and Pan (2016) highlighted a trend of industry momentum shifting from West to East. Markets in China, Japan, India were expected to directly compete with established global leaders by 2025. This prediction was reinforced by the recent report. According to the *(Pharmaceuticals Executive 2024)*, US and European players still dominated the list of the world's 50 largest pharma companies. Pharma giants such as Johnson & Johnson, AbbVie, Pfizer, Novartis, AstraZeneca and Merck successfully secured their leader positions. However, companies like Takeda (Japan), Sun Pharma (India), and Yunnan Baiyao (China) are also making significant progress. Firms from the Asia-Pacific region now hold more than a quarter of the positions on the global top 50 list, reflecting their growing influence in the industry.

2.1.2. Biopharma ecosystem and stakeholders

2.1.2.1 Quadruple helix model

To better understand innovation from a broader perspective, the Triple Helix Model was introduced in the 1990s (Etzkowitz & Leydesdorff, 2000). This framework describes the interaction between three key actors: universities, industry, and government—each representing knowledge, innovation, and policy consensus, respectively (Etzkowitz, 2017; Etzkowitz, 2008). According to the model, collaboration among these sectors plays a crucial role in supporting regional entrepreneurship and driving economic growth (Cai & Etzkowitz, 2020)

Despite its popularity, the Triple Helix has faced criticism. Etzkowitz (2008) noted that the model tends to emphasize top-down coordination while overlooking a bottom-up contribution which is described as "an active civil society in which initiatives are encouraged from various parts of society role".

To address this gap, (Carayannis & Campbell, 2009) expanded the Triple Helix to Quadruple Helix model by incorporating "civil society" or "public" as the fourth dimension in the helices. The authors even further precisely defined "public" as the "media-based and culture-based public", emphasizing the role of arts and cultural expression in innovation, which had previously been underrepresented(Carayannis et al., 2012). By engaging public environment into the model, the Quadruple Helix brings attention to the importance of social dynamics, including the societal behavior considerations (knowledge society) and democracy (knowledge democracy) (Campbell & Carayannis, 2013; Carayannis & Campbell, 2014). In this framework, users and patients are not passive recipients but active drivers of innovation (see Figure 1). This more inclusive model encourages a collaborative innovation ecosystem that benefits society as a whole. Notably, regions adopting the Quadruple Helix approach have reported higher levels of economic growth (Afonso et al., 2010)

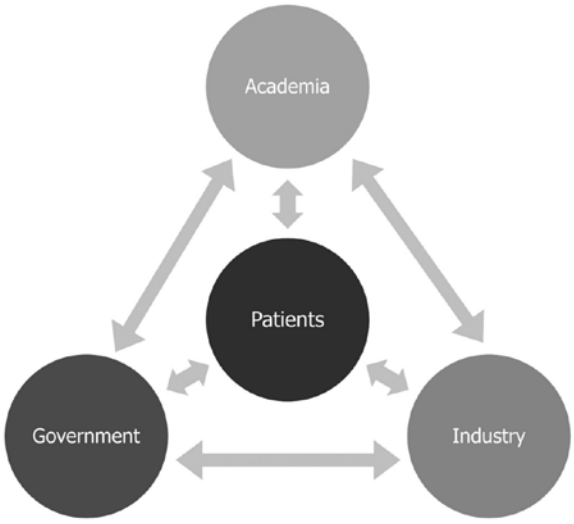

Figure 1: The quadruple helix which patient-centric approach (Durez, P. et al,; 2020)

2.1.2.2 Biopharmaceutical ecosystem:

Unlike many other technology-driven industries, biopharmaceutical innovation is heavily based on tacit knowledge and follows a nonlinear process, making it highly complex and difficult to replicate or transfer. These characteristics explain why the industry consists of a multi-layered and tightly connected ecosystem of stakeholders. Biopharmaceutical R&D innovation ecosystem depends on collaboration among a wide range of stakeholders, including patients, academic institutions, biotech startups, large pharmaceutical companies, venture capital, and regulatory agencies (Bettanti et al., 2021; Puślecki, 2021) (Figure 2). Patients are increasingly seen as central to this ecosystem, not only as recipients of value creation but also as vital contributors to patient-centric innovation (Puślecki, 2021). In this context, cross-disciplinary partnerships are critical for overcoming barriers in early-stage drug development, which is often described as the "valley of death due to its high risk of project failure (Calza et al., 2021).

While innovation ecosystems (IE) have received significant academic attention, their specific structure in the biopharmaceutical sector remains somewhat unclear. Bettanti et al. (2022) proposed a detailed framework that outlines the roles of key stakeholders in value creation.

Universities and research institutes act as central hubs for generating knowledge and transferring technology. They help turn academic discoveries into commercial applications (Triulzi & Pyka, 2011; Vlaisavljevic et al., 2020). This reinforces the earlier discussion of Moscho and Leiter (2001), who emphasized how higher education institutions promote biopharma growth through patenting and the creation of spin-offs. More recently, there has been a shift in academia toward applied research, further strengthening its role in the sector (Triulzi & Pyka, 2011). Universities are not only knowledge centers but also leaders in building entrepreneurial ecosystems (Audretsch, 2014; Graham, 2013). For example, Ghent University (Belgium) strategically partnered with Pfizer in the CESPE innovation cluster to accelerate pharmaceutical manufacturing (CESPE, 2023).

Industry players, including both large firms and startups, alongside venture capital, also play vital roles in the creation of an entrepreneurial society. These companies contribute to both drug development and commercialization by sharing knowledge, resources, and financial risk through strategic partnerships (Bettanti et al., 2021) Startups and biotech incubators bring cutting-edge technology and research, while established pharmaceutical firms offer funding and commercialization expertise (Bettanti et al., 2021; Domonkos & Hronszky, 2010). A notable example is the collaboration between Evotec, a German biotech company, and French drugmaker Sanofi. Sanofi committed €250 million in funding, while Evotec provided the research expertise to obtain rapid and efficient drug discovery and development (Evotec AG, 2018). More recently, Eli Lilly launched a $500 million biotech venture fund aimed at supporting startups and innovators focused on next-generation healthcare technologies, further reinforcing the industry's commitment to nurturing early-stage innovation (Fierce Biotech, 2025).

Governments are equally essential in shaping the sector. Given the tremendous R&D investment and high uncertainty of drug discovery, regulatory agencies encourage the development of novel innovations by providing financial support through loans, subsidy policies, tax incentives and R&D funding (Gao & Chen, 2022; Li et al., 2023). These policies are particularly important during preclinical stages. For instance, regulation agencies often fund early-stage research in public institutions, which reduces risk for firms later in the process (Songane, 2019). Such support has been shown to increase both private returns and social welfare (Chen et al., 2020; Hill et al., 2015; Huang et al., 2022). Additionally, policies that include new therapies in medical insurance schemes or offer price reimbursements improve market access and encourage further innovation (Huang et al., 2022). Policymakers also guide research toward public interest, and align industry innovation with society's health needs (Mazzucato & Li, 2021).

The role of patients is gaining attention in the drug development process. Recent studies have highlighted a shift toward patient-centric approaches, where patient feedback and engagement are central to shaping drug discovery and development processes (Fleissig et al., 2025; Michaels et al., 2019; Smith & Benattia, 2016; Timpe et al., 2020; Yeoman et al., 2017). Involving patients improves the relevance of drug development and ensures therapies are more closely aligned with user needs (Gorbenko et al., 2022; Smith & Benattia, 2016).

The biopharmaceutical industry also benefits significantly from regional clustering. The sector tends to thrive in areas with a high concentration of biotech firms and related institutions, forming regional and sectoral innovation systems (Cooke, 2002). These clusters enhance collaboration among academic institutions, healthcare providers, and pharmaceutical companies (Vlaisavljevic et al., 2020). Physical proximity fosters knowledge exchange and collective value creation that surpasses what individual firms could achieve alone (Adner, 2006). For example, pharma firms or biotech incubators within clusters can draw on shared regional expertise, encouraging targeted investment and partnerships for advanced innovations (Zeller, 2010). These clusters often show higher levels of patenting and innovation, as seen during the COVID-19 pandemic, when coordinated responses were especially critical (Gao & Zhu, 2022).

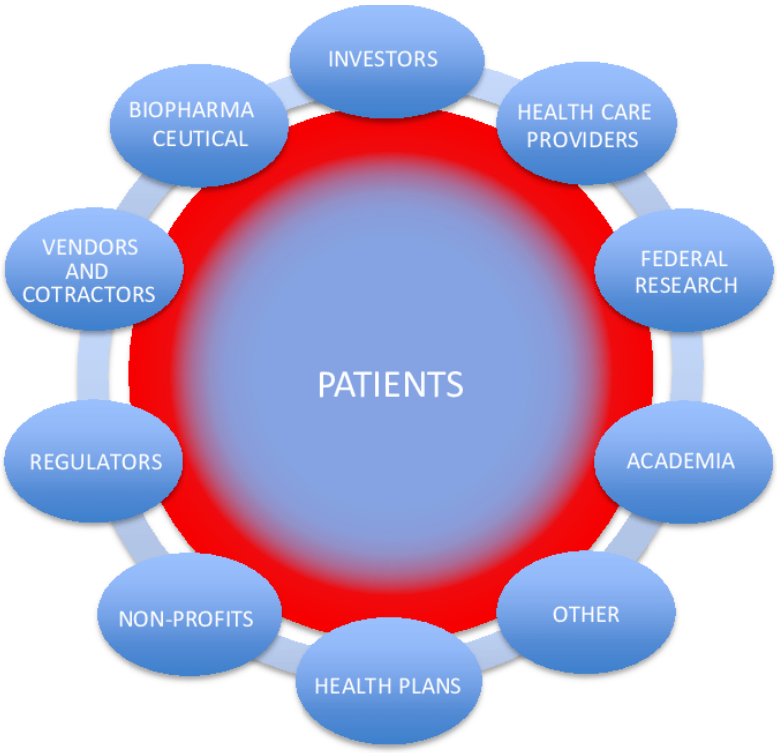

Figure 2: Illustrative biopharmaceutical R&D innovation ecosystem (Puślecki, 2021)

2.2. Business models innovation in the biopharma industry

2.2.1. Theoretical background of business model

Although the term "business model" first appeared in 1957 (Bellman et al., 1957), it gained widespread attention in both academic and business contexts with the rise of the internet and e-commerce in the 1990s (Hedman & Kalling, 2003; Wang & Wu, 2011; Zott et al., 2010). Since then, it has been widely used to describe how organizations create, deliver, and capture value (Osterwalder & Pigneur, 2009). A comprehensive business model typically includes elements such as customer segments, competitors, value propositions, core activities, organizational structure, resources, and interactions within factor markets. It also reflects causal relationships and how the model evolves over time (Hedman & Kalling, 2003). DaSilva and Trkman (2014) argue that a business model should not only describe an organization's current operations but must also be supported by strategy and capabilities to adapt to future changes. A similar view was shared by Richardson (2005), who emphasizes that the activities outlined in a business model should be strategically aligned, helping to close the gap between planning and execution.

Zott et al. (2010) highlighted the business model was treated as a new unit of analysis. Teece (2010) defined this unit as a value proposition that aligns an organization's offerings with customer needs. Building on this idea, (Gassmann & Frankenberger, 2014) proposed a more practical framework, breaking the business model into four key dimensions: who customers are, what business value proposition is, how they deliver their value, and why this model is profitable. Tools such as the Business

Model Canvas have since become popular for visually mapping and developing business models (Schmuck, 2021).

While much of the literature focuses on firm-level activities and mechanisms for creating and capturing value, several scholars have argued that the business model itself can be seen as a source of competitive advantage (Casadesus-Masanell & Ricart, 2010; Zott et al., 2010). A well-designed business model not only enhances value creation (Morris et al., 2005) but also fosters industry transformation by setting new model standards (Magretta, 2002). Both theoretical and empirical studies have identified a causal link between business model design and firm performance, reinforcing its importance in venture development and long-term success (Zott et al., 2010).

2.2.2. Business Model Innovation in (Bio) Pharmaceuticals Sector

The global biopharma economy has high business risks and is heavily reliant on its strong network collaboration. In this context, having a strategic business model is crucial for firms to manage the stakeholder complexity and improve the success probability.

Historically, due to the proprietary nature of drug development, most pharmaceutical innovation occurred behind closed doors within individual firms (Foege et al., 2019; Gillespie et al., 2019). This approach commonly known as closed innovation, which was long the standard approach in the industry (Chesbrough, 2003). Segers (2018) and (Thong, 2020) summarize the most common concepts of closed innovation, which are:

- **Product-based model:** The pharmaceutical firm controls the whole value chain from upstream research and development to downstream regulatory approval, sales, and marketing (Gillespie et al., 2019; Segers, 2018). The fully integrated biopharmaceutical company (FIBCO) is a typical form of this model, where revenue mostly yields from blockbuster drugs (Segers, 2018)
- **Technology-based platform:** Biotechnology firms that adopt this model can generate revenue by licensing out their platforms or technologies as a service to other downstream pharma organizations (Segers, 2018; Thong, 2020)
- **Asset creation and out-licensing business model:** This business model focuses on the early stages of drug development, creating a pipeline of proprietary assets - new drug candidates, or prototype formulations. These inventions are quickly patented as Intellectual Properties (IP) and out-licensed targeted biopharmaceutical firms for later-stage development and commercialization. Licensors enjoy revenues in the forms of licensing fees (Pure Licensing Business Model) or royalties on sales (Royalty Income Pharmaceutical Company model)
- **Hybrid business model:** Most young biotech firms pursue the hybrid approach – a combination of product-based and technology-based models. They generate income streams by out-licensing or technologically collaborating their platform with pharma giants, then in parallel reinvest earnings to develop their own product pipelines.

- **NRDO (No research, development only)**: the biopharma firms sorely focusing on the late development stage and commercializing drug candidates, which are in-licensed from the "unused patent bank" of other firms or research institutions

Despite its dominance, this traditional model now faces serious challenges including (i) looming patent cliffs, (ii) declining productivity of internal R&D (averaging just one new molecular entity per year), (iii) rising R&D costs, and shorter product life cycles (Chesbrough, 2003; Gillespie et al., 2019; Kessel, 2011). Among them, Gillespie (2019) pointed out that the expiration of blockbuster patents is a major concern causing a steep decline in big pharma profits. By 2030, the expiration of patents on 190 drugs is projected to result in a loss of $236 billion in industry revenue (Deloitte, 2023).

To respond, many biopharmaceutical firms urge to shift from sole dependence on blockbuster drugs and their own resources to an open innovation (OI) business model (Schuhmacher et al., 2013). OI promotes the exchange of knowledge across firm boundaries, enabling both the internal commercialization of unused IP and the integration of external ideas and technologies (Chesbrough, 2007; Chesbrough, 2003). In the biopharmaceutical context, OI spans a broad spectrum of activities, including drug discovery, data sharing, product development, and shared clinical testing platforms (Song & Shin, 2019).

Given the fast-paced of technology change (Nigro et al., 2014) and the urgency of complementary resources (Hill & Rothaermel, 2003), companies have to focus on the balance between exploitation and exploration (Chesbrough, 2003). Besides internal resources, they actively source new drug candidates through external partnerships with universities, biotech startups, and research centers (Chesbrough, 2011). Pharma giants such as GSK, AstraZeneca, Johnson & Johnson, Eli Lilly, Merck, Novartis, and Pfizer are actively embracing this model (Chesbrough & Chen, 2015).

According to (Segers, 2018), the following open innovation models are frequently adopted:

- **Networked business model**: The FIBCO company leverages its diverse network to build strategic partners for innovation co-development. Through their collaboration, companies can exchange pharmaceutical assets and expertise to effectively create and capture business value.
- **IP-oriented business model:** Companies actively protect their inventions with Intellectual property (IP). Patents are significantly vital to any innovation and can even be seen as the "final coat" to complete a drug discovery. With patent ownership, firms can yield substantial value by selling or licensing out pharmaceutical product/ technology portfolios to other organizations.

Amid the rapid advancements of the digital age and evolving social demands, business models are constantly changing to meet consumer preferences and strengthen competitive advantage. Among these, several emerging business models stand out:

- **Patient-centric pharmaceutical business model:** This model involves including patients throughout the entire drug development process—from early design to final commercialization. By incorporating patient feedback early on, even before drug discovery begins, companies can

develop treatments that better match real-world needs (Guideline, 2009). This approach not only leads to more personalized therapies but also helps to reduce risks and costly changes in later stages of development.

- **Pipeline in a product**: In this model, biopharma companies skip the early drug discovery phase and focus on later stages of development. Instead of creating new drugs from scratch, they repurpose existing or in-licensed drugs—often developed by other companies or research institutions—by testing them for new uses or indications (Segers, 2024). This approach allows firms to bring treatments to market faster and at lower cost, while still gaining strong profit margins by expanding the drug's approved uses.
- **Orphan drug business model:** Rather than developing treatments for large populations, companies using this model focus on rare diseases and small patient groups. These niche markets come with strong incentives such as faster, less expensive regulatory approval, which are especially helpful for smaller specialty pharma firms (Ku, 2015). Orphan drugs also tend to carry higher price tags, allowing companies to earn solid returns (Segers, 2024)
- **AI-driven business model**: This is reshaping the future of the biopharmaceutical sector. Biotechnology firms or pharma enterprises employ AI algorithms to identify and evaluate promising drug compounds in early-stage research. AI-driven drug discovery accelerates innovations, minimizes adverse effects, and delivers more precise treatment to patient personalization. This AI-automated process throughout pipeline development allows the chance for faster and more commodity medical treatments. (Paramasivan, 2021; Pharma.be, 2024a)
- **Digital E-health business model:** This model leverages information technology (IT) to streamline healthcare delivery to those who face limited access to centralized hospitals or doctors, such as rural residents, the elderly, or the disabled (Kimble, 2015). Despite its effective clinical applications and promising medical solutions to deal with an aging population, controversy remains about the cost-benefit assessment (Gamble et al., 2004)
- **The virtual R&D model** is an emerging approach in the biotechnology industry, where the entire pipeline is externally sourced through networks with other firms, enabling the utilization of knowledge assets, equipment, and market access (Segers, 2018)

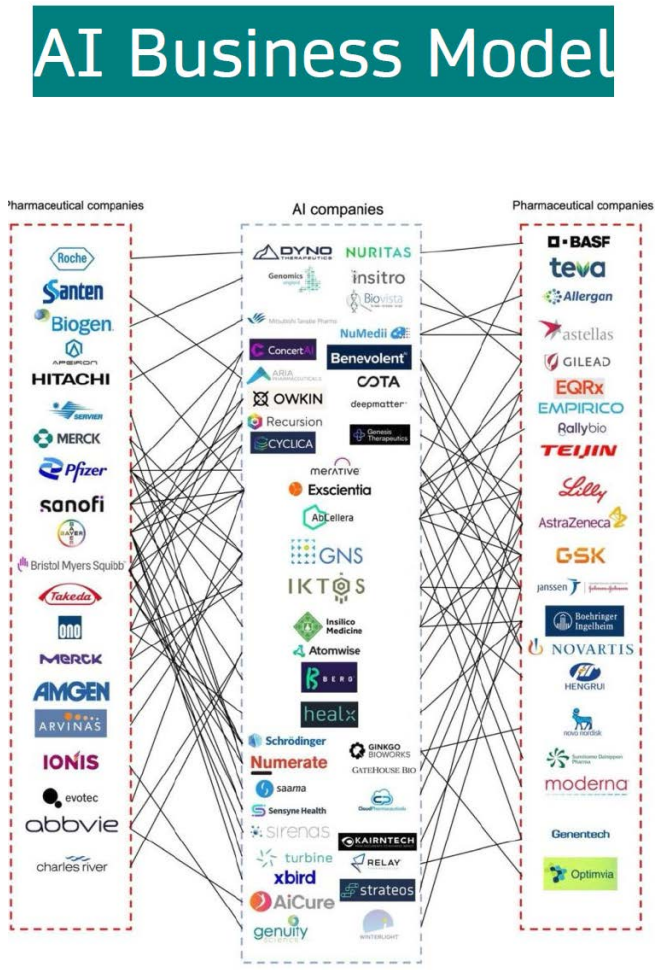

Figure 3: AI-driven business model in the (bio)pharmaceutical sector (Segers, 2024)

Table 2: Summary of popular business models in the biopharmaceutical industry

Closed model	Open innovation model	Emerging model
Product-based model	Networked business model	Patient-centric model
Technology-based model	IP-oriented business model	Orphan drug business model
Out-licensing model		Pipeline in a product
Hybrid model		AI-driven business model
NRDO (No research, development only)		Digital E-health business model
		The virtual R&D model

2.3. The emerging trends in Biopharmaceuticals

2.3.1 Artificial Intelligence Innovation

The Industry 4.0 era witnesses the ever-evolving period of Artificial Intelligence (AI) in transforming value chain reconfiguration and business model innovation ((Massa & Tucci, 2013; Massa et al., 2017). (Teece, 2018) explains the integration of AI yield significant economic and social benefits in various parts of the value chain. Indeed, the AI-powered system substantially enhances operational efficiency, cost optimization, innovation performance and service quality (Brynjolfsson et al., 2018; Burström et al., 2021; Davenport & Ronanki, 2018; Noy & Zhang, 2023). al., 2021). This phenomenon indicates the paradigm shift toward data-driven, customer-centric, and flexible business practices, fostering a new era of competitive advantage and innovation (Berente et al., 2021; Osterwalder & Pigneur, 2010). Over the past decade, AI solutions have been employed in various industries, including healthcare, logistics, finance and more (Chien et al., 2020; Navraj S Nagra et al., 2023; Truby et al., 2020). In healthcare industry, given the lengthy and costly research development, AI technologies not only assist in cost reduction and optimization, but also speed up the drug discovery process (Frederick & Alexander, 2023; Garbuio & Lin, 2019). This evolution is mainly driven by significant advancements in machine learning and deep learning technology, combining with predictive algorithm to facilitate more efficient operations under optimized cost (Agrawal et al., 2018; Cockburn et al., 2018). The AI-driven automation and data analytics are believed to support human-decision making in diagnostics, predictive maintenance, and digital security (OECD, 2020). In pharmaceutical landscape, Imran Haque, senior vice president of AI and digital sciences at Recursion, a start-up founded in Salt Lake City, shared similar point of view of AI potentials, especially in drug discovery. He explains “we know that many of these drug candidates are probably not going to work, but AI will allow us to identify those failures as fast as possible, early on” (Brazil, 2024). Despite of its promising future, AI deployment is also coupled with major concerns including legal and ethical data privacy, bias, and the potential misuse of AI-generated insights (Couture et al., 2023; Mökander et al., 2022; Ramanathan et al., 2023). For example, labor market is threatened by the growth of AI in business operations as automation replace roles traditionally held by humans (Bankins & Formosa, 2023). In response, there is a critical need of urgent actions undertaken by legislative bodies. The European Union has established itself as a leader with the introduction of the AI Act policy, providing the comprehensive regulatory frameworks for AI usage (AI Act, 2023). However, AI Act was challenged about ambiguous definitions, unclear roles and responsibilities for negative impacts presented by AI, thereby underscoring the necessity for more precise policies to effectively address the AI-related multifaceted ethical and socio-economic issues (Aagaard, 2024; Couture et al., 2023; Mökander et al., 2022)

2.3.1.1 Business models in response to AI innovation in biopharma firms

Realizing the promising capabilities of AI, almost all of the pharmaceutical giants have a least dipped their toes in the AI water in the recent years (Brazil, 2024; Garbuio & Lin, 2019). GSK was pioneer in building and training its own in-house first AI model named ‘Jules OS’, and Onyx platform as its next generation serving as a generative data source for its large language model. An AI-drug discovery firm

BenevolentAI is working with AstraZeneca and Merck for medicine development. In January 2024, both Eli Lilly and Novartis also finalized a deal with London-based Isomorphic Labs — a spin-off from Google's AI research lab DeepMind to enhance their AI capabilities (Brazil, 2024).

According to (Garbuio & Lin, 2019), there are three ways of AI integration in healthcare firms: assisted intelligence, augmented intelligence, and autonomous intelligence. Firstly, assisted intelligence refers to the business in which AI enhances value creation by repeatedly performing current activities to achieve better accuracy level. For example, medical image classification assisted intelligence to enhance accuracy compared to traditional processing techniques. Secondly, augmented intelligence, on the other hand, transforms the nature of business activities by new capabilities equipped with AI technology. Through sophisticated machine learning and cognitive technologies, AI enables businesses to discover deep insights and predict trends, providing greater precision and personalization in treatment regimens (Alanazi, 2024; Floresta et al., 2022). Lastly, autonomous intelligence represents the most advanced stage of AI-integrated business and possesses independence and flexibility in decision-making in regard to a set goal.

Its expected application is using robotics or technology to fully automate healthcare services, including doctorless hospitals or pharmacies. An early example is the automated hospital pharmacy at the University of California San Francisco Medical Center at Mission Bay (Khatib & Ahmed, 2020). This profound integration of AI across various business aspects not only strengthens operational capabilities but also reshapes value propositions, customer interactions, and revenue streams, allowing companies to adapt to the complexities of the modern market and maintain their competitive edge (Burström et al., 2021; Jorzik et al., 2024; Navraj S. Nagra et al., 2023)

2.3.1.2 AI adoption in business practice: case in China

To further gain insights of the business model changes in response to AI emergence, this study delves into China biopharmaceutical market using quadruple helix analysis. The global AI market grew over €180 billion in 2024 and is expected to reach nearly €1.9 trillion by 2030 (Statista, 2023). Report also shows China is the second-largest AI-leading regions, right after US (EU Parliament, 2024). Beijing earlier announced their ambitious vision of becoming the world leader in AI by 2030, with projections of a $150 billion industry (Larson, 2018). In January 2025, Chinese start-up DeepSeek shocked the global tech sector by releasing a breakthrough open-source AI model, seemingly outpacing US competition in both computing power and cost efficiency (Conroy & Mallapaty, 2025; euractiv, 2025). In pharmaceutical industry particularly, in the recent decades China experienced an impressive transformation from manufacturing hub to world's leading R&D player. Notably, until a decade ago the Chinese pharma sector lagged behind internationally, especially Chinese biopharma sector was almost non-existent. Notwithstanding, it grew exponentially to become now, a key part of the global biopharma market (Agten & Wu, 2024). Before 2010, generic drugmakers were dominant in the top 20 Chinese healthcare companies, however, from 2010-2020 biological drug firms emerged to present in the top 20 (Invesco, 2021). China now hosts a vibrant biopharmaceutical sector, encompassing thousands of

biotech companies (Agten & Wu, 2024). Combined together, all of these factors made China an interesting market to explore the AI adoption in biopharmaceutical companies.

The Chinese biopharma sector is undergoing their so-called “Golden Age” era with robust domestic growth in the pharma and biotech space. Beijing government can be seen as the orchestrator to foster this move. Policies, like Healthy China 2030 (“健康中国2030”规划) has reformed the whole industry by setting out the framework and guidelines for healthcare companies (Agten & Wu, 2024; Roberts et al., 2021; Schuerger et al., 2024). Healthy China 2030 also explicitly highlighted the pivotal role of technology in achieving redefined China’s healthcare strategy, stressing a shift from treatment to prevention, with AI integration as a means to achieve the target. In regard to AI, regulatory authorities show particular efforts on establishing wide-range policies for biodata collection and protection that could yield substantial benefits for AI-adopted bioeconomy. While US pharma companies only be able to access biodata under explicit partnership with medical or research institutions, Chinese drugmakers could easily access certain types of biodata to promote big data-informed health applications thanks to the country’s biodata holdings and standardization policies (CODE, 2019; Schuerger et al., 2024). The increased access to biodata also benefits university’s scientists and doctors to accelerate basic research and quickly analyse health trends in the national-level (Schuerger et al., 2024) Besides, Beijing government has far early noticed the role of academia in pushing drug innovation towards the next level. In response to AI Innovation Action Plan for Institutions of Higher Education (高等学校人工智能创新行动计划) initiatives, universities has incorporated AI into intelligent medical care and promote biotechnology research (CSET, 2019). This action highlights how China's educational system drives the growth of the AI-integrated biopharmaceutical sector.

Beijing also allocates financial support to private companies as part as a rocket booster for medical AI development (Schuerger et al., 2024). Furthermore, Chinese pharmaceutical companies are fostering international AI and biotech firms to access cutting-edge technologies partnerships in drug discovery (Koromina et al., 2019). According to (EMAG, 2022), Chinese AI biopharma start-ups became attractive to venture capitals as gaining US$17 billion of private investment, occupying one-fifth of the global total in 2021. Literature shows the rising trend of Chinese healthcare/ pharma-technology company (e.g., iCarbonX for AI-driven precision medicine, XtalPi for AI-enhanced drug discovery, AI-based internet medical and remote medical practices leverage online platforms and software network) (Hu et al., 2006; Sampene & Nyirenda, 2024).

Scholar stresses that AI strengthen customer relationships through personalized interactions and predictive customer service (Haenlein et al., 2019). This personalized approach helps identify effective treatment targets for specific diseases while tailoring therapies to individual patient profiles, potentially enhancing outcomes and reducing adverse effects (Liebman, 2022). (Liu et al., 2021), in his study of patient perceptions between AI applications and clinicians during COVID-19, shows that Chinese patients start shifting their preference to AI medicine and diagnosis due to its accuracy and diagnostic expense. Thus, AI-driven pharmaceutical and healthcare systems pose promising adoption in Chinese market.

Combined together all of stakeholders' analysis, AI innovation is currently well adopted in Chinese biopharmaceutical sector, shedding light for a more robust growth of this country's pharmaceutical ecosystem.

2.3.2 Digital technologies (IoMT, Data, blockchain, quantum technologies)

2.3.2.1 New emerging technologies in biopharma

Digitalization and digital technologies have been revolutionized the value creation and business-customer interaction in various key area (Aagaard, 2024). Businesses are enable to offer new range of product and service that tailored-made for diverse customers' needs (Abou-Foul et al., 2023; Lanzolla et al., 2020). Data collection and analysis through digital tools reveals hidden trend and preference patterns, offering firms valuable insights of unmet customer expectations to improve product development (Lanzolla et al., 2020). In addition, digitalized firms could expand the market penetration and accessibility due to enhanced reach to customer touchpoints (Abou-Foul et al., 2023). Furthermore, digitalization fosters optimal match between supplier and customers, increasing market efficiency (Benner & Waldfogel, 2023). The emerging technologies such as blockchain, Internet of Medical Things (IoMT) and quantum computing are opening the new era of biopharmaceutical industry - the Pharma 4.0 (Nargund et al., 2024; Steinwandter et al., 2019).

IoMT is the blend of medical devices with Internet of Things (IoT) enabling real-time tracking, data collection, and improved patient therapeutic outcomes. IoMT devices use a wide range of sensors put on the patient's body, thus health condition, diagnostic and drug operational efficiency can be monitored remotely and instantly to elevate patient care standards (El-Saleh et al., 2024; Vasantha et al.). In addition, wearable devices like smartwatches offer provide a non-invasive way to monitor various vital parameters of human body organs in real time.(Ahmed et al., 2024; Sun et al., 2020). Figure 3 illustrate an example of IoMTs where patient data are collected via sensor devices and centralize to the IoMT applications through the Internet.

In the biopharmaceutical sector, IoMT helps to streamline clinical trials and improve drug efficacy. Digital pills and smart drug delivery systems lead this innovation, providing solutions to enhance patient compliance and optimize therapeutic outcomes. (Vasantha et al.). Digital pills are ingestible sensors allowing personalization of treatment, medication adherence and monitor treatment effectiveness improvement through real-time health data tracking (Litvinova et al., 2022; Vasantha et al.). Moreover, biopharma industry also benefits from IoMT to enhance the drug development process. For example, by extracting various health-data points from vaccinated personnel, such as blood pressure, voice signal, to name a few, pharma firms can gain valuable insights through seamless communication and real-time feedback to improve vaccination effectiveness (Vasantha et al.). Worth mention one of the most outstanding IoMT advantages in healthcare is its capability to track patients' criticality remotely, even in the area with limited communication facilities, thus reducing cost for patients and enhance therapeutic efficiency (Mallick et al., 2022). Despite of its enormous benefits, IoT-based healthcare applications remain concerns regarding to data security, data integrity, and data availability (Jamshidi et al., 2023).

Patients' privacy could be threatened due to security vulnerabilities in IoMT devices (Sharma & Sharma, 2022). Scholars show that blockchain has emerge as a solution to strengthen transparency and security of IoMT model (Dilawar et al., 2019; Sharma & Sharma, 2022).

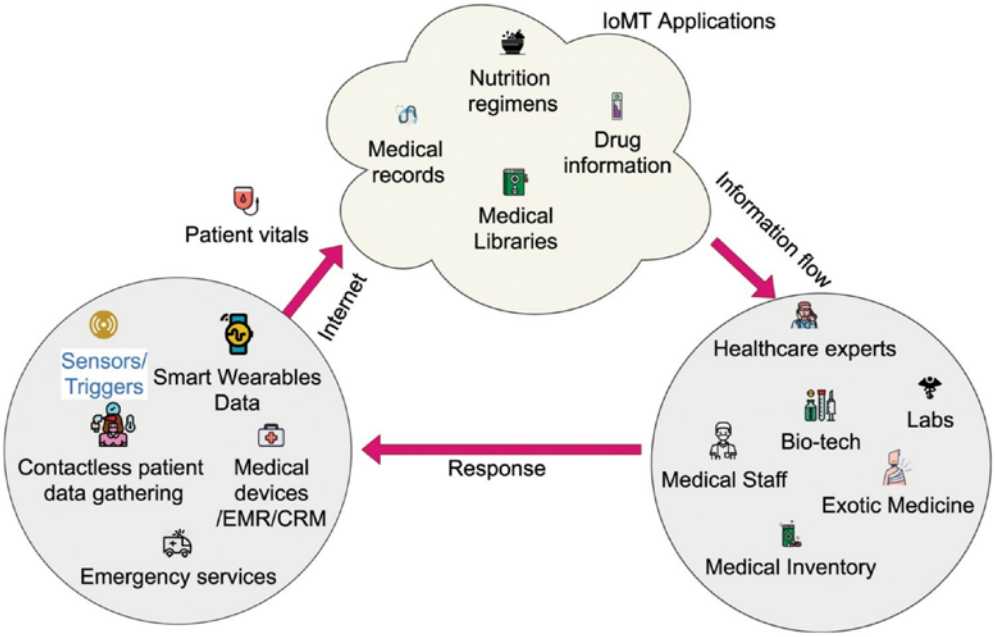

Figure 4: Internet of medical things (IoMT) (Razdan & Sharma, 2022)

Blockchain is not a new concept. This technology was first introduced in 1991 and more widely popularized in 2008 with Bitcoin, which provides unchangeable and irremovable transaction system (Leach et al., 2022; Nakamoto, 2008). Blockchain is a decentralized digital ledger wherein any peer-to-peer communication across network are store as blocks or nodes of data and can be used for cross-references (Mallick et al., 2022; Razdan & Sharma, 2022). These blocks are linked together as each of them takes reference from the previous one and public distributed among network users, making the data in these blocks remain tamper-proof (Dilawar et al., 2019; Sharma & Sharma, 2022). Although blockchain is most common for its association with cryptocurrency, its unique properties including anonymity, immutability, distributed, decentralized, secure, consensus, and transparency pose a significant potential for the privacy of sensitive healthcare data and other activities in biopharma drug discovery and commercialization (Leach et al., 2022; Tanwar et al., 2020). Blockchain can enhance the accuracy of patient information, facilitate faster medical record sharing, and bolster data security within the healthcare sector (Nimkar & Makhijani, 2024).Decentralized information distribution can revolutionize the biopharmaceutical industries by enhancing efficiency, reducing costs, preventing fraud, building trust, and enabling seamless data integration. Blockchain is applied in various pharma areas such as clinical trials, data management, drug authentication, intellectual property, licensing and royalties, supply chain compliance (Puranik et al.) For instance, initiatives like PharmaChain (Gomasta et al., 2023) aim to enhance drug traceability and authentication by utilizing blockchain to document

each stage of a medicine's journey from production to the end user, ensuring authenticity and regulatory compliance (Hang et al., 2019). When it comes to supply chain, MediLedger uses blockchain as a verification system across the pharmaceutical industry, enabling stakeholders to quickly verify the authenticity of medications, particularly during sales and return. Launched in 2019, the platform aims to simplify the sale and transfer of pharmaceutical products and collaborates with major industry players such as Bayer, McKesson, and Pfizer (Gaynor et al., 2024b). Blockchain technology offers a solution to enhance data security, strengthen privacy protection, and improve operational efficacy. However, the commercialization and adoption of blockchain in the medical sector are still in their early stages compared to its use in finance and supply chain management. To ensure successful implementation, it is crucial to consider scalability, interoperability, and regulatory compliance, along with perspectives from service providers and patients (El-Saleh et al., 2024; Kasyapa & Vanmathi, 2024)
Blockchain has the ability to improve patient information integrity, speed up the sharing of medical records, and strengthen data security in the healthcare industry

Quantum computing (QC) is another very much emerging technology expected to have a profound impact on the biopharmaceutical industry (Langione et al., 2019; Zinner et al., 2021). Quantum computers use qubits instead of regular bits, allowing them to exist in multiple states at once (superposition), unlike normal computers that process classical bits which are either 1 or 0 (Zinner et al., 2021). These properties allow quantum computers to solve complex problems much faster than traditional computers, with potential breakthroughs in drug discovery and development (Mishra et al., 2024). By harnessing the unique properties of quantum computing, drug discovery can rapidly evolve by enabling accurate simulations of molecular interactions. This enhances prediction accuracy and improves drug safety with greater precision during the drug design phase (Langione et al., 2019; Peruzzo et al., 2014; Zinner et al., 2021). As a result, researchers can develop more effective treatments faster, reducing costs and improving patient outcomes. Nevertheless, QC has yet to achieve practical application, and doubts remain about its ability to tackle real-world challenges in drug discovery. (Mishra et al., 2024; Zinner et al., 2021)

In short, the integration of advanced technologies, such as the Internet of Medical Things (IoMT), blockchain, quantum computing, and big data analytics, is transforming the biopharmaceutical industry. While some applications are still developing and carry uncertainty, their combined potential offers a promising path for reshaping drug innovation and accelerating progress across the sector.

2.3.2.2. Business model shift driven by digital emergence in the biopharma sector

The convergence of IT and healthcare is redefining the big pharma business models. Digital technologies provide pharma companies with new services or even a new paradigm with innovative strategies such as 'beyond the pill' or "pay-per-performance" (Buch et al., 2013; Kessel, 2011; Wenzel et al., 2014). The heart of these models is patient-centric care. This approach fosters the integration of pharmacy services, home care, and other technological applications to improve healthcare outcomes and

therapeutic costs (Elliott et al., 2020; Rocks et al., 2020). Novartis exemplifies the big pharma paradigm shift toward outcome-based healthcare. In an interview with *The Wall Street Journal*, CEO Joseph Jimene stressed that the company is transitioning from a product-focused sales model to an outcome-based approach. This strategic change underscores a broader transformation in the pharmaceutical industry, where success is increasingly measured by the impact on patient well-being rather than the volume of drugs sold (Falconi, 2013). Service strategies have the potential to improve the value of a drug by finding solutions for inefficiencies in the patient pathway and can be included in the value proposition of a product (Wenzel et al., 2014). As the pharmaceutical sector continues to grow, leveraging innovative technologies and strategic collaboration will be essential in unlocking the full potential of these models. Notably, tech giants like Apple and Google are driving disruption in the digital transformation of the healthcare industry (Gautam & Pan, 2016), as big data plays a pivotal role in advancing digital health technologies and data-driven innovations.

2.3.2.3. Digital technologies application in the biopharma sector: case in the US

The United States is the biopharmaceutical industry's market leader, encompassing almost half of the total global market share (Gaynor et al., 2024a). Fortune Bussiness Insight (2022) estimated the US market was valued at USD 534 billion in 2020, and forecasted explosive growth to USD 861 billion by 2028. Besides, the US has long been renowned as a global leader in embracing new technologies (Statista, 2025c). Combining the aforementioned characteristics of the US market, it is worth studying how emerging technologies are adopted in the country's biopharma sector.

The US biopharma industry is a dynamic and competitive market with many giant players such as Johnson and Johnson (J&J), Pfizer, Merck, and AbbVie. Although US biopharma has been lagging in embracing emerging technologies compared to other industries, some pharma companies have employed automation and achieved certain success. J&J is exemplified for leveraging AI and data science to accelerate drug discovery and develop innovative medical solutions. By analyzing a massive health record database with technological assistance, J&J can offer personalized therapeutic for patients, enhancing its value proposition. Moreover, J&J's subsidiary, Johnson & Johnson Medical Devices Companies (JJDMC) is building a platform on Microsoft Azure to integrate and manage IoMT devices in their digital ecosystem (Johnson & Johnson, 2023). BCG (2021) stated leading pharma firms are experiencing online launches for precision targets thanks to the popularity of digital channels. Telehealth, prescription delivery, test and vaccine management are new services offered by pharma giants. A prestige US pharma company, Pfizer launched PfizerForAll, an online platform designed to streamline healthcare access for patients. Through the platform, patients can consult with doctors via the telehealth provider UpScriptHealth, have prescribed medications delivered to their homes, purchase diagnostic tests through platforms like Instacart and Amazon.com, and book vaccine appointments at major retailers like CVS Health and Walgreens (MarketWatch, 2024). By doing this, they seem to shift to the direct-to-customer business model.

As mentioned earlier, the government plays a crucial role in reshaping the industry through its regulation and support. The U.S. government has taken proactive steps to accelerate technology adoption in the

biopharmaceutical industry by engaging experts from academia and industry. In 2022, the National Science Foundation (NSF) allocated nearly $4 million to the NNCTA for an academic initiative aimed at identifying key challenges and recommending critical areas for government funding. As part of this effort, biopharmaceuticals were highlighted as a priority sector, emphasizing the need for targeted investments to secure US leadership in this sector (Barbosu, 2024). In addition, the U.S. Food and Drug Administration (FDA) plans to expand digital health tech by enabling remote data collection from patients and clinical trial participants to assess real-world behaviors and outcomes. It also provides regulatory guidance for drug-related software and is enhancing its IT infrastructure with secure cloud technology to improve data review and analytics (Wang, 2021). This policy supports the emerging “beyond-the-pill” model where IoMT & patient data are well integrated for personalized healthcare solutions. Reimbursement is another critical policy influencing public healthcare access and industry dynamics. The White House's new policy is driving a shift from fee-for-service to outcome-based reimbursement, aligning with the pharmaceutical industry's transition to a pay-for-performance model. In this approach, drug pricing and market penetration depend on demonstrated clinical effectiveness and patient outcomes. As a result, pharmaceutical companies face increasing pressure to prove the high value of their products (Buch et al., 2013).

To fully apply the quadruple helix analysis, patients or society are non-ignorable entities. According to BCG (2021), consumers are more proactive in managing their well-being. In the US, 42 percent of customers track their fitness levels and set health-improvement goals on technological devices (Deloitte, 2020). The demand for personalized and real-time feedback is growing exponentially (BCG, 2021), indicating the huge effort needed for biopharma companies to improve their added-value offer beyond the traditional “pill alone” business model to engage and retain customers.

2.3.2 Sustainability

2.3.2.1. Sustainable development in the biopharmaceutical sector

In recent years, sustainability has become a critical focus across industries, driven by growing awareness of climate change, resource exploitation, and economic and social inequalities (Brenner & Drdla, 2023). To help create a better future, the United Nations introduced 17 Sustainable Development Goals (SDGs) to guide action on major challenges like poverty, hunger, environmental damage, and promote long-term economic and social development by 2030 (UN, 2015a, 2015b) (Figure 6)

For a long time, sustainability was viewed as a "nice-to-have" rather than a core strategy of business, mainly because of the difficulty in aligning different stakeholder interests and balancing profit with social and environmental impact (Segers et al., 2022a). But like many other industries, the (bio)pharmaceutical sectors are now under growing pressure to operate more responsibly. Today, sustainability is no longer optional but it is becoming a key value driver that is built directly into business strategy (Bowcott et al., 2022).

Figure 5: 17 Sustainable Development Goals (SDGs) (UN, 2015b)

The push toward sustainability is driven not only by regulations but also by growing demand from customers and employees. According to MCKinsey (2022), many customers consider a company's purpose and sustainability efforts as key factors in their purchasing decisions. To measure how well an organization meets its sustainability goals, the ESG framework—Environmental, Social, and Governance—was built as a set of evaluation standards for business practices and performance (Segers et al., 2022a). (Figure)

Today, success is measured not only by profit but also by how a company reduces pollution, treats people fairly, and follows strong governance. For biopharma, this includes ethical clinical trials, cleaner manufacturing, and making medicines more accessible. Patients, regulators, investors, and employees are all asking for better and more responsible practices (McKinsey, 2022; Makower, 2022).

Figure 6: Accountable areas of ESG (SEGERS et al., 2022b)

2.3.2.2. Business model shift toward sustainability

Business Model Innovation (BMI) is becoming important to foster large-scale change and align business performance with sustainable development goals. Sustainable Business Models (SBMs) represent a shift from the traditional business paradigm by positioning environmental and social goals at the heart of strategy. Instead of viewing sustainability as a side concern, SBMs treat it as a source of innovation and long-term value.

According to Lüdeke-Freund (2010), SBMs aim to build a competitive edge by offering strong customer value while also supporting sustainability at both the company and societal levels. These models follow the triple bottom line approach by measuring economic success with positive environmental and social impact, and recognize the planet and society as key stakeholders in business performance (Bocken et al., 2014)

A key sub-type of Sustainable Business Model is the Circular Business Model (CBM), which follows the ideas of the Circular Economy (CE). Unlike the traditional linear approach, CE promotes a model where materials and products are reused, refurbished, or recycled to reduce waste and make the most of resources (Geissdoerfer et al., 2020; Urbinati et al., 2017). This is especially relevant in the biopharmaceutical industry, where improving resource use and waste management is important for both environmental impact and regulatory compliance. In biopharma, the drug repurposing business model is a strong example of a Circular Business Model (CBM). It involves bringing shelved or previously developed drug compounds back into use for new medical indications, creating opportunities to maximize value from existing assets and improve access to treatments (Silvestre).

According to (Lüdeke-Freund et al., 2019), Circular Business Model Innovation (CBMI) includes 6 strategies, such as repairing, reusing, remanufacturing, recycling, and creating value through cascading use of materials. CBMI helps companies rethink how they create, deliver, and capture value in ways that align with environmental limits and stakeholder expectations (Brenner & Drdla, 2023). Particularly, CBMs promotes a shift from product-based to service-based model, helping companies lengthen lifecycle of their offerings and improve their sustainable performance. This paradigm might lead to the circular of supply chains for ingredients, shed lights to cleaner manufacture, and patient-focused outcomes.

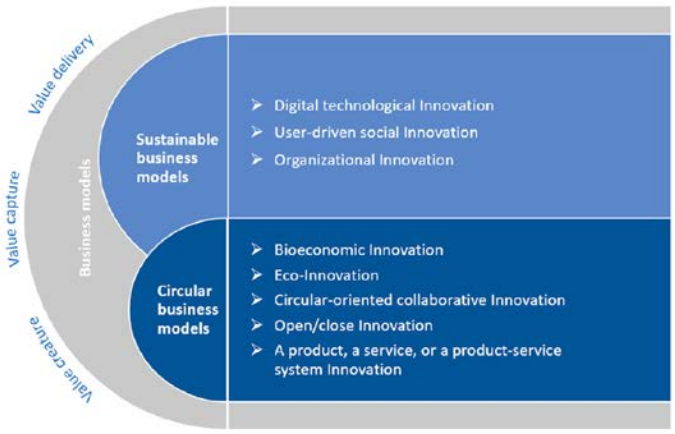

Figure 7: Business model innovation toward sustainability (Brenner & Drdla, 2023)

2.3.2.3. Sustainability application in the biopharma sector: Case in the Belgium

Europe is the second-largest market for the biopharmaceutical sector, accounting for 34.4% of the global market share, just behind the United States, which holds more than half (P&S Intelligence Research, 2024). Within Europe, Belgium stands out as a global leader, often referred to as a "Biopharma Valley. It is a major hub for the R&D, production, and distribution of medicines and vaccines. This position is supported by a strong biopharma industry, a well-connected ecosystem, high-quality infrastructure, and a strategic central location (Pharma.be, 2025).

When looking at R&D spending per capita, Belgium leads all EU countries. Although Belgium just places 8th place in terms of population, the amount invested by Belgian biopharma firms was nearly equal to the combined R&D investments of Italy, Denmark, Spain, and Sweden—countries that rank 4th through 7th in Europe for such spending. In 2023, Belgium's biopharmaceutical sector invested over €15 million per day in R&D, totaling €5.7 billion for the year. Over the past 25 years, R&D investment in the country has grown fivefold. In just the last five years, it increased by 58% (Figure 19) (Pharma.be, 2024b)

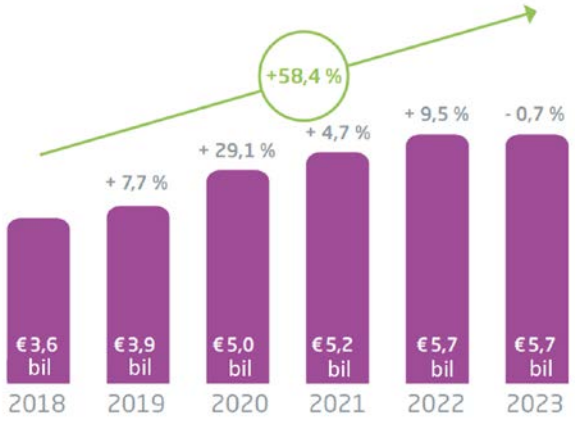

Figure 8: Evolution in investment 0&0 in Belgium (billion euros) (Pharma.be, 2024b)

As a regional leader in the biopharmaceutical industry, Belgian pharma companies are expected to quickly adopt sustainable practices. Europe's approach to sustainability is shaped by key global frameworks, including the United Nations' Agenda 2030, the 17 SDGs, and the Global Risk Reports released by the World Economic Forum (Segers et al., 2022)

Segers et al. (2022) emphasize affordable, high-quality healthcare through patient-centered innovation is a key driver for pharma firms to meet sustainability goals. Achieving this depends on strong collaboration across the healthcare ecosystem, particularly through public-private partnerships involving multi-stakeholders within the pharma ecosystem, such as governments, healthcare providers, industry players, and patients.

One example is UCB - one of the largest pharma companies in Belgium, listed on the BEL20. In 2019, UCB changed its approach by launching the "Patient Value Strategy." This new model puts patients at the center and includes sustainability as a key part of the company's long-term goals. UCB now works closely with patient groups and offers services that go beyond just selling medicine.

Another example is Janssen, part of Johnson & Johnson and based in Beerse, Belgium. Janssen has aligned its work with several SDGs, such as good health, gender equality, and global partnerships. Through its Global Public Health program, the company is finding ways to make medicines more accessible, reduce its environmental impact, and support diversity in the workplace. These efforts are tracked in Johnson & Johnson's "Health for Humanity" report.

Both companies show how sustainable business models can create value for patients, communities, and the environment. These models rethink how companies offer value, work with others, and deliver results—while also helping them stay competitive and innovative (Brenner & Drdla, 2023)

3. RESEARCH METHODOLOGY

3.1. Research Purpose:

This study aims to examine how business models in the biopharmaceutical industry are evolving in response to emerging trends such as artificial intelligence (AI), digital technologies, and sustainability. The focus is on the red biotechnology sector, which involves the application of biotechnology in medical and pharmaceutical fields—including vaccine development, drug discovery, molecular diagnostics, and regenerative therapies (Segers, 2015). A secondary emphasis of this research is to provide comparative insights into how business model transformation is shaped by regional context and organizational scale. The study is guided by the following research questions (RQs):

> ***RQ1:*** *How are emerging trends such as AI, digitalization, and sustainability reshaping business model innovation in the biopharmaceutical industry?*
>
> ***RQ2:*** *How do these transformations differ across company sizes and regional contexts (EU, US, Asia)?*

These questions are grounded in generating practical insights, particularly for actors navigating innovation in the biopharma ecosystem.

3.2. Research Design:

Given that business model strategy is a concern of the top management team of an organization, it was logical to explore this phenomenon through the lens of those having lived experience. To gain rich insights from the exploration of real-world settings, a qualitative research design was employed following the guidance of (Yin, 2015).

Since the biopharma space requires a dynamic ecosystem with systemic influence between stakeholders, the research draws on the Quadruple Helix framework, which emphasizes the complex interplay among industry, academia, government, and civil society (Carayannis & Campbell, 2010, 2014). This lens allows the holistic interpretation of how emerging trends with business models change.

This study used a purposeful sampling approach to select participants. To be included, interviewees had to meet three main criteria. First, they needed significant experience in the biopharmaceutical or healthcare sector—either through professional roles or academic research. Second, to capture a diversity of perspectives across the Quadruple Helix, interviewees must represent a blend of industry, academia, policy, and patient insights. Third, participants from the biopharma sector were required to hold senior-level positions within their organizations.

Beyond these core criteria, two additional factors were considered to examine how business model transformation varies by scale and regional context. Participants were selected to represent organizations of different sizes—from startups to large firms—and came from a range of geographic

locations. This helped capture the broader patterns of business model shifts across both company types and regions.

Table 3: Types of businesses

Type of company	Number of employees
Startups	<10
Small and Medium Enterprises (SMEs)	100-500
Large biopharma firms	500+

They were geographically spread across:

- Asia (Vietnam and Singapore) – 5 industry experts
- Europe (Belgium and France) – 3 industry experts and two professors
- United States – one industry expert

Data collection: The primary data collection method was semi-structured interviews with 10 participants, selected through purposeful sampling (see Table 3). Interviews were conducted either online or in person, depending on each participant's preference and availability. Each session lasted approximately 60 to 75 minutes. Before the interviews, participants received a guide explaining the study's purpose and the main discussion topics. All participants provided informed consent for data use and agreed to have their interviews recorded.

Table 4: Interviewee profiles

Nr.	Code	Interviewee	Type	Role	Company size (no. of employee)	Location
1	A1	Ms. Reem Al Adl	Industry, Patient	International Director Patient Engagement @Novartis	1,000	Singapore
2	E1	Prof. Fereshteh Barei	Academia	University Professor @ Université Catholique de Lyon	N/A	France
3	A2	Mr. Nghia Duong	Industry Expert	R&D Lead @Nanogen	200 - 500	Vietnam
4	E2	Prof. Wim Vanhaverbeke	Academia	University Professor @UHasslet & UAntwerp	N/A	Belgium
5	US1	Mr. Norman Fultang	Industry Expert	R&D Lead @Prelude Therapeutics	51 - 200	United State
6	E3	Prof. Martin Hinoul	Academia, Industry,	Professor, and entrepreneur at @KU Leuven and LCD	N/A	Belgium
7	A3	Mr. Phong Ho	Industry Expert	Co-Founder @N2TP Technology Solutions JSC	< 10	Vietnam

8	A4	Mr. Giang Nguyen	Industry Expert	CEO @Nanyang Biologics	11 - 50	Singapore
9	A5	Mr. Anh Pham	Industry Expert	Founder @Nutramax Innovation	< 10	Vietnam
10	E4	Ms. Arlene Derbaix	Policy & Industry Expert	VP Clinical Operations & Product Development Operations, Program and Portfolio Management @Curevac	700	Belgium

A semi-structured interview guide was designed to ensure consistency across interviews while maintaining flexibility to explore deeper, unexpected insights. The guide was structured around three main themes, each reflecting a critical dimension of transformation in the biopharmaceutical sector:

1. *Impact and Application of Emerging Trends*
    - The role of AI, digital platforms, and sustainability in product development, patient care, and operations
    - Opportunities and limitations in the adoption of these trends
    - How interviewee's companies/ institutions adopt these trends
    - What are advantages and barriers
2. *Quadruple Helix Collaboration*
    - The roles of governments, industry, academia, and patients in either accelerating or hindering transformation
3. *Future Outlook and Strategic Adaptation*
    - Predictions for the next 5–10 years regarding business model shifts

Data analysis: Interview data were analyzed using thematic analysis, following the framework outlined by (Yin, 2015) (See Figure 10)**.** After data cleaning and transcript verification, the researcher manually coded the data using Delve, a qualitative analysis software. This facilitated the identification of key codes, tracking of quotes, and clustering of themes.

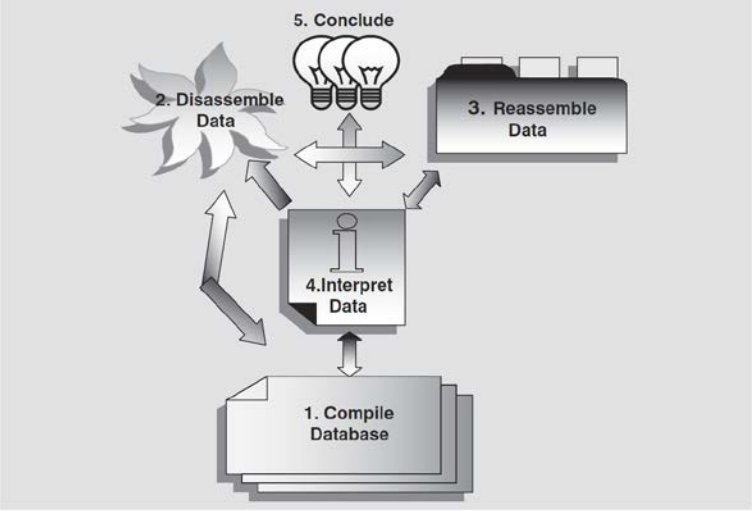

Figure 9: The full five-phased cycle of analyzing qualitative data (Yin, 2015)

Codes were grouped into higher-order categories aligned with the original interview themes, but emergent patterns were also allowed to shape the analysis inductively. The final set of themes and sub-themes are summarized in the coding tree below (Figure 10).

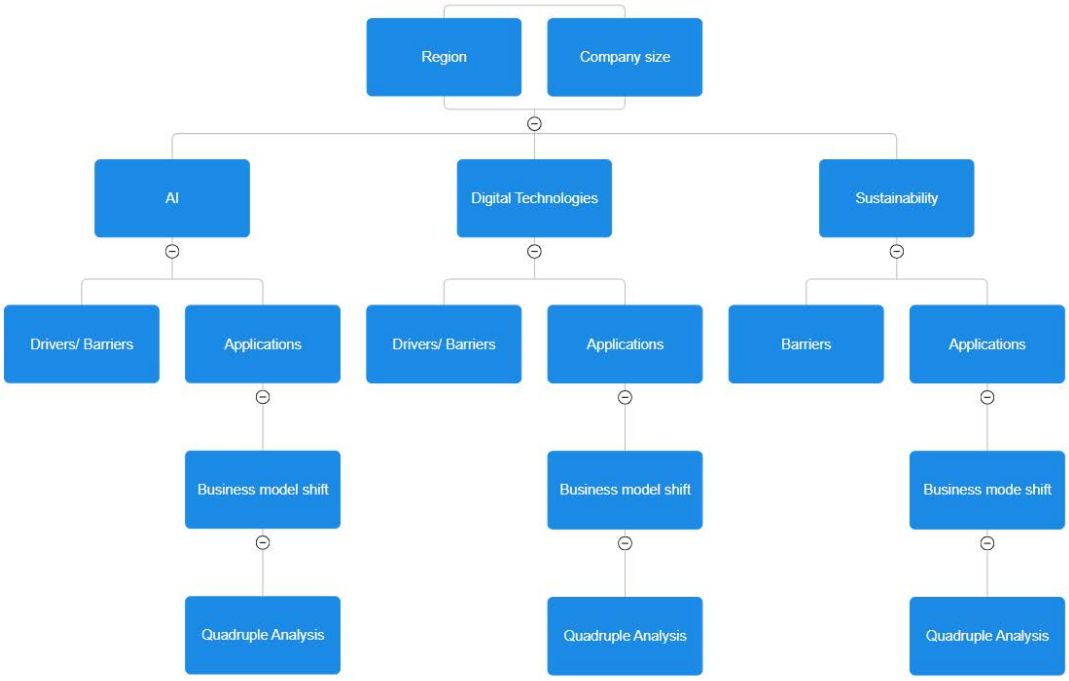

Figure 10: The coding diagram

4. RESULTS

The business models of biopharmaceutical companies have changed significantly over the past two decades, majorly driven by rapid technological progress. Companies are adopting emerging trends at different speeds, shaped by both external factors—such as societal expectations and regional dynamics—and internal factors like organizational resources and size. This chapter presents findings from qualitative analyses based on ten interviews with industry experts, consultants, and academics from Asia, Europe, and the United States. The results are organized around two main research objectives: (1) to explore how emerging trends are shaping the evolution of biopharmaceutical business models, and (2) to examine how these transformations vary across company sizes, regional contexts, and stakeholder roles, using the Quadruple Helix framework as a lens.

4.1 Business Model Evolution in the Biopharmaceutical Industry

4.1.1 General Industry Shifts

Over the past decade, the biopharmaceutical industry has witnessed a major shift from focusing on mass-market blockbuster drugs to more targeted therapies for niche diseases. This trend is apparent across various regions, leading to an increased emphasis on research and development (R&D) for rare diseases and personalized treatments. As some interviewees noted:

> *"Most of the pipelines of giant pharma companies have become drier and most of them is now moving instead of the mass market diseases to the niche…This is the trend for some years, the companies are starting to do personalized medicine" (A1)*

> *"We're seeing a lot more big companies really go after the smaller indications" (US1)*

This shift is partly driven by the high cost and complexity of drug discovery, which only large firms can afford. This situation creates a significant entry barrier for smaller firms and startups, further reinforcing the competitive edge of large corporations, especially in light of the rising of biosimilars due to patent cliffs. Additionally, government support plays a crucial role in facilitating this movement; as noted:

> *"Government incentives for orphan drug development, […]FDA makes it easier for you to get an orphan drug approval… (US1).*

Another trend influencing the business model evolution is the growing power of patient advocacy. Patients today play a much more active role in demanding better treatments and even influence the government and corporate actions. This empowerment has been accelerated by digitalization and AI technologies. With the "flat world" and the influence of virtual communities, patients can quickly raise their voices and exert pressure on social media, which is sometimes too loud to ignore.

> *"They now have their own voice rather than in the past to impact back to the firm and even the government. And this may be because of the technology or the internet thing they raised" (A1)*

"Digitalization and AI have also empowered patients. They have a voice now to ask for more, for better and faster treatments… If patients having trouble with kind of traditional treatment, they can also share their experience, and they can have an impact on this whole process" (E1)

The power of the patient voice can even go the extra mile to create social resonance, that captures attention and influences government actions.

"A child got saved because of some posts on the social media that got tracked and that had thousands, hundreds of thousands of people supporting it on social media. So the government took a decision to reimburse that medication, despite the fact that it treats a very small number of patients and it's worth millions of dollars to pay" (A1)

4.1.2 Impact of Emerging Technologies

4.1.2.1 Artificial Intelligence (AI)

AI is increasingly integrated into the biopharmaceutical industry. Although adoption rates differ among organizations and regions, all interviewees agreed on one crucial point that AI is greatly enhancing the efficiency and speed of drug development processes. What once took weeks or even years can now be achieved in days or months. For example, tasks such as market research can be completed in just a few hours, and early-phase studies can now progress significantly faster.

"AI has become transformational in drug discovery over the past 2-3 years, significantly improving efficiency and speed" (US1)

"Without all these AI and data tools, maybe it might take us a couple of years to finish just the first step of disruption while we process. But with AI, we can potentially finish the preclinical study, potentially in just 12 months up to 15 months" (A4)

"Two or three weeks talking with customers to see how is going on there in the market, what the geography issues or the medical issue are in each regions, now it could be done just few hours with AI" (A1)

Beyond improving speed, AI is also used to automate repetitive tasks and reduce human error. Interviewees explained how AI enhances precision and consistency in drug development activities. There is growing expectation about AI's potential to support virtual treatment models through innovations such as digital twins. These technologies could simulate human responses to treatments, potentially allowing clinical trials to be conducted digitally and reducing risk for real patients.

"AI is a thing now, and they use AI to replace the repetitive task to reduce human error" (A2)

"*What is fascinating in AI is the digital twins, […] this would avoid any danger from clinical trials and people, real people will be moved to the digital world" (E1)*

Although the advantages of AI application was clear, many interviewees expressed cautious skepticism. One of the primary concerns is the accuracy of the data that AI systems rely on. If flawed or biased

data is used at the input stage, the outputs produced by AI can amplify these errors, leading to serious consequence. Therefore, firm adopted in the conservative manner by mostly used for downstream activities, while upstream activities still depend on human.

> "*So if the information that has been fed initially is not correct, is biased, [...] then the results are going to be even amplified." (A1)*

> *"Incorrect or inaccuracy […] that is the huge point because if any input has a problem, the outcome can't go well" (E1)*

> "*At least in simple thing they have adopted for doing marketing because it's cheaper if you use AI for marketing. But in more scientific, for drug discovery or drug design. I think it is less adopted"*

> *"AI still have a lot to improve as is. It's just machine random-like generating things that is not constrained by science or physics or biology and still need the human to to improvise that supervise that. (A3)*

Another key concern raised was about over-reliance on speed. While AI tools offer impressive efficiency, several interviewees cautioned that this might tempt decision-makers to bypass essential validation steps, which are critical in medical contexts. Cutting corners in clinical development, even unintentionally, could lead to serious outcomes for patients.

> *"If you give people the ability to skip a two-year process with a tool, they're not always going to care about whether or not it's still done right. They're just going to skip the process altogether, […] and ultimately what's going to happen is when you go into patients, there's going to be a disaster (US1)*

> *"AI is a machine, and for pharmaceutical production, you need to have someone to take the responsibility since you cannot blame the computer for whatever is happening" (A2)*

> *"You need to understand the motives behind because that is the key main difference between info data that is brought by AI and real insights. Insight will not be insight until you're really validated with the real stakeholders" (A1)*

Beyond technical and ethical risks, the impact of AI on employment was another sensitive topic that emerged. Several participants noted that as AI takes over routine tasks, organizations are beginning to reevaluate their headcount needs. While some roles may disappear, others may shift toward supervising AI systems rather than performing the tasks directly.

> "*Many of the jobs that you used to do in the past, they will be automized […] They won't need anybody to do those jobs, may be probably recruited to supervise AI to do those jobs" (E1)*

> *"So adoption of AI has come in areas where they are just laying off people […] there are people who have been doing certain roles, but we do not need them anymore because AI is taking that place" (A1)*

In summary, it is clear how AI has become a pivotal element of biopharmaceutical innovation, particularly in drug discovery. AI empowers companies to streamline development, reduce costs, and enhance productivity, all factors that strengthen competitive advantage. However, the discussion does not end there. Concerns remain about data reliability, validation processes, and broader social implications, notably in terms of workforce restructuring. These issues indicate that while AI can be a powerful tool, its use must be carefully balanced with ethical safeguards and human oversight.

4.1.2.2 Digitalization

Digitalization is becoming an essential pillar of transformation within the biopharmaceutical sector. Although adoption levels vary across organizations and regions, all interviewees consistently recognized digitalization as a key enabler for enhancing patient engagement, accelerating internal workflows, and opening new business opportunities. Digital platforms, real-time data, and telehealth applications are reshaping how firms operate and how healthcare services are delivered.

A major change in the current digital era is the availability and abundance of health data. While data collection has always existed, digitalization has made it exponentially easier to access and analyze vast amounts of information. This shift has become a critical factor for maintaining competitive advantage, not only for large firms but also for smaller and emerging players.

> *"Previously, we also had data, but not that much. But now, let's say the real assets to have a competitive advantage, big firms or small firms, it doesn't matter." (E2)*

The availability and accessibility of medical databases enable the emergence of data-driven diagnostics, allowing early detection and driving a broader move from "sick care" to preventive healthcare. The future of treatment is closely tied to accurate diagnosis powered by comprehensive data analytics, particularly those linked to patients' genetic information.

> *"You will see that diagnostic becomes very important because diagnostic about data again, so you diagnose patients and diagnosis will always go together with the medicine because the medicine will only work if you have a particular DNA." (E2)*

Digitalization is not only changing how healthcare is delivered but also creating new business models. Digital health platforms, in particular, allow real-time patient data management, enhance transparency, and streamline interactions between hospitals, pharmacies, insurers, and patients. These digital ecosystems are creating a new dynamic, where value is delivered not just through the medicine itself but also through associated services and data-driven interactions.

> *"We have hospitals, we have pharmacies, we have insurance companies, we have the patients, and they're all connected to the same platform through which digitalization becomes very*

effective.[…] Platforms are very interesting because they improve the data sharing, they improve transactions." (E2)

However, while digitalization opens new opportunities, interviewees highlighted several critical concerns that need to be addressed. First, regulatory frameworks have not yet fully caught up with the pace of technological innovation. In many regions, the lack of reimbursement policies for digital health solutions remains a significant adoption barrier. Without a clear subsidy policy, insurance companies may not have strong incentives to reimburse digital healthcare services if these services do not align with their existing business models.

"…In Belgium, the government was not reimbursing them [digital health solutions] and that is a problem. No gain for the insurance company. And that's why the regulator has to push hard because now the regulator is paying everything (E2)

"In order to have a reimbursement, sometimes it's a joint reimbursement where the company would cover a part of the treatment, and the government covers another part, and a third part is governed by insurance companies. The point thereafter is the negotiations of how this can be reimbursed to cover more patients because this treatment is going to reduce the hospitalization by this number of days" (A1)

Another key concern raised was about patient trust. Although telemedicine and digital solutions offer convenience, many patients initially viewed them with skepticism, especially for health medication. Trust-building remains a significant barrier to the full adoption of digital health models. Concerns about liability were also expressed, suggesting that while digitalization promises efficiency, it must be accompanied by careful governance to avoid compromising patient safety.

"To tell you the truth about telemedicine from the beginning, it wasn't very much trusted by the patients. They still wanted to have this face-to-face meeting with their treating physician at the beginning" (A1)

"When something happens to the patient received the medication from digital health solutions, the physical doctor at the local have to be responsible for the patient or the one remotely consulting from miles away?" (A2)

In summary, digitalization represents a major innovation force reshaping the biopharmaceutical business landscape. It enables more responsive, data-driven, and patient-friendly care models. Nevertheless, the journey toward full integration is ongoing. Regulatory gaps, patient trust issues, and ethical responsibilities need to be carefully navigated to ensure that the benefits of digitalization can be realized without compromising fundamental healthcare values.

4.1.2.3. Sustainability

While sustainability remains less mature than AI and digitalization in the biopharmaceutical sector, it is no longer just an add-on element. Although still underexplored, sustainability is gaining attention and slowly being recognized as a relevant factor in shaping industry direction. Interviewees acknowledged this emerging shift, particularly in relation to social welfare, environmental responsibility, and more efficient use of existing resources. While not yet central to most firms' business models, sustainability is gradually moving beyond being treated as an afterthought.

One area where sustainability is starting to gain traction is through the evolving role of government and funding institutions. Several interviewees noted that public-private partnerships, policy incentives, and foundation grants are beginning to incorporate sustainability performance as a funding criterion—especially in areas like rare diseases and vaccine development. These funding shifts are driving research-intensive companies to align their innovation strategies with broader social welfare.

> *"There's additional funding opportunities for some of these really niche indications and that's driven both by the government and individual states and private foundations that set out to tackle individual diseases" (US1)*

> *"If a disease is represented as a threat, they might have some positive incentive from governmental institutions to develop some vaccines" (E4)*

Sustainability is viewed differently across regions, often influenced by population density and healthcare capacity. In many Asian markets, high patient volumes make it challenging for sustainability in patient care to serve as a meaningful differentiator. In contrast, in less densely populated regions—particularly parts of Europe—competition is increasingly shaped by the quality of care, including patient well-being and satisfaction.

In these settings, sustainability has moved beyond being a secondary concern. It is becoming a strategic advantage. Organizations that integrate sustainable practices with a focus on patient-centered care can stand out in the market. By enhancing patient experiences, firms not only build brand loyalty but also establish more resilient and future-ready business models. As a result, sustainability is emerging as a key factor in maintaining long-term competitiveness, particularly in markets where quality and care outcomes are valued alongside cost and access

> *So too many patients means there is no. There is no room for patient care. There's no time. But if there will be more and more doctors and less patients, then you will see the same as in Europe. So it's a competitive element. And in China or in Vietnam and probably also in Singapore, they have too much work. (E2)*

for instance about if you are pregnant, right? So you have to deliver the baby. Yeah. Where you want to have a good environment. So most of the time everything is fine, but you also want to be treated well, and this is basically competitive element. So it's a way of competing.So it's a competitive thing just to make sure that patients feel good and so patients go to the hospital where they feel good. So I can imagine that in Singapore and for sure in Vietnam, also in China, they don't care that much because they have way too much work, right? So there are too many patients, so they just want to make sure they have 20 patients a day. They don't care about the patient because they have too many patients (E2)

There is a recognition of drug repurposing as one type of shift that reflects sustainability objectives, preventing the waste of resources in the biopharma sector.

"..repurpose some of the existing drugs and run a more sustainable clinical trial to develop benefits for these patients without necessarily going through the whole process and redeveloping everything at the expense of people's time, energy, resources, and materials." (US1)

However, despite this momentum, the regulatory environment may vary significantly, impacting how sustainability is prioritized by firms in different regions.

"There is a kind of incentive for the company to be more environmentally friendly. But heavy regulation? I don't think so. No" (E4)

"On a micro level, throughout the drug discovery process is trying to be really mindful about waste of resources because that trickles down into just being less sustainable."(US1)

"So far I don't see any pressures or anything related to sustainability on this particular industry" (A3)

To summarize, sustainability in the biopharmaceutical industry is gaining relevance but remains at an early stage of integration. The current momentum is primarily policy- and reputation-driven rather than innovation-led. While some early adopters are exploring more sustainable initiatives, most firms are still not yet embedding sustainability into their core business.

4.1.3 Emerging business models

The integration of emerging trends such as AI, digitalization, and sustainability is not only transforming operational workflows but also driving a deeper rethinking of how value is created, delivered, and captured in the biopharmaceutical industry. As companies respond to rapid technological change and rising societal expectations, the traditional one-size-fits-all model is becoming outdated.

Instead, there is a noticeable shift toward business models that emphasize patient engagement, real-time data use, and service-oriented approaches to value delivery. The following section examines how

these shifts are unfolding through the adoption of innovative models that better reflect the demands of a dynamic, technology-enabled healthcare ecosystem

4.1.3.1 Patient-centric model

Although the patient-centric model has been discussed in healthcare for over a decade, its adoption in the biopharmaceutical industry has historically been more aspirational than operational. Recently, however, there is growing evidence that companies across regions are beginning to integrate patient perspectives more meaningfully into their core strategies—reshaping how value is both created and delivered. This shift is being accelerated by a combination of technological tools, changing societal expectations, and increased responsiveness from governments.

A key driver of this change is the growing influence of patient voices, amplified through digital platforms. Patients now have the means to share their experiences, express needs, and highlight treatment barriers in ways that resonate widely—reaching not only peer communities but also policymakers and companies. Several interviewees noted that governments are increasingly responding to patient-led campaigns, with social media emerging as a significant channel influencing public health decisions.

> *"Governments have taken decisions based on some campaigns that were done on social media highlighted the burden of a specific disease or some people need this medication." (A1)*

These shifts highlight the increasing relevance of the Quadruple Helix model, where collaboration among patients, governments, industry, and academia drives biopharmaceutical innovation. Public sector support, such as increased funding for social welfare and targeted health initiatives, encourages companies to develop treatments that address unmet needs within specific populations.

The most visible outcome of this evolving model is the growth in personalized and orphan drug development. Instead of focusing solely on mass-market diseases, companies are now investing in highly tailored therapies that reflect the unique needs and experiences of defined patient groups. This shift is not only changing how value is created in the industry but is also transforming the research and development process, making it more responsive, inclusive, and aligned with real-world outcomes.

Many companies are now incorporating patient feedback at the earliest stages of the product lifecycle—even before molecule development begins. This approach allows firms to better identify unmet medical needs, design more targeted and effective treatments, and improve both patient satisfaction and adherence. In turn, these outcomes contribute to stronger long-term competitiveness by aligning innovation more closely with real-world patient priorities.

> *"For lung disease, most of the medications that were developed were mainly to improve the breathing of the patients, how they can breathe better. But later on, when they started to talk with the patients, it was found that it's not the lung condition but another factor was the cough. They should take into consideration this cough and how this treatment can improve or stop it completely, which is taken lightly or not that much considered by the healthcare professionals but means much more to the patient." (A4)*

This direct feedback loop—from patient to chemist to final product—represents a major shift in how drug innovation is understood and executed. It signals a move toward more collaborative, needs-driven development that puts patient experience at the center of the innovation process.

> *"Patient perspective can really change the product development." (A1)*

> *"So you go into those patients, try to figure out what a drug for them would look like, and then you bring that idea to the team and then the chemists work on a drug for those patients, then you take that through the discovery process and get something that looks good in the clinic." (US1)*

In addition to drug discovery improvement, patient-centric could also change the way pharma firms engage with patients to build their loyalty. An interviewee shared a compelling example of how a pharmaceutical company turned patient insights into actionable strategies to boost long-term treatment adherence. Many elderly patients with vision problems delayed visiting doctors, thinking their symptoms were just part of aging and not wanting to burden their families. As a result, diagnoses often came too late to preserve their eyesight. To solve this, the company partnered with Uber to offer free rides to and from clinics, making access to care easier. This initiative significantly improved early diagnosis, treatment continuity, and overall patient outcomes by simplifying the patient journey.

These examples highlight how integrating patient insights can reshape the entire R&D approach. It not only strengthens product relevance but also enhances the customer relationship, deepening their engagement with the treatment and improving long-term outcomes.

To sum up, while the idea of patient-centricity is not new, its practical implementation across biopharmaceutical firms is gaining real impact thanks to digitalization, society demand, and policy support. By moving beyond traditional, top-down R&D models, companies are increasingly involving patients as co-creators of value. This evolution is setting the foundation for a more responsive, trust-centered, and personalized drug innovation.

4.1.3.2 Platform-based business model

While the concept of platform-based firm is not new to the biopharmaceutical industry, it is now being adopted more widely and strategically, particularly among companies focused on the early stages of drug discovery. Advances in AI and digital technologies are driving this shift, enabling platform-based business models to evolve beyond basic infrastructure sharing or service bundling. Today, these platforms serve as dynamic ecosystems that foster data sharing, cross-sector collaboration, and accelerated innovation.

In this context, platforms typically take two main forms: product platforms and transaction platforms. Product platforms are built on a core scientific foundation—such as a flexible compound library or mRNA technology—that can be applied to multiple diseases or therapeutic areas. This model helps early-stage firms develop a pipeline of drug candidates more efficiently, reducing discovery timelines. AI significantly enhances these platforms by enabling high-throughput compound screening, accelerating molecule

synthesis, and improving predictive modeling. These capabilities are especially valuable for companies aiming to move faster through phase one development while increasing the quality and success rate of lead compounds.

> *"You have a library of compounds and want you discover disease associated with one target. You can just call a Active Pharmaceutical Ingredient (API) to that library and you get the compound for you to start testing the next day" (A4)*

In parallel, transaction platforms are being developed to improve the flow of information and interactions between healthcare stakeholders including pharmaceutical firms, hospitals, pharmacies, insurers, and patients. hese platforms are designed to enhance efficiency, promote system integration, and make healthcare delivery more responsive to real-time needs and outcomes.

> *"And we have hospitals, we have pharmacies, we have insurance companies, we have the patients, and they're all connected to the same platform through which the digitalization becomes very effective. [...] Platforms improve data sharing and improve transactions." (A1)*

> *"Our audience is the doctors, the nurse, the hospitals. And we already gained their trust with our platform" (A3)*

The growth of platform is not only technology-driven but also shaped by the broader ecosystem through Quadruple Helix. Several drivers from across the ecosystem are pushing this model forward.

Digitalization is empowering patients to become more informed and actively involved in their care. Their growing demand for transparency and real-time access to health information is driving the development of platforms that support meaningful participation in medical decision-making.

> *"This digitalization and AI have also empowered patients and patients' organizations, patients' families, patients' ecosystems." (E1)*

Pharmaceutical firms, especially those focusing on the early research pipeline, are shifting to platform models as a way to diversify their revenue. Freemium approaches or subscription-based services are being explored alongside traditional drug development pathways.

> *"I think the change is more on the platform. They give you some platforms for free and then they will charge for the follow-up products, that's the real core products" (A3)*

The platform is becoming a modern approach to business models in the biopharmaceutical sector, shaped by the convergence of AI, digitalization, and cross-sector pressures for more open, efficient, and data-integrated systems. Whether structured around versatile compounds or real-time transaction flows, platforms provide flexibility, scale, and access that align with the demands of a patient-centered, innovation-driven healthcare system. Their growth is not driven by technology alone, but also by empowered patients, efficiency-seeking institutions, and firms rethinking how they generate and deliver value.

4.1.3.3 Drug repurposing

Drug repurposing is gaining momentum as a strategic business model in the biopharmaceutical sector, driven by growing sustainability demands and advances in AI. Although the concept has existed for some time, recent technological developments have made it more scalable, data-driven, and economically attractive. This model involves identifying new therapeutic applications for existing compounds—particularly those that have passed safety trials but were previously shelved due to limited efficacy or weak commercial prospects. Instead of restarting the full drug development process, companies are revisiting these compounds through more targeted clinical trial designs and by focusing on narrower, well-defined patient populations.

One of the biggest advantages is improved efficiency. By skipping the early, high-risk stages of research, firms can focus on clinical validation and faster market entry. In some cases, the original compound does not need to be altered; firms simply explore new indications using more targeted, effective trial designs and then license the compound for commercial use.

> *"They don't even change the drug. They just use the drug as is. So they just license the drug and then just run a better clinical trial." (US1)*

Paxlovid is a powerful example of this approach as it was originally developed for Ebola but later repurposed and became a blockbuster treatment during the COVID-19 pandemic. This illustrates the strategic agility and market opportunity embedded in this model.

Although this model has been in the market for years, it was widely adopted until the AI era. The integration of AI has been a major enabler of this shift as it enables screening through massive datasets, identifying overlooked compounds, and running more targeted clinical trials based on historical data.

> *"I would say there's a specific type of company that has been popping out a lot and it's for drug repurposing. So these are companies that use a lot of them leverage AI systems to look at drugs that have been made, have gone into clinical trials and have been safe in humans, but maybe haven't been efficacious." (US1)*

> *"People have been trying to do this for ages, but there's just no way to go through the amount of data you would need to parse through at once, figure out which drugs might still have an opportunity, figure out where that new opportunity might be." (US1)*

Beyond technology, the repurposing model is also seen as a response to greater sustainability. Rather than investing massive time, cost, and resources to develop a new drug from scratch, companies are opting to optimize what already exists. This approach aligns with more responsible innovation and resource stewardship.

> *"...repurpose some of the existing drugs and run a more sustainable clinical trial to develop benefits for these patients without necessarily going through the whole process and redeveloping everything at the expense of people's time, energy, resources, and materials." (US1)*

These strategic shifts also reflect the growing pressure to accelerate timelines. In competitive markets, speed to market is a key advantage. Once an opportunity is identified, firms must move quickly, especially when competitors are using similar tools to pursue the same targets.

> *"The interesting thing is you're never alone. So when you find that opportunity that you think, you know, it's a great market opportunity for a new drug, other companies are doing the same thing. [...] So you really need all the help you can get to move as quickly as possible." (US1)*

To conclude, drug repurposing is becoming a recognized and efficient business model, especially for startups and SMEs aiming to innovate within constrained budgets. By combining AI technologies, existing clinical assets, and a growing emphasis on sustainable development, this model offers a faster, lower-risk route to market. It is especially relevant in a healthcare landscape where precision, personalization, and cost-efficiency are becoming critical to both commercial success and public health value.

4.1.3.4. Telemedicine (Belgium, China) – NEW EMERGING

The rise of telemedicine is a clear example of how digitalization is reshaping business models in the biopharmaceutical and healthcare space. After COVID-19 pandemic, telemedicine is gaining strong momentum, especially in densely populated countries where healthcare systems face the twin challenges of overloaded staff and limited patient access. This model uses digital platforms and wearable technologies to support remote consultations and continuous monitoring, reducing the need for in-person visits and expanding care access for underserved or immobile populations.

Interviewees consistently highlighted that telemedicine is particularly suitable for settings where healthcare infrastructure is stretched and travel barriers are high. In places like Vietnam or China, where doctors may only have a few minutes per patient due to demand, remote care provides a more flexible and scalable alternative.

> " *It's now having the remote healthcare or treatment and it's changing the… like in the future it might change the way that we interact with a patient. So now people who are in very remote areas, just by using those wearables and telemedicine, connecting with the HCPs is making things easier. They don't have to pay this amount or to get transported from here to there and so on." (A1)*

While adoption varies across regions and healthcare systems, most interviewees agreed that telemedicine is more than a short-term response, it represents a long-term solution, particularly as populations age and chronic disease rates continue to rise. Besides, patients themselves are also evolving in how they access care. With the growth of home delivery services and virtual consultations, even pharmacy visits are being replaced. For elderly or less mobile individuals, these changes represent more than convenience, they are essential enablers of continued access to healthcare.

> *"Telemedicine would be a very good alternative. So it depends on the culture, it depends on the place, but definitely it's taking over and it'll simplify life for sure. [...] You can just reach*

everywhere from your home, which is far more comfortable, especially for elderly patients or patients with chronic diseases when this adds to the burden of the disease as well." (A1)

"People don't go anymore to the pharmacy. They just get their medicines at home. [...] For elderly people, this is really a problem because a lot of people are immobile. [...] So for elder people, this is great." (E2)

The business model implications for firms are significant. Telemedicine enables companies to expand their customer segments to include remote and elderly populations, while also offering time- and cost-saving services. The model reduces the number of in-person check-ins required, improves convenience, and can increase patient adherence, particularly for chronic disease management. These shifts also reflect a movement from volume-driven care toward value-based outcomes, where patient satisfaction and ongoing engagement are key.

However, the adoption of telemedicine is not without barriers. Interviewees noted that patient trust in remote care remains a concern, particularly in cultures where physical consultations are still preferred. There are also questions around responsibility as who is accountable if something goes wrong in a virtual consultation. From a policy perspective, the lack of reimbursement frameworks remains a major challenge. In many countries, telemedicine services are not yet fully covered by national insurance schemes, which can deter both providers and patients from using them regularly.

In a nutshell, telemedicine represents a growing business model driven by digitalization and changing patient needs. Its adoption is especially relevant in densely populated or aging societies, where access to in-person care is either limited or inconvenient. While challenges remain around trust, reimbursement, and clinical responsibility, the potential benefits—wider access, improved adherence, and reduced system burden make telemedicine a key area of innovation in the evolving biopharmaceutical landscape.

4.1.3.5. Innovations and technology transfer business model– case in US, Belgium, Vietnam

Technology transfer is becoming an increasingly important business model in the biopharmaceutical innovation landscape, particularly where academic research intersects with commercial application. While the concept is not new, there is growing recognition of its strategic and financial value—especially in research-driven settings where many promising discoveries remain underexploited. Technology transfer involves moving scientific findings from universities or research institutions into the market, typically through patent licensing, the formation of spin-offs, or partnerships between academia and industry.

A key driver behind this model is the need to bridge the gap between basic research and product development. Many researchers lack the knowledge or resources to protect and commercialize their innovations. As one interviewee noted, valuable technologies can easily be overlooked if not identified early and managed with strategic foresight.

> *"CAR-T therapy where they take T cells and they engineer them to make a new anti-cancer drug.[...] The original lab that developed that technology was at University of Pennsylvania and the researcher just published a research. They didn't patent the technology, they didn't have any protections around it. [...] And every big biotech company jumped on that, and they each made billions and billions of dollars off this, and the University of Pennsylvania has missed out on all that revenue." (US1)*

In this model, the financial incentives of technology transfer are also significant. Universities and individual researchers can benefit from licensing agreements, patent deals, or equity stakes in spin-off ventures. In developed ecosystems like the US and Europe, dedicated innovation and tech transfer offices (TTOs) help facilitate this process.

> *"A lot of the times what you will see is all of the institutions have innovation offices, innovations and technlogy transfer offices." (US1)*

A very successful example is the KU Leuven Research & Development (LRD) office in Belgium, which supports researchers in patenting innovations and selling those patents to interested pharmaceutical firms. They have 145 active spin-off at the end of 2024 with 5 IPOs among them. Total capital with total capital raise is €2.1 billion, creating 7,700 jobs in the region. (E2; LRD, KU Leuven)

Technology transfer also takes place within industry, especially in regions where academic-industry collaboration is less developed. In Vietnam, for instance, startups are using internal R&D to develop biosimilar drugs and sell them to emerging markets such as Pakistan or Bangladesh. Their business model combines product licensing with technical consultancy, providing not only the compound platform but also guidance on drug development protocols and equipment.

From a Quadruple Helix perspective, technology transfer draws support from multiple stakeholders. Universities act as innovation hubs, offering novel discoveries and contributing to knowledge valorization, while firms benefit from accessing up-to-date innovations that can be adapted to meet their strategic needs, without having to initiate discovery from scratch. Besides, governments play a critical role by providing funds to foster regional innovation ecosystems and supporting tech transfer infrastructures that can stimulate economic growth.

However, this model remains underdeveloped in parts of Asia, such as Vietnam, where there is a shortage of professionals who understand both scientific research and practical engineering. Moreover, the current fund model did not motivate researchers since the majority of projects are funded by the government through universities expecting guaranteed outcomes, which could be a huge entry barrier for any researcher. In addition, the incentive system was less appealing as a significant portion of the revenue may belong to the government.

> *"Vietnamese government's push in the investment is very appreciative. But if your research is funded by the Vietnamese government, you monetize this and 80% will belong to the government" (A3)*

Successful technology transfer requires individuals who can connect lab-based research to product development and market realities.

> *"First, people think that once we've done the fundamental research, we can do application. But the reality is very different [...] And we need someone who knows the engineering and the science at the same time to connect those tubes. And in Vietnam there's not much people who can do it." (A3)*

As a result, countries without sufficient infrastructure or trained personnel may struggle to convert research into market-ready solutions, leading to lost opportunities and innovation gaps.

The technology transfer model represents a valuable mechanism for translating academic discoveries into commercial impact. It enables universities to unlock new revenue streams, allows companies to access fresh innovation with reduced R&D risks, and helps governments promote regional economic development. While this model is well established in the US and parts of Europe, it remains at an earlier stage in many Asian contexts. Addressing the talent and system gaps required for effective transfer will be essential to unlocking its full potential globally.

4.1.3.6 Virtual biotech firm

The rise of virtual biotech firms represents a significant shift in how pharmaceutical innovation is organized and delivered. Although still in its early stages, this model is gaining traction, particularly in the context of growing digital capabilities and AI integration. Enabled by virtual collaboration tools and outsourcing frameworks, these firms are able to pursue drug discovery and development with minimal internal resources, often operating with lean teams of just a few individuals.

This model challenges the conventional structure of biopharma organizations, which traditionally rely on large R&D teams, in-house laboratories, and high fixed costs. By contrast, virtual biotechs leverage external partnerships and contract research organizations to carry out essential research tasks, while digital platforms facilitate coordination and decision-making remotely.

> *"Virtual biotechs can now develop drugs with minimal staff. If you get to the point that you have something you think works, you can contract the research organization to do some of the early work for you. [...] You have companies that just have two employees that get a drug into patients just on the basis of virtual drug discovery and leveraging these collaborations." (US1)*

AI plays a pivotal role in making this model viable. By automating key stages of the drug discovery process such as molecule screening, data analysis, and target prediction, AI allows virtual firms to achieve milestones that once required large scientific teams and infrastructure.

> *"In terms of other business models, virtual biotechs are huge. There's companies that just do entirely virtual drug discovery." (US1)*

Beyond drug development, an interviewee predicted virtual operation could even expand into clinical support and specialized procedures. For instance, highly skilled professionals, such as surgeons, could perform procedures remotely through digital interfaces, highlighting the growing potential of virtualization in healthcare delivery as well.

> *"But digitalization, for instance, is allowing—and they are very far in that already—allowing doctors, specialists, highly skilled specialists to do a surgery from Belgium into Latin America, for instance." (E2)*

The business model implications of virtual biotechs are substantial. These companies benefit from dramatically lower overhead, increased agility, and the ability to scale project teams dynamically based on need. This makes them especially attractive for early-stage innovation and high-risk drug candidates, where flexibility and cost-efficiency are critical. Startups and smaller players, in particular, are finding this model effective for entering the pharmaceutical space without needing large-scale investment upfront.

Through the lens of Quadruple Helix, industry leads the shift by creating flexible, innovation-driven structures, whereas academia and contract research partners provide scientific input and services. However, policymakers are still conservative in promoting this new model, especially in Europe where the face-to-face interaction are more preferred by patients.

Overall, virtual biotechs represent a forward-looking business model powered by digitalization and AI. While adoption remains limited compared to more traditional models, their emergence signals a broader transformation in how the industry operates towards greater decentralization, collaboration, and lean innovation strategies. As enabling technologies continue to mature, virtual models may become a cornerstone of next-generation drug development.

4.2 Different transformation

4.2.1 Different in company sizes

Biopharmaceutical companies of different sizes such as startups, Small and medium-sized enterprises (SMEs), and large firms face varied realities in responding to emerging trends such as artificial intelligence (AI), digitalization, and sustainability. These trends are shaping not only operational models but also how value is created and captured. The following section analyzes how each firm type adopts these trends, highlighting their respective opportunities and constraints, and how these dynamics influence the emergence of new business models.

4.2.1.1 Startups

Startups are often early adopters of emerging trends, particularly AI and digitalization, which they embed them as part of their core value proposition. Their lean structures, fast decision-making, and test-and-learn culture make them highly responsive to change. With fewer internal layers and legacy constraints, startups can explore new technological pathways more flexibly than larger counterparts. This agility allows them to quickly iterate, pivot based on real-time data, and embed innovation across the entire value chain from drug discovery to patient engagement. Several interviewees emphasized that startups are particularly well-suited to business models such as AI-powered platform and technology transfer, where rapid experimentation and digital tools are essential to compress development timelines and optimize scarce resources.

However, while startups may lead in adoption speed, they also face notable constraints that limit their ability to sustain or scale innovation—especially in the resource-heavy biopharmaceutical context. Financial pressure is a recurring theme. Startups typically operate under tight funding conditions and must demonstrate return on investment (ROI) within short timeframes. This demand from investors can be misaligned with the inherently long and uncertain nature of biopharmaceutical innovation.

> *"Funding and resources remain major constraints for biotech startups despite their advantage in faster decision-making." (US1)*

> *"The major disadvantage they will have compared to established company, especially giants, is financial." (A2)*

In addition to financial strain, investor expectations often pose a mismatch. In emerging ecosystems deep tech startups frequently struggle to attract funding due to limited awareness of long-term R&D cycles and their social or clinical impact.

> *"Investors in Vietnam tend to look for short term cash flows like e-commerce or fintech. Not many people understand the concept of deep tech startups that require large investment before any returns." (A3)*

> *"For the biotech is very difficult. These small guys are willing to survive, but every day they see these guys for the money return on investment. Come on guys, where is the product? Practically nearly impossible." (E3)*

Even when successful, collaboration or acquisition by larger firms may come at a cost: loss of agility and identity. Startups may be required to adopt more bureaucratic systems from their partners, diluting the very speed and differentiation that initially gave them an edge.

"When you collaborate with big pharma, you might have to adopt some of their processes. It's more bureaucratic, and you lose the agility you had in a startup." (EU4)

"Small businesses rely on widely accessible technology, but if they don't have a unique differentiator, they lose their competitive edge." (A3)

However, their growth and scalability are often constrained by limited funding, especially in deep tech, and credibility gaps when engaging with investors, regulators, or pharmaceutical partners. These barriers can prevent otherwise promising technologies from scaling.

In short, startups are bold adopters of new trends and drivers of emerging business models, but face structural and ecosystem-level limitations that can undermine their long-term competitiveness. Their success often depends on finding the right balance between innovation speed and sustainable growth—supported by patient capital, strategic partnerships, and a clear differentiation strategy.

4.2.1.2 SMEs

SMEs represent a unique middle ground in the biopharmaceutical landscape. They are generally more resourceful than startups, but less complex than large pharmaceutical corporations, enabling them to strategically adopt emerging technologies such as AI, digitalization, and sustainable practices though often with a selective and cautious approach.

Unlike startups, SMEs are not typically built around a single innovation or radical new model. Instead, they tend to embed technologies into existing processes where the benefits are clear. Many SMEs are now integrating AI-based platforms for drug discovery, repurposing drugs through data analytics, virtual biotechs or working as technology transfer offices to bring university research into the market.

"There are some companies which are not biotech, but they are called kind of bioinformatics company… their specialization is really antigen discovery leveraging AI." (EU4)

One of the key enablers for SMEs is their access to moderate yet stable resources, allowing them to invest in enterprise tools, internal data infrastructure, or AI licensing. Unlike startups that may struggle to afford advanced platforms, SMEs can support technical teams and tools that enhance operational efficiency and innovation potential.

"We definitely have the resources as a company that's slightly bigger to support employees and groups that want to leverage these AI tools. […] We have enterprise licenses for every AI tool that we use." (US1)

This relative stability gives SMEs the capacity to experiment with emerging business models such as drug repurposing, bioinformatics, or platform collaborations but usually within well-defined commercial constraints. Their innovation direction is often shaped by investor expectations or financial sustainability goals. SMEs may prioritize areas that promise quicker returns rather than tackling high-risk, high-impact

challenges. This results in a business mindset that prioritizes financial viability over unmet societal or clinical needs.

> *"I'm looking for an opportunity for a drug, I'm not really looking at which patient needs this most. I'm looking at which patient population is going to make my company the most money. That's realistically the only way in which we approach drug discovery so that innovation really just drives value for shareholders" (US1)*

This tension between innovation and investor return may limit SMEs' capacity to pursue truly disruptive or sustainable models unless external funding, government incentives, or academic partnerships play a supportive role.

In summary, SMEs have enough infrastructure to adopt and benefit from emerging technologies like AI, and enough flexibility to partner across the innovation chain. Business models such as AI-powered platforms for drug discovery, repurposing drugs, virtual biotech firms, or operating as technology transfer offices are emerging within SME. However, their transformation journey is shaped by calculated decision-making, financial returns, and a need to continually balance innovation with investor expectations.

4.2.1.3 Big pharma corporate

Large pharmaceutical companies are the most experienced and well-funded in the biopharma industry. With strong research teams, knowledge of regulations, and access to global markets, they are in a good position to adopt and grow new trends. However, their transformation journey is slower and more complex, primarily due to their organizational scale and rigid legacy structures.

Although these companies could integrate AI and technology at early stage but limited group, they were lagging in scale up and rapid adoption due to their size and complexity.

> "Working at a bigger company, if I have an idea I need to generate…spend months generating data… then pitch that idea to my group lead… and the board has to give a decision by the end of the quarter… then I start doing it." (US1)

> "*Big companies of course, do have resources. But they also have a business model or at least what we call dominant logic. […] They have a resource and they have competencies, so they should be okay, but they also have the rigidity related to that. And the rigidity means that they think like before, and they have businesses that gonna resist changing into a digital-led business model"(E2)*

Despite some challenges, big pharma is clearly evolving, with several new business models emerging. One standout example is the patient-centric model, where companies involve patients throughout the drug development process. Novartis, for instance, has set up a dedicated Patient Engagement

Department to bring patient insights into early development stages, helping to design treatments that better reflect real-life needs.

This patient-centric transformation is also closely linked to a shift toward personalized and niche therapies, especially for rare diseases or orphan indications. Big pharma companies are increasingly moving away from mass-market drug models as patent cliffs and biosimilar competition pressure traditional pipelines.

> *"Most of the pipelines of the big pharma companies have become drier… now moving instead of the mass market and the medications for mass market diseases." (A1)*

Another remark of transformation of big pharma is the adoption of platform-based models, especially transaction platforms that digitally connect internal and external healthcare stakeholders such as clinics, hospitals, insurers, and patients. These integrated platforms improve data sharing, facilitate real-time communication, and create new service-based revenue models.

In summary, big pharma firms are gradually evolving through patient engagement strategies, personalized therapies, and ecosystem-based platforms. Their deep resources and global influence allow them to drive large-scale innovation, but transformation is often slowed by internal rigidity, conservative cultures, and an over-reliance on traditional revenue streams. As new technologies and models become more widespread, these firms must continue balancing stability with agility to stay relevant in a rapidly shifting healthcare landscape.

4.2.2 Different in region

4.2.2.1 Asia (Singapore/ Vietnam):

In Asia, particularly in Singapore and Vietnam, the biopharmaceutical transformation landscape is shaped by a dynamic but uneven interplay among stakeholders in the Quadruple Helix. While digital readiness among patients is relatively high, especially in urban and tech-forward contexts like Singapore, the adoption of new business models and technologies by firms, academia, and policy structures remains inconsistent and fragmented.

Patients in this region, especially in Singapore, are highly digitally literate and quick to adopt mobile technologies as part of their daily lives. Healthcare access via digital tools is increasingly normalized, reflecting the wider digital ecosystem. This tech savviness provides a strong foundation for digital health innovations and patient-facing platforms.

> *"Everyone from the youngest to an old person 99 years old, they're all having their mobiles. You cannot really live in Singapore without your mobile; everything is on apps, access to places on an app, everything, your life is on your mobile, which is different." (A1)*

However, the translation of digital adoption into healthcare behavior remains limited. In many parts of Southeast Asia, including Vietnam, users engage with digital tools primarily for basic communication or news rather than for critical health services. Cultural trust and usage habits play a key role in slowing the transition.

> *"Southeast Asia is far more advanced compared to any other country in the world in that aspect. They have everything on the mobiles, but they use the mobiles mainly to talk and follow up the news, but not for the other vital activities in life. So there are differences definitely between, tech literacy and tech avenues" (A1)*

Moreover, price sensitivity is a defining trait among patient-consumers in Asia, particularly in Vietnam. Even when a product is innovative or offers clear benefits, there is strong resistance to paying premium prices. This cultural emphasis on affordability creates pressure on companies to limit technology adoption in their operations, as added costs may ultimately be passed on to patients

> *"They want the best product at the cheapest price. So that's why any kind of fancy technology, it's hard." (A5)*

On the **firm side**, Singaporean and Chinese companies have begun incorporating AI and digital tools into R&D workflows, while in Vietnam, digitalization is still seen more as a supportive tool than a transformational core. Many Vietnamese biopharma companies remain cautious, largely due to concerns about the return on investment and a lack of internal expertise in deploying complex systems. Digital solutions are often used for market research, administrative streamlining, or promotional activities rather than for deep R&D or drug discovery purposes. This reflects a lower level of readiness and a conservative approach to technology integration.

> *"I don't think it would be that fast to like, we use that as the core main thing yet right now. Like right now, we don't really see it." (A5)*

On the other hand, **governments** have taken proactive steps to stimulate digital health innovation. Policies supporting high-tech enterprises, including favorable tax incentives and formal recognition of biotech sectors, are gradually improving the enabling environment.

> *"Actually, the government of Vietnam, they already help tech companies […] If a company registers themselves as high tech, they get tax incentives, like 50% reduction of tax." (A2)*

> "The government is adopting this […] While in Singapore, I can finish everything while I'm in my home using my mobile." (A1)

Academia presents another contrasting picture. In Singapore, institutions like Nanyang Technology University (NTU) are pushing boundaries in translational research and commercialization. For example, AI-powered compound platforms as a spin-off from NTU. This valorization of academic output aligns with global trends in innovation-driven economies. In Vietnam, however, the transition from research to application remains weak. Despite strong academic potential, limited cross-sector talent with both

scientific and commercial expertise prevents research findings from being turned into marketable solutions.

> *"We need someone who knows the engineering and the science at the same time to connect those tubes. And in Vietnam, there's not much people who can do it." (A3)*

Overall, Asia, particularly Singapore and Vietnam, patient readiness and government intention are notably strong, but firm-level unevenly adopted technology and academic-commercial disconnects create structural barriers. Singapore shows strong momentum across the helix, whereas Vietnam reflects a transitional stage, ready for innovation but still developing the capabilities and confidence to act on it. The potential of emerging biopharma business models in this region will be platform, telehealth and drug repurposing.

4.2.2.2 The United States:

In the United States, the transformation of the biopharmaceutical industry is strongly shaped by a mature ecosystem with advanced technological integration and well-established academic-commercial linkages. However, changes in political and budgetary priorities are shifting the roles of key actors across the Quadruple Helix.

Government support has long been essential in the biopharmaceutical sector, especially through agencies like the National Institutes of Health (NIH). However, several interviewees raised concern that this support is declining due to budget constraint and changing policy priorities. A drop in funding could have serious implications, particularly for foundational research and early-stage drug development.

> *"Depending on how this administration goes, it might become less and less the government because we're already seeing all of these cuts in the NIH and all of these government agencies." (US1)*

Despite the decline in general funding, government and state-level programs continue to play a key role in supporting orphan drug development. These initiatives provide financial incentives and regulatory advantages that help make treatments for rare diseases more commercially viable, encouraging companies to invest in smaller, often overlooked patient populations.

> *"There's additional funding opportunities for some of these really niche indications and that's driven both by the government and individual states and private foundations that set out to tackle individual diseases." (US1)*

In the **industry**, there is widespread adoption of AI, which is now deeply embedded across the drug discovery and development pipeline. This integration is not only transforming workflows but also shaping business models, including virtual biotechs and AI-powered drug repurposing. Interviewees noted that

the momentum for AI integration is particularly strong among younger scientists as they are more tech-savvy.

> *"There are AI systems now throughout the entirety of the drug discovery pipeline that really fundamentally change how we approach drug discovery. […] The push to really emphasize and use AI even within my company and within the field is being driven by the younger generation." (US1)*

Business model innovation in the U.S. reflects this digital maturity, with firms increasingly operating as virtual biotechs, leveraging external partnerships and contract research to reduce overhead. Similarly, AI-powered drug repurposing and university-industry tech transfer are emerging as prominent strategies to improve speed, efficiency, and return on investment in drug development.

Patients in the U.S. are also benefiting from these shifts, particularly in terms of focusing on personalized therapies. The rise of niche indications also allow for faster regulatory approval and more meaningful patient outcomes.

Academia plays a proactive role in the U.S. biopharma ecosystem. Most major institutions maintain dedicated innovation and technology transfer offices that actively encourage researchers to commercialize their findings. Academic staff are often guided and supported to patent discoveries, form spin-offs, and seek venture or grant funding. This focus on valorization ensures that promising research does not remain in the lab but is transformed into viable health innovations.

> *"A lot of the times what you will see is all of the institutions have innovation offices […] In the U.S., you would get really pushed to do it. Your grants and technology office is going to tell you to file patents, start companies, apply for startup funding." (US1)*

Taking everything into account, the United States remains a leading environment for biopharmaceutical innovation, driven by a strong research base, technological leadership, and a vibrant entrepreneurial culture. However, diminishing government funding poses a risk to early-stage research, potentially increasing reliance on private investment. The country continues to be a key hub for business model experimentation, particularly in areas such as tech-transfer, AI integration, virtual biotech structures, and repurposing strategies, enabled by a collaborative Quadruple Helix where academia, industry, and patient needs are well-aligned for innovation.

4.2.2.3 Europe (Belgium, France)

Europe presents a well-established, research-intensive biopharmaceutical ecosystem, yet one shaped by both institutional strengths and regulatory constraints. When analyzed through the lens of the Quadruple Helix, the region reveals a dynamic interplay among firms, governments, academia, and patients, marked by a strong commitment to innovation, but also a cautious approach to change, particularly in the realm of digital healthcare.

Pharma firms in Europe continue to demonstrate deep R&D capabilities, with a strong focus on scientific rigor and advanced discovery methods. A notable trend is the rising integration of artificial intelligence and big data in drug development, particularly through partnerships or acquisitions. Rather than building these capacities entirely in-house, many companies are increasingly turning to specialized bioinformatics firms, indicating a shift toward collaborative innovation ecosystems.

> *"What we see today is that there are some companies which are not biotech, but they are called kind of bioinformatics companies. [...] Their specialization is antigen discovery leveraging AI and big data. This is a kind of innovation or capabilities that companies are going to buy or acquire rather than really developing in-house." (E4)*

This outsourcing strategy reflects both the region's maturity and its pragmatic approach to technological adoption—favoring incremental integration through collaboration over internal disruption.

On the **patient** side, adoption of digital health tools like telemedicine has been slower than expected. Despite the global surge in telehealth during the COVID-19 pandemic, many European patients still prefer in-person consultations, underscoring the enduring value placed on human interaction in medical care.

> *"I expected that Europe would be the first to adopt telemedicine and feel comfortable using it. [...] But to my surprise, they didn't really adopt it. They wanted to have this face-to-face meeting with their treating physician at the beginning. [...] We still respect this human touch and we need to have it." (A1)*

This cultural preference for physical interaction poses challenges for business models that rely on virtual care or patient-facing digital platforms. While infrastructure may be available, patient engagement strategies must account for emotional and relational dimensions of pharmaceutical sector.

Government policies in Europe are highly supportive of research and startup innovation, especially through programs such as Horizon European program, which provide generous funding opportunities for early-stage ventures and cross-border R&D collaboration. However, the policy landscape is also marked by regulatory rigidity. Interviewees highlighted the tension between data privacy regulations, such as the General Data Protection Regulation (GDPR), and the need for open data sharing in digital innovation.

> *"We are very careful about privacy of data for sure. But digitalization is all about sharing data. And so if you're not allowed to share data, you will not have any innovation. In this way, I think China is a little bit smarter—they make the legislation while the developments are moving on." (E2)*

This forward-looking legislative approach, while commendable for consumer protection, may be stifling innovation by creating preemptive barriers to experimentation and data interoperability—two critical elements for scaling AI and digital health platforms.

In addition, reimbursement policies at the national level can act as another bottleneck. In countries like Belgium, where medical costs are mostly covered by the government, the absence of reimbursement for certain digital or non-traditional treatments discourages adoption by providers and patients alike.

Academia in Europe is traditionally strong in research and development, with universities producing high volumes of scientific output in biotechnology and healthcare. In recent years, the emergence of technology transfer offices and bio-incubators has helped bridge the gap between academic research and commercial application. These mechanisms not only support researchers in navigating patenting, licensing, and startup creation but also generate significant revenue for universities while stimulating regional economic growth by creating thousands of jobs. Although the technology transfer ecosystem in Europe is still catching up to the more mature U.S. model, it has gained considerable momentum and stands at a more advanced stage compared to many Asian countries. This institutional evolution marks a growing recognition of academia's role not only in discovery but also in innovation valorization and market impact.

> *"Most of them fail there because they do not know what is growth in a startup company. [...] Most of them are scientists, researchers, not entrepreneurs. So we create the office, we create awareness that you can transfer your knowledge. [...] Try to convince that researcher to transfer his knowledge at a price. It's very complex.*

> "*In a lot of cases, the researchers sitting there without knowing that he can transfer it to a company. Most of them are scientists, researchers, not entrepreneur so we create the office that can transfer their knowledge. We negotiate the contract with that company" (E3)*

To sum up, Europe remains a science-strong biopharmaceutical region, supported by robust academic institutions, generous public funding, and steadily evolving commercialization frameworks. The rise of technology transfer offices and incubators has improved the pathway from academic research to market application, although commercialization is still less dynamic compared to the U.S. Business model innovation, particularly in AI-powered drug discovery, platform development, and technology transfer, is emerging, but moderated by cultural preferences and regulatory caution. Patient adoption of digital health remains limited, and regulatory frameworks like GDPR and rigid reimbursement systems continue to slow innovation uptake. Still, with its deep R&D foundation and growing infrastructure for valorisation, Europe is well-positioned to accelerate transformation.

5. DISCUSSION

5.1 Impacts of emerging trends to business model transformation

A key finding of this research is that artificial intelligence (AI) outpaces other emerging trends – notably digitalization and sustainability – in terms of adoption across regions and firm sizes. This suggests that biopharmaceutical firms worldwide view AI as a primary driver of innovation, regardless of their geographic location or scale. This observation is consistent with broader industry evidence: a recent global survey indicated that nearly 70% of pharmaceutical companies have at least partially integrated AI into their operations (Statista, 2025a). The prominence of AI reflects its perceived ability to enhance research efficiency, reduce development costs, and improve predictive capabilities through advanced big data analytics.

The drivers behind AI adoption are both external and internal. Externally, market pressure compels firms to innovate and stay competitive. Internally, the younger generation of scientists who are more fluent in digital technologies serve as active proponents of AI integration. This has led to the emergence of novel business models such as AI-powered drug repurposing, virtual biotech companies, and platform-based discovery systems. These models not only reduce development timelines and costs but also shift how value is created and delivered in the pharmaceutical landscape.

Despite AI's wide penetration, most firms remain cautious in its deployment. Current usage is often limited to downstream functions such as marketing and market research, while upstream activities like target identification and compound design continue to rely heavily on human expertise. This caution stems from persistent concerns around regulatory uncertainty, lack of internal capabilities, and the potential risks associated with algorithmic decision-making. Over-reliance on AI without robust governance mechanisms raises significant societal risks, particularly in healthcare where ethical missteps or errors can have profound consequences. These findings align with recent literature, which underscores the need for ethical AI frameworks and stronger oversight, particularly in life science sectors (Aagaard, 2024; Tijd, 2024)

Digitalization, in parallel, is facilitating the industry's shift toward a real-time, data-centric paradigm. The ability to translate large-scale data into actionable insights supports faster decision-making and fosters tighter collaboration across stakeholders. One notable outcome is the emergence of transactional platform business models, which digitally connect pharmaceutical companies, healthcare providers, insurers, patients, and regulators. This interconnectedness improves transparency, enables better diagnostics, and supports a broader shift from reactive "sick care" to proactive, preventive healthcare models. Telemedicine, for instance, illustrates a disruptive model enabled by digitalization, particularly effective for aging populations, underserved rural regions, or densely populated countries experiencing healthcare access bottlenecks. These findings support previous studies advocating for value-based healthcare approaches to address systemic issues such as workforce shortages and healthcare inequality (PwC, 2024).

Sustainability, while gaining attention, remains less embedded in core pharmaceutical business models, particularly in comparison to AI and digitalization. However, it holds long-term potential as a competitive differentiator, especially in developed economies like Europe and the United States, where regulatory incentives and public expectations around environmental and social responsibility are increasing. In contrast, sustainability considerations remain less central in emerging markets across Asia, where economic pressures and dense populations place more immediate emphasis on affordability and efficiency. Interestingly, government policy plays a critical role in nudging firms toward sustainable practices. Initiatives such as favorable reimbursement policies or incentives for orphan drug development demonstrate how public institutions can shape firm behavior. In turn, pharmaceutical firms are gradually pivoting toward patient-centric models, focusing on rare or niche indications through the development of personalized or orphan drugs. While these treatments may generate less revenue per unit than blockbuster drugs, they offer strategic advantages. First, developing treatments for smaller indications often requires deep expertise and complex infrastructure—resources typically concentrated in larger firms—thus creating a competitive edge. Second, the accelerated regulatory pathway for niche treatments allows firms to enter markets faster, extending their revenue windows and offsetting patent cliffs.

These findings also highlight how different emerging trends shape specific elements of the business model. AI primarily influences value creation and operational efficiency; digitalization transforms customer relationships and channels; and sustainability reshapes value propositions and cost structures. However, the evolution of business models in practice is rarely driven by a single trend. Rather, it is the convergence of multiple forces that results in more holistic transformations. For example, patient-centricity is not only a product of sustainability goals but also a reflection of digitalization's role in amplifying patient voices through social media and data platforms.

The table below (Table 5) provides a summary of how each emerging trend impacts key business models mentioned in this study. The level of influence (low, moderate, high) is indicated to reflect the varying degrees of trend-driven transformation observed across the biopharmaceutical sector.

Table 5: The level of emerging trend influence in business model evolution

Business model	**AI**	**Digitalization**	**Sustainability**
Patient-centric model	Moderate	High	High
Platform-based model	High	High	Moderate
Telemedicine model	Low	High	High
Drug repurposing model	High	Moderate	High
Technology transfer	Low	Low	High
Virtual firm	High	High	Moderate

5.2 Transformations across company sizes and regional contexts (EU, US, Asia)

5.2.1 Comparative Analysis of Organizational Transformation Across Firm Sizes

Our findings highlight how company size shapes the way firms approach transformation—especially when it comes to AI, digitalization, and sustainability. While all types of firms are engaging with new business models and tools, their priorities, pace, and pain points look very different depending on their size.

Startups: Agility in Innovation, Constraints in Sustainability

Startups are clearly the fastest in picking up emerging trends, especially AI and digital tools. These technologies are often at the core of their business from day one. Thanks to flat structures and a test-and-learn culture, startups can move quickly, try new things, and pivot based on real-time feedback. They're also well-suited for AI-based platforms and technology transfer models, where speed and flexibility are key.

SMEs: Strategic, Flexible, and Focused on Viability

SMEs fall somewhere in between. They're more stable than startups and have enough resources to invest in things like enterprise AI tools, internal infrastructure, or platform licenses. Many SMEs are finding ways to apply AI and digital solutions to improve current operations whether through virtual biotech models, drug repurposing, or bioinformatics platforms.

Unlike startups, SMEs tend to work within clearer commercial limits. They're not usually built around one disruptive innovation but rather try to embed technology where it adds obvious value. Their financial base allows them to experiment, but they still prioritize projects that offer near-term returns. This often means their innovation is shaped by investor expectations or business sustainability goals, not necessarily long-term patient impact. As one interviewee said, "We're looking at which population gives the highest return—not who needs the drug most." So while SMEs are active in transformation, it's often a calculated move rather than a bold leap.

Big Corporations: Strong Foundations, Slower Moves

Large pharmaceutical firms have the resources, expertise, and global presence to lead change at scale. But in practice, they tend to move slower. Their size and legacy systems often mean more layers of decision-making and less flexibility to quickly test and scale new models. Internal approval processes, traditional business logic, and fear of disrupting existing revenue streams can slow innovation, even when teams have good ideas.

That said, big pharma is making progress, especially in areas like patient engagement and personalized therapies. Companies like Novartis are building internal departments focused on co-creating treatments with patients. There's also growing investment in platform-based models that connect various players such as clinics, insurers, patients through digital tools that improve data sharing and real-time coordination. These shifts reflect a broader move away from mass-market drugs toward more targeted,

sustainable approaches. However, these firms still face the challenge of balancing innovation with operational stability and a deeply embedded corporate mindset.

This variation in how firms adopt new technologies is clearly captured in the summary table below, offering a quick snapshot of where each type of company stands.

Table 5: The level of emerging trend influence in different firms' sizes

Type of company	AI	Digitalization	Sustainability
Startups	High	Moderate	Low
SMEs	High	High	Moderate
Big corporations	Moderate	Moderate	High

5.2.2 Comparative Analysis of Organizational Transformation Across Regional Contexts

This study reveals distinct regional patterns in how AI, digitalization, and sustainability shape business model transformation across Asia, the United States, and Europe. While all regions demonstrate movement toward innovation, the maturity, priorities, and institutional drivers of change vary significantly, reflecting each region's unique configuration of the Quadruple Helix—government, firms, academia, and patients.

Asia (Singapore & Vietnam): Digital Enthusiasm Meets Uneven Implementation

Asia, particularly Singapore and Vietnam, presents a mixed landscape of innovation readiness. Patients in Singapore are among the most digitally literate globally, with widespread use of mobile platforms embedded into daily life. This digital savviness makes the region highly suitable for telehealth and platform-based care delivery. However, actual adoption by firms and institutions remains uneven.

Vietnamese firms remain cautious about investing in AI and digital transformation, often limiting application to administrative or marketing functions. Concerns about cost, return on investment, and limited technical capacity are key barriers. Singapore is further ahead, with firms and universities piloting AI-based discovery platforms and biotech spin-offs. But across the region, price sensitivity among patients and a fragmented tech-commercial ecosystem continue to constrain adoption.

Governments, especially in Vietnam, are actively incentivizing digital transformation through tax breaks and tech-friendly policies. Meanwhile, academia in Singapore is increasingly commercializing its research, wheras Vietnam still struggles with bridging scientific innovation and market application due to a lack of cross-disciplinary talent. Overall, the region shows strong potential but remains in a transitional phase, particularly in markets like Vietnam, where the foundation for innovation is still being built.

United States: Innovation Engine with Shifting Public Support

The U.S. remains at the forefront of biopharmaceutical transformation, characterized by deep technological integration, advanced R&D capabilities, and a vibrant startup ecosystem. AI is widely embedded across the drug discovery pipeline, with younger scientists playing a key role in driving adoption. Virtual biotechs and AI-driven drug repurposing are particularly prominent, signaling a shift toward asset-light, computationally intensive business models.

Despite these advances, the U.S. government supports that historically a pillar of biopharma innovation is showing signs of contraction. Reduced funding for foundational research (e.g., NIH) poses a long-term risk, potentially increasing reliance on private investment. However, targeted policies supporting orphan drug development and tech transfer continue to foster niche innovation.

Academic institutions in the U.S. actively encourage commercialization through robust tech transfer offices and spin-off support. Patients benefit from faster access to personalized treatments as companies increasingly focus on narrow indications with high value. The U.S. continues to lead in business model experimentation, although policy uncertainty may affect its long-term stability.

Europe (Belgium & France): Research Powerhouse, Regulatory Caution

Europe maintains a strong research foundation and is actively exploring digital and AI applications in drug development. However, the pace of business model transformation is tempered by cultural and regulatory factors. Firms often acquire AI capabilities through external partnerships, such as with bioinformatics companies, rather than developing them in-house. This strategy reflects a pragmatic, risk-managed approach to innovation.

Patient adoption of digital tools like telemedicine remains low. Despite robust infrastructure, cultural preferences for face-to-face interaction create resistance to remote care models. Government funding programs like Horizon Europe offer strong support for R&D and startups, but rigid regulatory frameworks, especially data privacy laws like GDPR often hinder digital experimentation and data sharing.

Academia is a key strength in Europe. The emergence of technology transfer offices and incubators has improved commercialization outcomes and stimulated local economies. Although not as dynamic as in the U.S., this infrastructure is more mature than in many parts of Asia. The European model is moving steadily toward integrated innovation but continues to be constrained by policy complexity and patient behavior.

Table 6: The level of emerging trend influence in different regional contexts

Regional context	AI	Digitalization	Sustainability
The United States	High	Moderate	High
Europe	Moderate	Low	High
Asia	High	High	Low

5.2.3 Practical implications

The findings of this research carry valuable implications for biopharmaceutical firms, policymakers, and academic institutions seeking to navigate business model transformation in response to emerging trends. One key insight is the importance of contextualizing strategic choices, particularly in relation to firm size and regional characteristics.

Asia: Leverage Digital Readiness and Unlock Valorization Potential

In Asia, especially in tech-forward countries such as Singapore and emerging markets like Vietnam, firms should capitalize on the population's high digital literacy. Patient familiarity with mobile technology presents a unique opportunity to scale digital health models such as telemedicine and platform-based services. However, while digital infrastructure is well established among users, the gap between academic research and commercial application remains a significant barrier. This indicates strong potential for expanding technology transfer models that can better valorize scientific discoveries into marketable solutions. Government incentives and growing academic capabilities suggest that this is a timely opportunity for stakeholders to strengthen translational ecosystems.

Europe: Advance Digital Innovation and Double Down on Sustainability

Although European firms and patients have been relatively cautious in adopting digital health tools, structural changes are underway. Reports such as PwC (2024) have underscored the urgency for European health systems to embrace digital innovation in light of an aging population and healthcare workforce constraints. Therefore, firms operating in Europe should continue to build digital capabilities and prioritize models such as telemedicine and data-driven platforms, which can deliver efficiency and scalability. Moreover, Europe's leadership in sustainability offers a strategic edge. Companies that embed sustainable practices into their R&D, production, and access strategies will be better positioned to align with both regulatory incentives and shifting societal expectations. Business models that integrate environmental and social responsibility may also benefit from consumer trust and policy alignment.

United States: Balance Agility with Strategic Resilience

In the U.S., rapid innovation has enabled widespread adoption of AI-powered business models such as virtual biotechs and AI-driven repurposing. However, growing uncertainty around federal funding became more severe by recent political shifts and budget cuts to science agencies, raising questions about long-term stability. In this environment, virtual models that minimize physical infrastructure and maximize flexibility are particularly well-suited. They offer firms the ability to remain agile and reduce dependency on traditional R&D pipelines or fixed resources, making them more resilient to policy fluctuations. For startups and SMEs, such models are also more cost-effective, while for large corporations, virtual units could complement traditional operations in navigating disruption.

In summary, the successful application of emerging business models depends heavily on local enablers and constraints. Firms that align their strategies with regional digital maturity, regulatory environments, and patient behavior will be more likely to achieve competitive advantage and sustainable innovation.

6. CONCLUSION

This thesis explored how emerging trends—artificial intelligence (AI), digitalization, and sustainability—are reshaping business models in the biopharmaceutical industry. Using a qualitative approach based on expert interviews across different regions and company sizes, the study examined how these forces are changing how value is created, operations are run, and strategies are set in this highly regulated, innovation-driven field.

Among these trends, AI stood out as the most disruptive and widely adopted. It plays a crucial role in business model innovation and sheds light on AI-powered drug repurposing, virtual biotech companies, and platform-based discovery tools. However, its use remains cautious. Most applications are limited to downstream areas like marketing and analytics. Concerns about policies, ethical risks, and internal capabilities make companies hesitate to migrate into a full AI-driven drug development process. These findings also reflect broader industry discussions about how to balance AI's potential with responsible use.

Digitalization is also making a strong impact, especially through models like real-time data platforms and telemedicine. These innovations support more integrated healthcare ecosystems and encourage a shift from product-based to service-enhanced business models. Still, adoption levels vary widely across regions and organizations. Sustainability, while not yet central for many companies, is gaining momentum—particularly in Europe, where stronger regulations and public expectations are pushing companies to act. This trend highlights a growing focus on social responsibility and preventive healthcare strategies, which could strengthen companies' long-term benefits and competitiveness.

The study also emphasizes how the company size acts as an important factor in business model transformation, especially in response to new trends. Startups are often quick and creative, especially with AI and digital tools, but they face obstacles like limited funding, scaling issues, and the need to build credibility. SMEs tend to focus on balancing innovation with short-term financial goals. Larger pharmaceutical companies, while well-funded and experienced, often move more slowly due to their complex structures. Even so, they continue to grow in patient-centered care and expanding partnerships across the healthcare ecosystem.

Regionally, the U.S. continues to lead in innovation and experimenting with new business models, driven by strong ties between universities and industry. However, shifts in funding and policy are creating some uncertainty. In contrast, Europe benefits from solid R&D capabilities and mature innovation systems, but tighter regulations and cultural norms often slow down adoption. In Asia, countries like Singapore

and Vietnam show high patient readiness for digital solutions and increasing government support. However, firm-level adoption is uneven, and academic research is less frequently commercialized.

In conclusion, this study deepens our understanding of how biopharmaceutical business models are changing in response to new technologies and societal demands. It highlights the importance of aligning the business model with each organization's characteristics and cultural context to achieve effective transformation.

7. RESEARCH LIMITATIONS AND FUTURE OUTLOOK

7.1 Research Limitations

While this study offers a comprehensive exploration of business model transformation in the biopharmaceutical industry under the influence of emerging trends, a few limitations should be noted.

First, the Asian regional sample does not include China, which is a major player in global pharmaceuticals and a leader in AI adoption. Lacking insights of this largest market, the study may overlook key factors impacting the broader Asian market.

Second, the U.S. input comes from just only one interviewee. Although their insights were valuable, a single perspective cannot represent the complexity and diversity of the American biopharma sector. Therefore, scholars should view findings of the U.S. markets as supporting insights rather than core conclusions.

Lastly, in aiming to capture global shifts, this study may neglect the complexities at the local level. A more focused analysis at a national scale has allowed for a deeper dive into local factors, such as policy, infrastructure, and cultural attitudes that shape how business models evolve.

Future research could build on this by increasing the number of participants in key regions like the U.S. and China, and by conducting more localized comparisons to better understand what’s driving change in each context.

7.2 Future Research Recommendation

Building on the findings of this study, some possible directions for future research can be considered to deepen the understanding of business model transformation in the biopharmaceutical industry.

One area worth exploring is how companies can develop more adaptive models to better handle political and economic disruptions. For example, changes in U.S. trade policy—like new tariffs or shifts in federal

funding—have had real effects on R&D investment and international partnerships. Future studies could look at how firms build resilience through tools like digital infrastructure, flexible operations, or strategic alliances, helping them stay competitive in an increasingly unpredictable global market.

Another promising direction is to focus more closely on startups. This research touched on their speed and tech-savviness, but future work could deep dive into how these smaller players can scale their innovations and stay competitive over time. Many face difficulties like limited funding, trust from partners, and fitting into an ecosystem dominated by larger firms. Understanding how they can form stronger links with universities, big pharma, or investor networks without losing their DNA could offer practical lessons. Comparing startups that thrive with those that struggle would help identify what makes the difference in a tough and regulated industry.

Together, these research paths could offer more detailed insight into how firms of all sizes and in different regions can evolve their business models under both technological shifts and systemic shocks.

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