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Faculty of Business Economics

Master of Management

Master's thesis

A comparison of Biopharmaceutical Ecosystems from a Quadruple Helix Perspective: leveraging AI and lessons learned for Hanoi (Vietnam)

QUOC HUY PHAN

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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Executive Summary

1. Research Purpose

This thesis aims to investigate the biopharmaceutical ecosystems of Hanoi, Leuven, Boston-Cambridge and Fukuoka in order to analyze them through their integration with Artificial Intelligence (AI). This study was performed to strategically identify the SWOT (Strengths, Weaknesses, Opportunities and Threat) through the perspective of Quadruple Helix Model within those top ecosystems enabling necessary insights facilitating Hanoi's Biopharmaceutical sector. The research will apply those real-world lessons from these trailblazing locations then to develop strategies that can contribute innovation and change the competitive dynamic for Hanoi's biopharmaceutical industry.

By learning from these global leaders, Hanoi can gain a holistic vision into the significance of having strong R&D infrastructure for its AI sector and how collaboration through Quadruple Helix Model really works in practice along with integration of AI by creating conducive government policies and financial support. The lessons from these case studies can provide Hanoi with a blueprint to transform its biopharmaceutical ecosystem into one that is more vibrant, dynamic, and forward leaning in keeping with international norms.

2. Research Methodology

This thesis chose to use a mixed-methods approach, which means quantitative data on the internet and qualitative information from the interviews are collected and analyzed - in this case that meant interviewing key stakeholders at various levels of the biopharmaceutical ecosystem.

Quantitative data collection: secondary data was collected through various newspapers with cuttings, university annual reports and government reports were relied on for the quantitative aspect as well while industry information from major news sources had been valuable, alongside patent databases. The Hanoi Data was further utilized as a benchmark against the most well-recognized regions such Leuven, Boston-Cambridge and Fukuoka. Factors reviewed were the degree of innovation capacity-building, levels and impact of entrepreneurial talent, R&D investment for tech sectors (from public and private sources), number of sector-related patents (internationally recognized metric to gauge competitiveness); existence or potential formation/spin-offs for start-up companies in some targeted areas; developmental aspects related to collaboration which can be influenced by support/operational conditions within Quadruple Helix Model processes layout across key regional flows among target groups as well relative focus on entrepreneurship based academia-industry linkages boosting collaboration.

Qualitative data collection: This qualitative part of the research included a series of structured interviews with experts from regions concerned, who shared their perspectives and experiences as well as made specific recommendations known to them by professionals within that section. These interviews were further supplemented by an extensive literature review that placed the results in context with broader trends of biopharmaceutical innovation and AI adoption. The data derived from these sources were examined in consideration of the Quadruple Helix Model, which represents an investigation into interactions among academia, industry, government, and society.

3. Findings

The study reveals significant insights into the biopharmaceutical ecosystems of the four regions, highlighting their respective strengths, weaknesses, opportunities, and threats:

Leuven, Belgium:

- Strengths: rich in R&D investment, moderate numbers of patents and spin-offs, strong academic-industry collaboration and a prevalent Quadruple Helix model.
- Weaknesses: the region needs more seed and early-stage capital relative to Boston-Cambridge as well as long innovation cycles.
- Opportunities: There is potential to expand the integration of AI, collaborations, and open more high-value VC investment.
- Threats: The area also faces exposure to economic instability, difficult in retaining talent, higher operational costs and competition for biopharma companies from other hubs.

Boston-Cambridge, The United States of America:

- Strengths: Boston-Cambridge has high R&D investment, significant venture capital funding, many patents, and an extensive network of collaborations.
- Weaknesses: The region struggle with high operational costs and some regulatory complexities.
- Opportunities: Opportunities exist by using AI for drug discovery and clinical trials, fostering public-private partnerships and global collaborations.
- Threats: However, potential threats are increasing competition and a fragile economy which could turn on its head at any moment accompanied with unclear regulatory policies.

Fukuoka, Japan:

- Strengths: Fairly good government support, a decent number of patents and spin-offs; excellent in talent development.
- Weaknesses: high intellectual property maintenance costs, challenges with talent engagement and adaptation of AI being very slow.
- Opportunities: Growing global aid and AI integration, establishing a strong data system.
- Threats: Lack of infrastructure for database systems and budgets to apply the research on new grants.

Hanoi, Vietnam:

- Strengths: Hanoi is growing as a biopharmaceutical center with strong growth prospects, supported by government initiatives and rising Foreign Direct Investment.

- Weaknesses: Still continues to have issues dealing with poor infrastructure, regulations and lack of research capabilities.
- Opportunities: Hanoi can undertake global best practices initiatives, improve AI integration and attract more venture capital as well as increased government support in order to grow its biopharmaceutical sector.
- Threats: Regulatory hurdles, financial fluctuations and competition against older biopharma hubs.

This study, therefore, contributes to the current literature by analyzing these ecosystems resulting in a better understanding of where Hanoi stands regarding them; and suggesting measures that could help raise its biopharmaceutical activities through experiences from leading regions.

4. Critical Considerations and Recommendations

To advance Hanoi's biopharmaceutical ecosystem, the following strategies are recommended:

Strengthen Collaboration: Adopt the Quadruple Helix Model to foster alignment with academia, organization industry and citizens. By working together, Hanoi can drive innovation through joint research projects and public-private partnerships, fostering a dynamic environment for growth.

Increase Funding: The use of government funding application, attract venture investment, rely on international financing is necessary to support biopharmaceutical research and AI integrated deployment. The funds will attract innovation for high-potential projects and serve the development of a part of Hanoi as both an industry-oriented locality where drugs are developed, manufactured, and registered with regulatory agencies.

Encourage Innovation: Invest more into R&D, establish new AI research centers, and create start-up incubators to help early-stage biopharmaceutical companies. These efforts can speed up the time taken to enable new products into development and then on towards commercial issuance.

Improved Regulations: Hanoi need to create strong data privacy and AI regulations that support the ethical and safe practice of AI. This also makes it easier for global collaborations and foreign investments if its standards match international norms.

Talent Development: The world-class facility will encourage talent development in the country, with its state-of-the-art education courses and international internships enabling creation of an expert workforce capable of leading this critical sector. In order to keep up with that pace, government-funded scholarships and collaboration activities with reputable research institutions can be leveraged to expand the pipeline of trade leaders through a strategic alignment between development and retention initiatives.

Through these strategies, Hanoi can learn from global best practices to create a dynamic and innovative ecosystem for biopharmaceutical manufacturing that will compete successfully with those established in regions such as Leuven (Belgium), Boston-Cambridge (USA) or Fukuoka. This fuel sustainable economic development, resulting in better healthcare outcomes while allowing Hanoi to set a foothold within the Southeast Asia region and globally.

The research from these leading centers serves as a case study, illustrating the need for an all-encompassing approach - one involving intensive collaboration, in depth financial commitment and stringent regulation - complimented with continuous nurturing of skills. Through the implementation of such practices, Hanoi can become a global biopharmaceutical hub and sustain an ecosystem which not only leans towards achieving better health outcomes but also economic good fortune.

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1. Problem Statement

The Biopharmaceutical industry contributes as a major junction in the process of development and advancement, or establishment of economic benefits associated with improvement in healthcare, which become significant around the world. While the potential is evidently there, barriers have slowed the development in lower income countries like Vietnam where premiums are low and capacity, regulatory and infrastructure challenges weigh down on an ambitious biopharma ecosystem.

This master's thesis is studying about the biopharmaceutical ecosystem and AI integration in Hanoi advancing itself towards these regions Leuven, Belgium Boston-Cambridge (USA), Fukuoka (Japan). These regions are internationally recognized as leaders within the global biopharmaceutical industry and offer extremely important case-studies on how to best manage government regulations, collaboration with third parties, and implement new innovation strategies.

Leuven is a biopharmaceutical hub in Flanders region in Belgium, backed by significant government support for R&D and public-private collaboration as well as AI implementation on top. The area where the region currently uses AI are mainly drug discovery and developing, and clinical trials. AI technologies are used for faster screening of chemical compounds, and to improve predictive modeling in drug development applications. This partnership between academic institutions like KU Leuven, KU Leuven Research and Development, and biopharma companies is a way to include AI seamlessly in an increasingly supportive ecosystem of innovation that helps drive growth.

The Boston-Cambridge region is one of the leaders of biopharmaceutical R&D; AI is integration playing an important role in the knowledge exploitation, various from-scratching utilize on compound screening to optimization of large molecule design and clinical trial procedures. With AI-driven platforms in place, the process of drug discovery is streamlined, clinical trials are made more efficient and therapeutic interventions can be targeted with high precision. This interplay between academic research institutions, biotech startups and venture capital investment results in a dynamic ecosystem that constantly pushes the frontier of innovation and commercialization.

In the biopharmaceutical sector, Fukuoka is becoming an increasingly important player in Kyushu region, Japan. With growth also assisted by Japan's proactive government policies and significant investment in research infrastructure, the nation boasts a robust biopharmaceutical sector. AI integration in Fukuoka is already beginning, and the government is pushing for more. There are some powerful images used in the article that pose Fukuoka as a serious biopharmaceutical contender based on their ability to develop talent and foster innovation, especially from those talented souls who graduate from Kyushu University.

Hanoi's biopharmaceutical landscape is not as mature when compared to those areas. The region has many challenges ranging from regulatory issues, sparse infrastructural facilities to no advanced research capabilities. Yet using the insights of Leuven, Boston-Cambridge and Fukuoka as practical models Hanoi can pave strategies to tackle these issues. The development will largely be driven by policies to improve regulatory landscapes, enable Quadruple Helix Collaboration (Government-Academia-Industry-Society) and increased investment in AI-based R&D.

This paper will present the results of applying a systematic comparative analysis to identify strengths, weaknesses, opportunities, and threats (SWOT) within Hanoi's developing biopharmaceutical ecosystem as drawing actionable insights from Leuven in Belgium, Boston-Cambridge in the USA and

Fukuoka in Japan. Collectively, these insights can help the Hanoi region craft policies that work to attract strategic biopharmaceutical investments and initiatives. This is an effort to accelerate inclusive economic growth, improve health systems and outcomes, reduce the burden of infectious diseases on countries.

From this comparison, it emphasized the regionally-focused strategies and AI driven global lifecycle approaches that contributes to developing biopharmaceutical ecosystems for Hanoi.

2. Literature Review

2.1 Introduction

The rapidly growing Hanoi, capital of Vietnam is also the city with potential for setting up a biopharmaceutical ecosystem. The city has a favorable landscape for biopharmaceuticals as it offers upgraded healthcare infrastructure, surging income levels and higher population act favor of its growth. Yet, the biopharmaceutical sector in Hanoi is debilitated by various challenges that prevent it from delivering its full potential towards economic development and public health.

Looking to global best practice in biopharmaceutical regions: Hanoi can learn from biopharma hubs worldwide if it is overcome these challenges and reach its full potential. Hanoi can thus learn from all of these regions on how to craft and implement region-specific strategies promote its biopharmaceutical capabilities.

Leuven (Belgium), one of the top leaders for its thriving biopharmaceutical ecosystem featuring strong government support, world class research infrastructure and an ideal of a flourishing industry-academia-government-society collaboration. This success story is attracting attention from cities like Hanoi, where the city council has been studying best practices to foster collaboration, establish policies and invest in public R&D infrastructure.

The case of Boston-Cambridge in the US, a hub for biopharmaceutical industry innovation and commercialization. This includes top-tier research organizations, a thriving entrepreneurial ecosystem, and supportive regulations. Hanoi can indeed learn from those successful elements, such as champions for nurturing a research ecosystem with strong innovation orientation and vibrant entrepreneurship landscape encouraged by enlightened policies.

Finally, in addition to the promising biopharma work, Fukuoka is a very notable place of innovation with an established tradition as a key player into Japan's Kyushu region. Advantages in the area include strategic government intervention, large research infrastructure investments and a focus on talent development. Through these realizations, the Vietnamese capital can look for mutual benefits and cooperation to push its biopharmaceutical industry one step further — by understanding what Fukuoka has done.

The maturing clinical results of artificial intelligence (AI) are changing every facet of biologic drug discovery, and its integration into regions' business model. If Hanoi (Vietnam) wanted to learn from the most innovative leaders regarding how they leverage AI, it would pay off for them to see what Leuven, Boston-Cambridge and Fukuoka are up to. These regions speed up drug discovery, as a result of the accelerated development in drug and optimized molecular design as well predictive modeling. It becomes clear that AI makes clinical trials faster offering Vietnam ways to utilize artificial intelligence for it's biopharma industry.

This Master thesis will provide a comprehensive review of the literature on regulatory frameworks, cooperation drivers, barriers, and economic effects in global biopharmaceutical ecosystems. Its main objective is to search for strategic concepts and lessons learned that can be transferred to Hanoi, which wants to create a sustainable economic development process in an AI-enabled biopharmaceutical industry. The study will show what actionable insights can be derived about the ecosystem development in Hanoi if compared with Leuven, especially Boston—Cambridge and Fukuoka.

Through learning from these best-in-class regions, Hanoi or Vietnam can create robust policy frameworks and strategic investments to strengthen its biopharmaceutical capabilities on the one hand so as to drive economic progress; enhance healthcare delivery outcomes on the other; whilst contributing positively towards global health outcomes.

2.2 Industry-Academia-Government-Society Collaborations: The Quadruple Helix Model

2.2.1 Conceptual Framework of the Quadruple Helix Model

The Quadruple Helix model is a conceptualization for the complex interactions of industry, academia, government and society as being related to innovation system. This model is a further development of the Triple Helix Model, which consists in principle only by industry, academia and government, and adds society as a new important forth helix into account that can increase innovation and societal impacts (Carayannis & Campbell 2009). In this way, the social dimension deepens and completes theoretical contributions that have emphasized elements whose relevance are often overlooked to build sustainable innovation ecosystems: social capital, public engagement in R&D process or co-creation of knowledge (Etzkowitz & Zhou, 2017).

The industry is a pivotal component in the Quadruple Helix Model for boosting economic development and facilitating technology adoption by commercializing research and development (R&D) (Leydesdorff & Etzkowitz, 1998). Collaboration between academic institutions and companies through research and development which enables them to tap the latest in science and technology, boosting innovation to create new products or services. This partnetship increases company competitiveness and guides academic research to tackle the needs of firms in real-world problems (Perkmann et al., 2013).

Academia contributes by generating new knowledge, conducting fundamental and applied research, and providing education and training to develop a skilled workforce (Gunasekara, 2006). Universities and research institutions are pivotal in advancing scientific frontiers and translating theoretical findings into practical applications (Benner & Sandström, 2000). Collaborative research projects, joint ventures, and academic spin-offs are common mechanisms through which academia engages with industry and other stakeholders (Powers & McDougall, 2005).

Government plays a facilitating role by creating a conducive environment for innovation through policies, regulations, and funding programs (Kuhlmann & Rip, 2018). Government agencies support R&D activities, provide incentives for collaborative projects, and establish regulatory frameworks that ensure the safe and ethical development of new technologies (Mazzucato, 2013). By setting strategic priorities and investing in infrastructure, governments can drive national and regional innovation agendas (Uyarra & Flanagan, 2010).

Society, as the fourth helix, includes the public at large, civil organizations and individual citizens. Thus, engagement of society is important to speak for the inclusive and democratic innovation processes which orientated by addressing societal needs (Carayannis & Rakhmatullin, 2014). Society contributes to the Quadruple Helix Model through public participation in science and technology initiatives (e.g. citizen science projects) or social innovation practices (Arnkil et al., 2010).

Together these four helices interact, creating a dynamic synergetic environment for enabling innovation and socio-economic development (Leydesdorff, 2012). This Quadruple Helix model places specific emphasis on new ways of bringing together multiple actors supported by mutual interest to co-evolve knowledge and innovation capacities among different sectors. (Carayannis & Campbell, 2012). Particularly when one is talking about complex global challenges such as climate change, public health, and sustainable development an integrated approach. (Lindberg, Danilda, & Torstensson, 2012).

Completely, the existence of industry that dominates this model makes breakthrough innovations by converge those three sectors with were discussed in Triple Helix Model and keeping it remain committed to aligning arising blanket technology for social concern (Schütz et al., 2019) This model gives a holistic view to understand and measure the dynamics in innovation ecosystem interactions that are key for building more Resilient society and Inclusive world. (Colapinto & Porlezza, 2012).

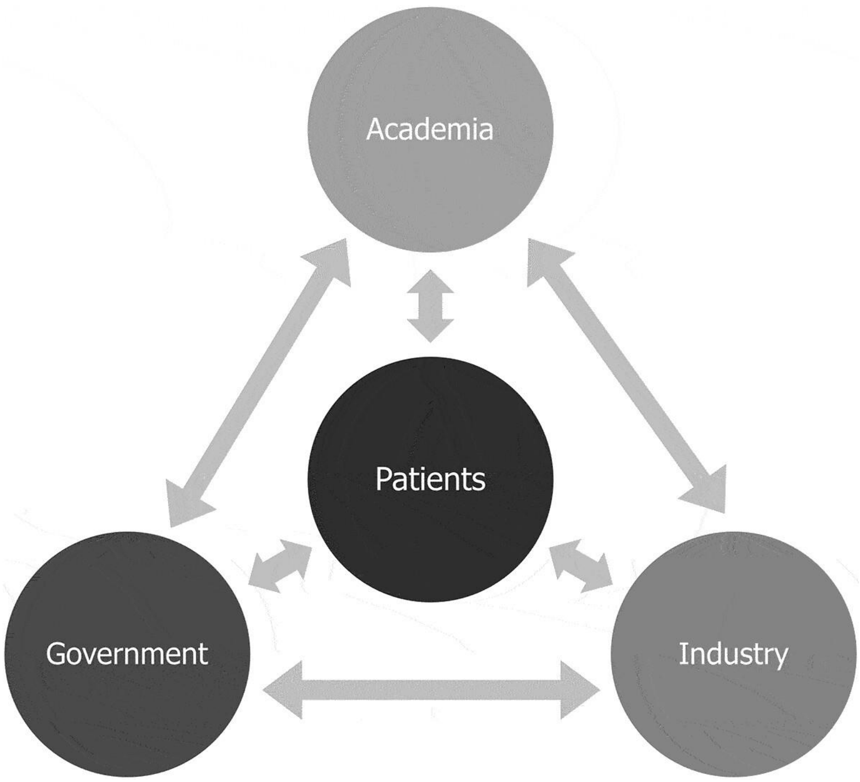

Figure 1. *The Quadruple Helix Model. (Durez, P. et al.; 2020)*

2.2.2 Importance of Collaboration in Biopharmaceutical Innovation

The foundation of brilliance in the biopharmaceutical sector is Collaboration. It leverages a range of expertise and resources to facilitate the development cutting edge therapies for which any one entity might not be capable on its own (Powell et al., 1996). This industry-academia-government-society collaboration contributes to create an environment of shared ideas and incentives for cross-fertilization between sectors (Etzkowitz & Zhou, 2017).

Biopharmaceutical research in particular is dependent on cross sector collaboration between industry and academia. Academic institutions contribute because they produce new scientific knowledge and carry out original research, which is then a basis for the applied R&D activities of pharmaceutical companies (Perkmann et al., 2013). For instance, numerous innovative drugs and therapies originated in university research labs before being developed and marketed by biopharmaceutical companies (Cockburn & Henderson, 1998). This was strengthened with high quality collaborations, thus as a model assisted in effective transformation of scientific discovery into clinical application (Calvert, 2006).

Government intervention in collaborations among biopharmaceutical agencies is likewise necessary. It is the role of governments to fund R&D, create regulatory environments that ensure safety and efficiency as well as policies that facilitate innovation and cooperation (Mazzucato, 2013). Public may play an important financial risk game in biopharmaceutical R&D as grants and subsidies where are given compensates for the high novelty innovation says (OECD, 2019). In addition, regulatory agencies are at the center of approving and unleashing new therapies on a market that is also vital in realizing innovation for patients (Kaitin, 2010).

The involvement of society in biopharmaceutical collaborations guarantees that the public health needs and ethical requirements are met through new therapy developments. Patients, professionals from health care and patient advocacy organizations should be involved in the innovation process as they are able to bring essential information on patients' needs or preferences that help for improved treatments (Arnkil et al., 2010). Promoting public participation may increase transparency and accountability of pharmaceutical research, ultimately resulting in increased social trust as well (Carayannis & Rakhmatullin, 2014).

The collaborative model is exemplified in the development of COVID-19 vaccines. Global partnerships between pharmaceutical companies, academic institutions, governments, and international organizations resulted in vaccines being created at an unprecedented rate (Slaoui & Hepburn, 2020). The combined scientific expertise from academia, the development and manufacturing capabilities of industry, and regulatory, funding support by governments all underscored that when facing immediate public health crises nothing can match coordinated effort (Graham, 2020).

Collaboration therefore is likely to promote IP and resource sharing within the biopharmaceutical industry which in turn could be conducive for faster innovation mode. Such collaborative efforts provide the companies with an opportunity to develop and commercialize these innovations through later-stage development, where competitive advantages are more prevalent (Bititci et al., 2003).

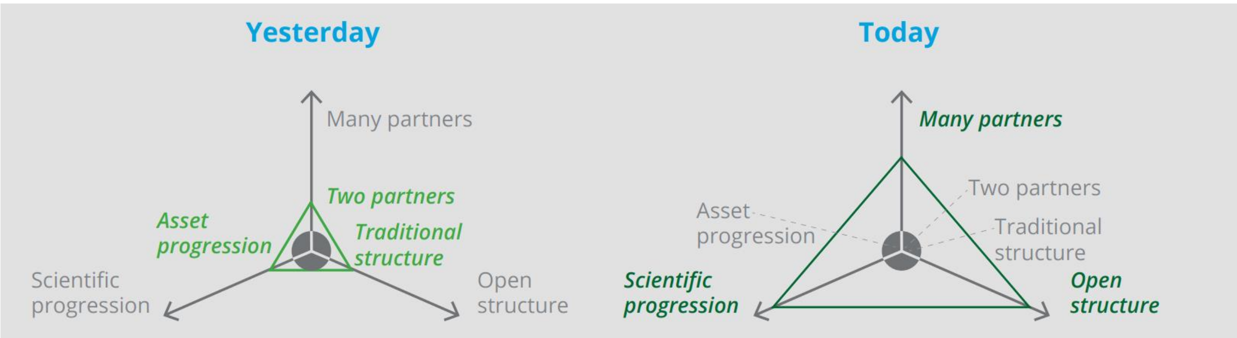

Figure 2. *Biopharmaceutical R&D ecosystem partnering trend. (Deloitte Consulting LLP; 2015)*

2.2.3 Quadruple Helix Model in Driving Innovation and Economic Growth

The Quadruple Helix Model plays a crucial role in driving innovation and economic growth by fostering collaboration among industry, academia, government, and society (Carayannis & Campbell, 2009; Etzkowitz & Zhou, 2017). This model emphasizes the importance of integrating diverse perspectives and resources to address complex challenges and create value (Leydesdorff, 2012; Schütz, Heidingsfelder, & Schraudner, 2019).

The Quadruple Helix Model fosters the generation, exchange and enhancement of knowledge by increased collaboration between stakeholders (Carayannis & Rakhmatullin, 2014; Arnkil et al., 2010). Such collaboration not only leads to more effective and readily embraced solutions (Colapinto & Porlezza, 2012; Ranga & Etzkowitz, 2013), but also promotes the blueprint of collective ICT-enabled citizen-centric innovation. Through the engagement of a broad base of stakeholders, it assures that innovations are socially relevant and public needs oriented (Lindberg et al., 2012; Carayannis & Campbell, 2012).

The integration of industry in the Quadruple Helix Model enables economic development by turning academic research to commercial services and products (Powell et al., 1996; Chesbrough, 2003). This support is crucial, as prior studies have found that industry partners are necessary for the commercialization of inventions; they provide key resources-including funding, technical expertise and market knowledge important to this process (Perkmann et al., 2013; Cockburn & Henderson, 1998). This process not only creates income and employment, but also develops the competitive advantage of firms as well as regions (Benner & Sandström, 2000; Gunasekara, 2006).

By creating leading edge research and spinning out newly developed technologies into innovative products and services, continued contributions to economic growth are made by academia (Calvert, 2006; Etzkowitz & Zhou, 2017). With respect to the human capital base that drives innovation and economic development, universities and research institutions have long been regarded as key in providing well-trained professionals (Powers & McDougall, 2005; Mazzucato, 2013). Academic and industry collaboration is an essential ingredient to have academic research in line with needs of market, allow translation into practices more relevant (Perkmann et al., 2013; Gunasekara, 2006).

Government participation in the Quadruple Helix Model is necessary for providing favorable conditions to nurture innovation and economic development as well (Kuhlmann & Rip, 2018; Mazzucato, 2013). Policy frameworks, funding and infrastructure provision from governments are critically important (OECD, 2019; Uyarra & Flanagan, 2010). Governments can drive national and regional innovation agendas by setting strategic priorities in collaboration between stakeholders (Haffner et al., 2008; Paris & Belloni, 2013).

In the Quadruple Helix Model, societal engagement allows for innovations that are socially relevant and ethically sustainable (Arnkil et al., 2010; Carayannis & Rakhmatullin, 2014). Public participation in innovations, can also indeed influence the transparency, accountability as well as acceptance of new technologies (Schütz et al., 2019; Lindberg et al., 2012). The model is a promotion of economic growth in ways that are socially inclusive and environmentally sustainable based on democracy, competition, and societal needs (Colapinto & Porlezza, 2012; Leydesdorff, 2012).

2.3 Biopharmaceutical Ecosystems: Overview

2.3.1 Definition and Scope of Biopharmaceutical Ecosystems

2.3.1.1 Definition of Ecosystem and Biopharmaceutical Ecosystem

The biopharmaceutical ecosystem is the complex network of relationships among stakeholders such as pharmaceutical companies, biotech firms, research institutions, regulatory agencies and healthcare providers that facilitate innovation and yield therapeutic solutions (Bettani et al., 2022). Ecosystems, in the wide sense, refer to dynamic, interconnected networks where entities interact with each other and exchange resources which results co-evolution as well values gets created together (Moore, 1993).

In the context of biopharmaceuticals, the ecosystem is the network of independent entities who are contributing to development, manufacture and marketing of bio-pharma products. Vaccines, monoclonal antibodies and recombinant proteins used as ingredients in modern medicine are examples of these products which essentially constitute biologicals (Pisano, 2006). The biopharmaceutical industry is known to be science and technology driven, involving huge R&D investments through a stringent regulatory framework for safety and efficacy (Powell & DiMaggio, 1991).

James F. Moore (1993) was the first to introduce business ecosystems as networks of interdependent organizations that co-evolve their capabilities around a new innovation concept in economic, strategic and technological terms (Moore, 1993). The biopharmaceutical industry has integrated this concept into its operations, recognizing that new drugs and therapies can no longer be developed outside of an innovation ecosystem (Powell et al., 1996). The success of a biopharmaceutical ecosystem depends on the synergy between its participants, which include academia, industry, government, and non-profit organizations, each contributing unique resources and expertise (Etzkowitz & Leydesdorff, 2000).

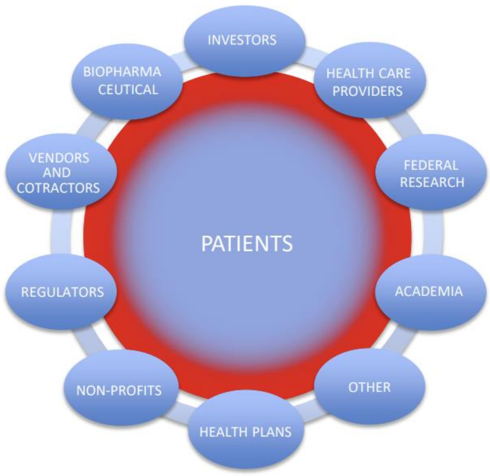

Figure 3. *Illustrative biopharmaceutical R&D innovation ecosystem. (Puślecki, 2021).*

Biopharmaceutical ecosystems are particularly important in the development of new drugs, this is especially true, where complex biological problems demand an interconnected total that spans multiple scientific disciplines and technologies - so-called biopharmaceutical ecosystems. By bridging gap, this interdisciplinary approach provides a stimulating climate for innovation and speed the conversion of scientific finding into clinical practice (Cockburn & Henderson, 1998). In addition, the regulatory environment is very important for shaping biopharmaceutical system effectiveness through setting standards of safety, efficacy and quality that are essential to raise public trust and market access (Higgins & Rodriguez, 2006).

In addition to regulatory and scientific challenges, biopharmaceutical ecosystems also face economic and market pressures. The high cost of biopharmaceutical research and development, coupled with the uncertainty of clinical success, requires substantial investment and risk management strategies (DiMasi, Grabowski, & Hansen, 2016). Consequently, collaborative relationships and strategic alliances are necessary to spread risks and pool resources as well as for knowledge transfer in order to foster innovation (Chesbrough 2003).

2.3.2 Regulatory Frameworks and Policy Initiatives

2.3.2.1 Overview of Regulatory Environment in Biopharmaceutical Industry

The regulatory environment in the biopharmaceutical industry is critical for ensuring the safety, efficacy, and quality of pharmaceutical products. Different regions have unique regulatory frameworks and policy initiatives that shape the industry's landscape, particularly in Leuven, Boston-Cambridge in the U.S., Fukuoka in Japan, and Hanoi in Vietnam.

(1) Leuven, Belgium

In Belgium, national regulations are combined with European Union (EU) directives to make the country a reliable environment for drug approval and monitoring as part of its biopharmaceutical regulatory framework. The regulation of drugs in Belgium falls under The Federal Agency for Medicines and Health Products (FAMHP), assuring compliance to EU guidelines (European Medicines Agency [EMA], 2020). This dual regulation allows high standards on drug safety and efficacy, while encouraging innovation by accompanying policies such as tax incentives or grant mechanisms to support Research en Development (Van Norman, 2016; FAMHP, 2019).

(2) Boston-Cambridge, United States

Boston-Cambridge is heavily influenced by the US Food and Drug Administration (FDA) because most of the drug approval and pharmaceutical regulation in this area takes place here (FDA, 2021). The FDA has a system of clinical trials and post-market surveillance to determine the safety and efficacy of drugs (Carpenter, 2010). Massachusetts also offers state support for biopharmaceutical companies, including funding and tax incentives via the Massachusetts Life Sciences Center (MLSC) to encourage innovation and industry growth in the region (MLSC, 2021).

(3) Fukuoka, Japan

In Japan, the Pharmaceuticals and Medical Devices Agency (PMDA) and Ministry of Health (MHLW) are responsible for regulating biopharmaceuticals (Hirai, 2015). Quick approval fast track system under the new drug act by Japan Regulatory abridgment process on innovative drugs, especially in areas urgent needs unmet medical restrictions (PMDA, 2019). The government also encourages cohesion between academia and industry as well offering financial assistance for R&D to the biopharmaceutical sector (Ministry of Health, Labour and Welfare [MHLW], 2018).

(4) Hanoi, Vietnam

The biopharmaceutical regulatory environment in Vietnam is regulated by the Drug Administration of Vietnam (DAV) from Ministry of Health (MOH). The regulatory framework in Vietnam is evolving, with increasing efforts to align with international standards such as those set by the World Health Organization (WHO) (DAV, 2020). On the contrary, this country has constrained resources that are put at risk of dilapidation because it lacks infrastructure and stipulations required to handily regulate (Pham et al., 2019). Vietnam has laid policy initiatives to strengthen the capacities of local regulation bodies and promote investment in biopharmaceutical sector by giving incentives and better regulatory processes (Nguyen et al., 2020).

2.3.2.2 Impact of Regulations on Innovation and Market Access

The biopharmaceutical industry is heavily regulated, which affects both innovation and market access. The purpose of regulatory frameworks is to guarantee the safety, efficacy and quality of biopharmaceutical products (Carpenter 2010), which are fundamental for protecting public health. At the same time, these regulations can also impose significant innovation-related costs by lengthening times to market for new drugs and increasing both direct and indirect-drug development expenses (DiMasi et al., 2016)

Regulatory approval by bodies such as the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), typically require a strict set of clinical testing data which can therefore increase time needed to develop an indication for treatment in comparison with other types medical device technologies (Hirai, 2015). While this regulatory rigor is necessary to protect patients, it can delay the implementation of new therapies (Kaitin 2010). The entire process from drug discovery to market approval of a single medication can take more than 10 years, primarily due the comprehensive regulatory scrutiny (Munos, 2009).

Another key point is that it all comes at a cost to be compliant with regulation Large clinical trials are expensive, and it can be cost prohibitive to follow regulatory standards that require long-term data and studies with a requested duration of at least 23 weeks (Paul et al., 2010). Studies have found that the fully loaded cost of developing a new drug averages $2.6 billion, including costs for failures and post-approval studies (DiMasi et al., 2016). This high cost is a potential roadblock to innovation as it may reduce firms' funds available for multiple or risky projects (Grabowski & Vernon, 1990).

Apart from tariff structures, availability to the market additionally is determined by regulatory rules which influence pricing and reimbursement decisions. The introduction of a new drug, in many countries, an evaluation for its cost-effectiveness which will lead to either reimbursement or no-reimbursement by national health systems (Sood et al., 2009). While strong level of value for money is essential from the point of using assessment to make new treatments available, pricing and reimbursement decision can result in limited or without market access if drug deemed too expensive relates to it benefits (Sorenson et al., 2008). As a result, biopharmaceutical companies face request regulatory and economic appraisal as the same time to gain decent commercialization of medicines (Paris & Belloni, 2013).

At the same time, regulations can even serve as a base for further innovation by requiring stringent safety and efficacy standards that push research to produce higher quality products (Carpenter, 2010). Regulatory incentives such as orphan drug designations, and fast track review processes are developed to encourage medicinal innovation within unmet medical needs (Haffner et al., 2008). Sync in this regulation can be boon to Drug companies who face a pressure of coming out with new drug for multiple markets and also helpful from consumer's perspective (Thiers, Sinskey & Berndt, 2008).

2.4 Four Pillars and the impact of AI to the Biopharmaceutical Ecosystem

2.4.1 Academia

Academia has a major footprint in the biopharmaceutical ecosystem as it bears immense responsibility to the advancement of scientific knowledge and innovation (Perkmann et al., 2013; Powell et al., 1996). Academic and research institutes are the main entrepreneurs of primary as well as applied knowledge in terms of basic and translational discoveries leading to discovery new drugs or treatment paradigm (Etzkowitz & Zhou, 2017). Creating a environment of interrogation and exploration, which is critical for the types of innovations required in biopharmaceutical development (Calvert, 2006; Benner & Sandström, 2000).

Academic-Industry collaboration is imperative in transforming scientific findings into applications (Ranga & Etzkowitz, 2013). University research is important for identifying new drug targets that can be utilized by biopharmaceutical firms and developing novel systems of technologies (Perkmann et al., 2013). Many of today's most important drugs (e.g., insulin, antibiotics) resulted in large part from work done in academic research labs rather than by industry alone (Cockburn & Henderson, 1998; Sampat & Lichtenberg, 2011).

Academia also contributes to the biopharmaceutical ecosystem by training the next generation of scientists and professionals (Gunasekara, 2006). Universities offer educational programs that encompass training in advanced technologies and approaches to develop students for the biopharmaceutical industry (Powers & McDougall, 2005). This education is fundamental to develop the adequate workforce required for innovation and industry growth (Salter & Martin, 2001).

In addition, universities are often hotbeds for start-ups and spin-offs that can also help to get new treatments on the market (Etzkowitz & Zhou, 2017). These new companies often emerge from academic research, leveraging university resources and intellectual property to develop new products (Lockett & Wright, 2005). The process of contributing economic growth, combined with a constant delivery of new ideas and technologies into the biopharmaceutical industry (Wright et al., 2004).

Given the records of success in these areas, one can argue that academia is at the forefront for fostering collaborative research initiatives. Industry and government partnerships are central to solving large scientific problems, due to their complexity which often requires fragmented expertise (Carayannis & Campbell, 2009). These collaborations frequently entail the joining of resources, expertise and data which can greatly improve research efficacy (Bozeman & Boardman, 2014).

Academic research in biopharmaceuticals relies on funding from both the government and private sectors (Mowery et al., 2004). Government grants and philanthropic funding can assist fundamental information (Geuna & Muscio, 2009). This money is crucial for furthering our knowledge of processes in biology and the creation of new therapeutic strategies (Salter & Martin, 2001).

2.4.2 Industry

The industry pillar, which represents a powerful segment within the biopharmaceutical ecosystem; contributes to fostering innovation, economic growth and generation of novel therapeutic solutions (Cockburn & Henderson, 1998; Chesbrough, 2003). Biopharmaceutical enterprises focus mainly on how to develop scientific discoveries into commercial opportunities, including drugs and vaccines for a variety of medical problems (Pisano, 2006; DiMasi et al., 2016)

Investing in Research and Development (R&D) - Perhaps the most impactful contribution of biopharmaceuticals is its investment into research and development. The industry spends billions of dollars per year on a research and development to identify potential new drugs (Scannell et al., 2012). Investments like these are critical for advancing the medical science and help in long run to improve public health outcomes. For instance, much of the R&D that has gone into creating new therapies for diseases such as cancer and diabetes is attributable to biopharmaceutical corporations (Munos, 2009; DiMasi et al., 2016).

In addition, biopharmaceutical industry fosters cooperation with academic institutions and government department which allow sharing knowledge and resources (Powell et al., 1996; Perkmann et al., 2013). Such partnerships are essential to capitalizing on the advantages of various stakeholders working together, in order to accelerate drug development.

It is a key player in clinical trials for testing the safety and efficacy of new drugs (Wong et al., 2019). To secure regulatory approval for existing drugs, hundreds of biopharmaceutical companies around the world engage in broad clinical-trial programs that generate and evaluate safety data (Kaitin, 2010). These trials are necessary to make sure the new treatments are safe for patient use, and they comply with standards on its therapeutic value (Hirai, 2015).

While pharmaceutical industry is a major economic contributor, being heavily involved in R&D and clinical trials industry. It creates significant job markets, among which are the obvious ones in pharmaceutical companies but also provide ancillary jobs via related sectors like biotechnology, healthcare, and manufacturing (PhRMA, 2019; Powell & DiMaggio, 1991). The industry's economic impact is beyond its borders and lies in a broader economic context when accounting for international trade balances and taxes (OECD, 2019).

Moreover, the biopharmaceutical industry is at the forefront of technological innovation. This institute is one of the biggest early adopters in cutting-edge technologies such as Artificial intelligence, Big data analytics, Advanced manufacturing techniques (Mak & Pichika, 2019; Topol, 2019). These technologies consequently improve the efficiency, speed, and costs of drug discovery/development for unmet therapeutic needs (Vamathevan et al., 2019; Stokes et al., 2020), ultimately delivering useful medicines more rapidly.

The capacity to navigate intricate regulatory environments is also essential for the industry. The higher safety and efficacy standards imposed by regulatory compliance, known as new drug applications, are important for fostering public trust in a product ultimately destined to the marketplace (Higgins & Rodriguez, 2006). Because the market for biopharmaceuticals is tightly regulated, regulatory agencies specify strict guidelines and work closely with sponsor to accelerate approval of new therapies (Kaitin 2010; Hirai 2015).

2.4.3 Government

Firstly, government is very much embedded in the biopharmaceutical ecosystem: its role both an enabler of innovation and safety crucial for public health (Mazucatto, 2013; Kuhlmann & Rip, 2018).

Biomedical research, which underpins many drug development breakthroughs is significantly funded by governments (Salter & Martin, 2001; Geuna & Muscio, 2009). Public funding also supports basic and applied research, facilitating discoveries that private entities might not pursue due to high risks and long timelines (Nelson, 1959; Bozeman & Boardman, 2014).

Regulatory frameworks established by government agencies, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), are essential for ensuring that new drugs are safe and effective before they reach the market (Hirai, 2015; Kaitin, 2010). These regulations include strict evaluation of testing procedures to prevent potentially dangerous or ineffective drugs from being brought to market (Carpenter, 2010; Kuhlmann & Rip, 2018).

Governments also act as critical enablers of interaction between industry and academia by introducing policy instruments, funding mechanisms that promote public-private partnerships via collaboration with business firms in innovation (Perkmann et al., 2013; Ranga & Etzkowitz, 2013). These collaborations are essential for bridging the divide between research and commercial products as well unlocking the unique capabilities of various components in a biopharmaceutical innovation ecosystem (Etzkowitz & Zhou, 2017, Carayannis & Campbell, 2009).

Public policies related to health directed by governments are key in identifying and addressing important medical needs that need effort of R&D, defining biopharmaceutical research priorities (Mazzucato, 2013; OCED, 2019). These programs typically are those for which no market may exist and investment in priority research areas such as rare diseases, infectious disease, or chronic condition is unlikely to be profitable if deferred solely to industry (Haffner, Torrent-Farnell, & Maher, 2008).

Governments also support the biopharmaceutical ecosystem by providing intellectual property rights that protect innovation and promote investment into R&D (Graham et al., 2002; Scotchmer, 2004). Companies can recover costs of drug development putting the pharmaceutical compound through a patent system granting them time-limited exclusive right to market their inventions (DiMasi et al., 2016; Munos, 2009).

Economic policies and incentives, such as tax credits for R&D expenditures, markets by purchase price auctions contracts and grants for subsidy to startup companies-as pivotal Enablers of innovation in biopharmaceutical sector (Lazonick & Tulum, 2011; Audretsch, 2003). By doing so, they reduce some of the financial barriers firms face when it comes to investing in new and potentially revolutionary technologies (OECD, 2019; Salter & Martin, 2001).

Additionally, in an interconnected world states engage together as part of global health governance that is necessary for taking on the challenges of international public health and tiered medical access (Fidler, 2010; Gostin, 2014). International agencies such as the World Health Organization (WHO) with national governments coordinate to response pandemics, develop vaccines and enhance global health security (Yamey et al., 2019; Frenk & Moon, 2013).

2.4.4 Society

Society plays an integral role in the biopharmaceutical ecosystem reflecting the larger public including patients, advocacy groups and non-governmental organizations (NGOs) (Arnkil et al., 2010; Carayannis & Campbell, 2009). Biopharmaceutical innovation is also led by the needs of society, through public engagement, feedback, and involvement in clinical trials (Carayannis & Rakhmatullin, 2014).

In order to ensure that societal needs and ethical norms were met by biopharmaceutical innovations, public engagement is critical (Arnkil et al., 2010). The involvement of patients and advocacy groups provide companies with a better understanding on patient experiences and current needs, which triggers the development of more effective/targeted yet palatable therapies (Carayannis & Campbell, 2012; Ranga et al., 2013)

Engagement in clinical trials is an additional valid role that society plays into the bioscience sector (Wong et al., 2019). Patients who volunteer for clinical trials provide the data that is used to determine whether new drugs are safe and efficacious (Topol, 2019). This participation is critical to the progress in medical research and new therapeutic approaches (DiMasi et al., 2016; Esteva et al., 2019).

Non-Governmental Organizations (NGOs) and other advocacy groups have a very important role in the communications of diseases, advocating patient rights and policy making constructs within public healthcare (Gostin, 2014; Fidler, 2010). They may have been able to influence funding and research priorities favouring treatments for neglected diseases or conditions that are commercially unattractive to private companies (Haffner, Torrent-Farnell & Maher, 2008). This is because they act as advocates in order to ensure that broader needs of society are well represented on the research agenda (Salter & Martin, 2001; Geuna & Muscio, 2009).

Furthermore, the inclusion of society in biopharmaceutical innovation provides a basis for transparency and accountability (Schütz et al., 2019). The more open to public scrutiny and involvement in decision-making for biopharmaceutical companies and their products, the trust would be built, linking transparency with legitimacy (Lindberg et al., 2012). In this way, data is transparently reported to the public and trust from those areas in need (e.g. vaccine development/distribution) remains intact due to that transparency (Frenk & Moon, 2013; Yamey et al., 2019).

Social educational initiatives and advertising by NGOs will also promote a greater knowledge of biopharmaceutical research including public awareness (Perkmann et al., 2013; Powell et al., 1996). Such initiatives may in turn translate into broader public backing for biopharmaceutical innovations and enhanced health ecosystem participation (Schuhmacher, Germann, Trill & Gassmann, 2013).

2.4.5 Artificial Intelligence and the Biopharmaceutical Ecosystem

Artificial Intelligence (AI) is revolutionizing the biopharma ecosystem in making an impact at four discrete pillars: drug discovery and development; clinical trials, manufacturing, and healthcare delivery (Mak & Pichika, 2019; Esteva et al., 2019).

(1) **Drug Discovery and Development:** AI helps decrease the time necessary for drug discovery; this process utilizes traditional techniques instead, focusing on identifying possible candidates a little faster (Zhavoronkov, 2018; Lavecchia, 2019). Using machine learning algorithms to analyze large biological data sets, researchers can predict interactions of different compounds with their corresponding biological targets in order to accelerate drug development at a reduced cost (Stokes et al., 2020). The model depth of AI in representing complex biological systems will be able to identify those new drug targets

as well as allow for the repurposing available drugs into novel therapeutic applications (Ekins et al., 2019; Vamathevan et al., 2019).

(2) **Clinical Trials:** AI improve patient recruitment, stratification, and monitoring in the design and conduct of clinical trials (Topol, 2019). By analyzing electronic health records and genetic data, predictive analytics can identify appropriate subjects for trials as well (Wong et al., 2019), making the trial more representative and efficient. Furthermore, AI decrements real-time monitoring and data analysis during trials increasing the accuracy and speediness of drug efficacy & safety (Esteva et al., 2019).

(3) **Manufacturing:** For the biopharmaceutical manufacturing process, AI is used to improve regulatory activities within the industry and increase quality control (Goodman, 2020; Yang et al., 2020). Example is AI algorithms that monitor manufacturing processes in real-time and alert of anomalies as well as predict issues prior to affecting quality (Kourti, 2020).

(4) **Healthcare Delivery:** AI helps deliver healthcare by developing individualized treatment plans and boosting the accuracy of diagnosis (Jiang et al., 2017; Topol, 2019). AI-assisted diagnostic tools utilize medical images and patient information to scout out diseases well in advance, long before they were traditionally detectable (Esteva et al., 2019). Personalized medicine, enabled by AI, ensures precision treatments according to the patient's genetic and healthcare history which improves outcomes preventing harmful effects (Yu et al., 2018; Johnson et al., 2021).

In conclusion, the inclusion of AI in biopharmaceutical induces innovation and increases efficiencies for overall better outcomes across all stages of drug development and healthcare delivery (Mak & Pichika, 2019; Topol, 2019). The application of AI technologies in the biopharmaceutical industry is expected to help tackle these complex challenges and expedite the development process for new therapies resulting in better health globally, (Zhavoronkov, 2018; Vamathevan et al., 2019).

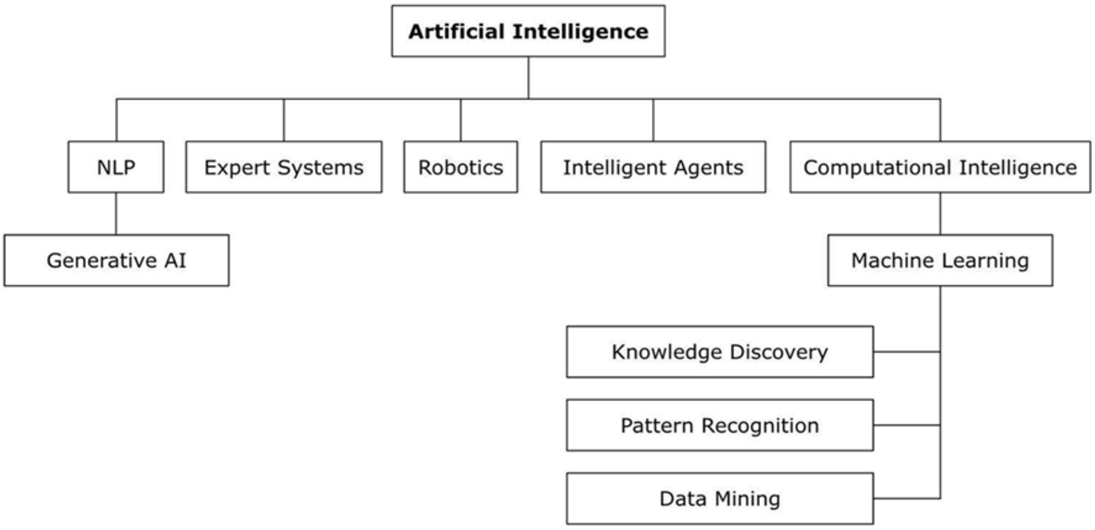

Figure 4. *Key elements of the AI family tree (Anifowose, 2021b)*

3. Methodological framework

The biopharmaceutical industry is essential for driving innovation, public health and economic development. For identifying the central drivers of innovation and challenges, it is important to deep dive into how an ecosystem operates with a Quadruple Helix approach. With regards to AI integration this study has the following objectives: To investigate and compare Hanoi, Leuven, Boston-Cambridge and Fukuoka biopharmaceutical ecosystems. The aim is to conduct an investigation based on SWOT analysis and give some recommendations for Hanoi concerning the biopharmaceutical ecosystem.

Research Questions:

1) What are the key strengths, weaknesses, opportunities, and threats (SWOT) of the biopharmaceutical ecosystems in Hanoi, Leuven, Boston-Cambridge, and Fukuoka?
2) What are the barriers and drivers for AI integration in the biopharmaceutical industry in these regions?
3) What strategies can Hanoi adopt to improve its biopharmaceutical ecosystem and AI integration based on the experiences of Leuven, Boston-Cambridge, and Fukuoka?

A qualitative research approach will be used in this thesis to answer these questions. With interviews of experts in various industries in Biopharmaceutical Sector Such research approach helps to arrive at a practical view of the Biopharmaceutical industry within developing countries and compounds this perception with equivalent knowledge regarding the competitive landscapes for global markets.

ID	Candidate	Function	Duration	Date	Interview Mode
C1	Dr. Martin Hinoul	Business Development Manager at KU Leuven R&D, Leuven, Belgium.	117 mins	08/07/2024	Face to face
C2	Prof. Dr. Jean-Pierre Segers	Professor / Faculty of Business Economics, Hasselt University, Diepenbeek, Belgium.	117 mins	08/07/2024	Face to face
C3	Assoc. Prof. Dr. The Hai Pham	Associate Professor, Lecturer / Department of Pharmaceutical Chemistry, Hanoi University of Pharmacy, Hanoi, Vietnam.	68 mins	10/07/2024	Online
C4	Hai Phong Ho	Founder of N2TP Technology Solution Company (Start-up company), Hanoi, Vietnam.	48 mins	12/07/2024	Online
C5	Dr. Patrick Chaltin	Managing Director of Drug Design and Discovery (CD3) division at KU Leuven R&D, Leuven, Belgium.	45 mins	17/07/2024	Online
C6	Assoc. Prof. Dr. Mori Takeshi	Associate Professor / Faculty of Engineering, Kyushu University, Fukuoka, Japan.	42 mins	18/07/2024	Online
C7	Prof. Dr. Yoshiki Katayama	Professor / Faculty of Engineering, Kyushu University, Fukuoka, Japan.	58 mins	26/07/2024	Online

Table 1. *Interview information*

3.1. Research context

Swedberg (2020) highlights this approach as a way of opening up social behaviors and experiences. The qualitative research tradition is once again highlighted here, noting the flexibility it possesses and uses to conduct interviews as part of a systematic case study approach (Yin, 2011).

In this thesis, the researcher embarked on a qualitative exploration through in-depth interviews. This method allows the researcher to gain rich insights into the participants' perspectives, attitudes, and actions. Qualitative research excels at unraveling complexities within social issues by gathering nuanced data that fosters profound analysis.

3.2. Research questions

The study employs the SWOT analysis to map out Vietnam compared with best performers in other regions, based on triple helix model and investigates how AI would be incorporated into business sector using Quadruple Helix Perspective: academia (Universities), government (Policies makers) industry and public. Ultimately, the goal is to learn from interview participants how these four pillars play into and enable involvement of AI in drug discovery kind management. This study aims to have practical implications arising from a refined understanding of the diverse dynamics between those stakeholders involved. This will be done by working to addresses the following research questions:

(1) What are the key strengths, weaknesses, opportunities, and threats (SWOT) of the biopharmaceutical ecosystems in Hanoi, Leuven, Boston-Cambridge, and Fukuoka?

This question is aimed to provide a SWOT analysis of the biopharmaceutical ecosystems in those regions, collaborating with other questions mentioned below. The study with identify forces, such as strengths, weaknesses, opportunities and threats; are also expected to provide Region-wise analysis of West Pace Deft System market dynamics. This analysis will then form the basis for comparisons with more advanced ecosystems such as those in Leuven, Boston-Cambridge and Fukuoka. By knowing all of these, it will be easier for us to devise specific strategies that Hanoi can build upon and counteract.

(2) What are the barriers and drivers for AI integration in the biopharmaceutical industry in these regions?

What are the drivers and barriers to AI adoption in biopharmaceutical industry? A well-balanced ecosystem of these is important to understand the barriers and drivers from many different perspectives. This look will provide an understanding of the kind of bottlenecks faced by each stakeholder and complex systems supporting AI collaboration. It will also show how collaboration between its Quadruple Helix stakeholders can promote AI adoption, providing important guidelines for Hanoi.

(3) What strategies can Hanoi adopt to improve its biopharmaceutical ecosystem and AI integration based on the experiences of Leuven, Boston-Cambridge, and Fukuoka?

This question helps frame possible responses that Hanoi might take to strengthen the local biopharmaceutical ecosystem and integration with AI. Informed by the experiences of Leuven, Boston-Cambridge, and Fukuoka; this study aims to provide Hanoi with these tailor-made recommendations that will meet its own needs and constraints. These strategies will be informed by the best performing policies in addition to innovative practices characteristics cross-national comparative analysis. An initiative to create a roadmap for Hanoi to develop the development of its biopharmaceutical industry and more effectively integrate AI into innovation, enhancing global competitiveness.

3.3. Methodological Approach

The research adopted semi-structured interviews were used as the main source of obtaining data to understand how different elements in Quadruple Helix model (government, industry, academia, and civil society) work together on supporting AI integration within biopharmaceutical sector. This research manner assists in yielding practical ideas and recommendations, together with a more realistic view of the biopharmaceutical industry throughout diverse areas.

3.4. Data Collection

In this study, we conducted multiple rounds of interviews through face-to-face as well as online platforms (Google Meet and Zoom). This method enables seamless and practical interviews for orally situated participants in various areas.

Quantitative contemporary scholastic research was used throughout the data collection alongside interview testimonials. Semi-structured interviews encouraged openness on the part of respondents, and they could respond to researchers' open-minded questions. Initial broad questions within these themes (interview guide) were used to understand the role and image of respondents, then more particular in-depth questions.

To guarantee that participation had a basis to the participants, questionnaires were shared with them before interviews giving time to prepare their perspectives for discussion.

3.5. Data Analysis

Transcribing the recordings must come before processing, structuring and analysing of interviews data (Sutton et al., 2015). The main objective of qualitative interviewing is to interpret the point-of-view or perspective (experience, meaning, understanding) participants have regarding a particular phenomenon that one wants to understand. Throughout the data analysis it was strived that on any given time point, there would be no subjective interpretation by the researchers and that only to what respondents had said could have been answered.

Interview recordings were transcribed and analyzed in a varied way. Using thematic analysis of the transcripts. Theories and models were used to inform data collection, arranged into themes following laborious inductive coding related broadly to four pillars of the Quadruple Helix Model (Gibbs, 2007).

The process of performing data analysis, in turn included three sequential steps:

(1) **Initial Reading:** Reading the text in order to understand it on a whole.

(2) **In-depth Exploration:** Conduct a more extensive investigation in order to discover major themes and patterns.

(3) **Coding and Summarization:** Instead of text we outline the themes through coding with keywords to represent that category. A coding tree table is prepared with an aim to maintain consistency for the readers.

4. Findings

This study aims to provide a comprehensive understanding of the biopharmaceutical ecosystems in Hanoi (Vietnam), Leuven (Belgium), Boston-Cambridge, US and Fukuoka (Japan) particular focus on the AI integration within these sectors. The study combines the Quadruple Helix model (which includes government, academia, industry and society) around strengths-weaknesses-opportunities-threats (SWOT) analysis of each region. Drawing on a detailed literature review and interviews with industry stakeholders, the research provides an intricate picture of AI integration and its prospects for further adoption in biopharmaceuticals.

The regions studied were selected due to their varying levels of development and unique characteristics:

- Hanoi, an emerging biopharma hub with growing prospects overshadowed by technological and regulatory challenges.
- Leuven has strong research institutions and government policies favorable to biopharmaceutical innovation.
- Boston-Cambridge is a clear-cut leader in biopharma R&D and AI integration, benefits from a vibrant innovation ecosystem of startup, research institutions and tremendous venture capital support.
- Fukuoka is known for its strategic government-led programs and cutting-edge technology, positioning Fukuoka as a key player in the Asian bio-pharmaceutical market.

Based on the Quadruple Helix Model, the analysis of the four regions in terms of how they interact with AI technologies to impact their biopharmaceutical sectors providing a detailed SWOT analysis which can be seen as actionable insights for Hanoi to enhance its own local ecosystem.

STEP 1	STEP 2	STEP 3
RQ1: What are the key strengths, weaknesses, opportunities, and threats (SWOT) of the biopharmaceutical ecosystems in Hanoi, Leuven, Boston-Cambridge, and Fukuoka?	4.1 Leuven, Belgium	4.1.1 Introduction
		4.1.2 Strengths
		4.1.3 Weaknesses
		4.1.4 Opportunities
		4.1.5 Threats
	4.2 Boston-Cambridge, USA	4.2.1 Introduction
		4.2.2 Strengths
		4.2.3 Weaknesses
		4.2.4 Opportunities
		4.2.5 Threats
	4.3 Fukuoka, Japan	4.3.1 Introduction
		4.3.2 Strengths
		4.3.3 Weaknesses
		4.3.4 Opportunities
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	4.4 Hanoi, Vietnam	4.4.1 Introduction
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		4.4.3 Weaknesses
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		4.3.5 Threats

Table 2. *Coding Tree for Research Question 1*

4.1. Biopharmaceutical ecosystem in Leuven, Belgium

4.1.1. Introduction

Innovation does not come from the whole country but the regions in the country. Belgium has separated regions: Flanders, Wallonia, and Brussels.

"…how would you describe the kind of state of climate? I have to disappoint you, you cannot talk about Belgium here…". (C1)

"…We have roughly 12 million people, but when it comes to R&D, when it comes to transfer, when it comes to patents, when it comes to your spin-offs, etc., it's the region who defines, it's not the country...". (C1)

Leuven, located in the Flanders region of Belgium, is a prominent hub in the global biopharmaceutical sector. Known for its strong emphasis on research and development (R&D), Leuven is home to leading institutions such as KU Leuven and various biotech and pharmaceutical companies like UCB and ThromboGenics. This region excels in the integration of academia, industry, government, and civil society, which collectively drive innovation and economic growth in the biopharmaceutical field. Leuven's strategic position within the European Union also provides it with a significant advantage in terms of regulatory support and access to a broader market.

4.1.2. Strengths

Research and Development (R&D) Investment

Leuven benefits significantly from government support and strategic investment in R&D. In 2023, KU Leuven R&D raised €389.2 million euros, and about 55% of that came from contracts, services, and government funding.

Figure 5. *Overview of KU Leuven Research & Development (LRD) (KU Leuven R&D, 2023)*

Belgium's performance as an innovation leader is highlighted by the European Innovation Scoreboard 2023, which shows that Belgium's innovation performance is 125.8% of the EU average (European Innovation Scoreboard, 2023).

"The availability of funding is a significant driver for innovation in Leuven's biopharmaceutical sector. The combination of government support and private investment ensures that promising ideas receive the necessary resources to be developed and brought to market." (C1)

Belgium	Performance relative to EU in 2023	Performance change 2016-2023	Performance change 2022-2023
Finance and support	**123.6**	**38.4**	**-4.1**
R&D expenditures in the public sector	101.6	11.3	-12.9
Venture capital expenditures	103.4	46.6	3.4
Government support for business R&D	176.0	67.1	0.0

Figure 6. *Government R&D investment in Belgium (European Innovation Scoreboard 2023, Country profile: Belgium)*

In 2023**,** KU Leuven reported a total research expenditure of € 739.9 million, excluding University Hospitals Leuven. In fact, 81.1% of KU Leuven's acquired funding stems from external sources: 45.1% from competitive regional or national funders, 8.6% from European funding (FP7/H2020) and 27.4% through industrial contracts (KU Leuven, 2023).

In addition, in Horizon Europe, KU Leuven participates in 334 projects (coordinating 130 projects), ranking 1st with regard to budget awarded (€ 207.6 million) and number of projects in the league of Higher Education (HES) Institutes. In the MSCA-Doctoral Network program, KU Leuven is the leading HES with 53 projects focusing on the training of young scientists. (KU Leuven, 2023).

Patents (IP)

Leuven is home to KU Leuven, which is recognized as one of the most innovative universities in Europe. KU Leuven's contributions to scientific research and innovation are substantial, with 163 granted patents and a license income of €150.9 million in 2023 (KU Leuven, 2023). The university's state-of-the-art research facilities and substantial funding underpin its leading role in biopharmaceutical research. Additionally, the Leuven Research & Development (LRD) office facilitates technology transfer, promoting the commercialization of research outputs. This reflects the region's strong emphasis on innovation and the translation of research into marketable products.

"The high number of patents filed is indicative of the cutting-edge research and innovation happening in Leuven. The ability to consistently generate new intellectual property not only highlights KU Leuven's scientific prowess but also strengthens our competitive position in the global biopharmaceutical market." (C5)

Spin-offs and start-ups

What makes Leuven unique is how well they connect academia and industry. LRD office at KU Leuven has helped establish 156 spin-offs reflecting a thriving startup culture (Hinoul, 2023; KU Leuven, 2023). They are supported by an ecosystem of start-up incubators and accelerators such as KU Leuven LRD (Leuven Research & Development) or Imec's iStart program.

"The infrastructure and support for spin-offs in Leuven create an environment where innovative ideas can thrive and reach the market. KU Leuven's programs provide not only financial support but also mentorship and access to a vast network of industry experts, which are crucial for the growth and success of these new ventures…" (C1)

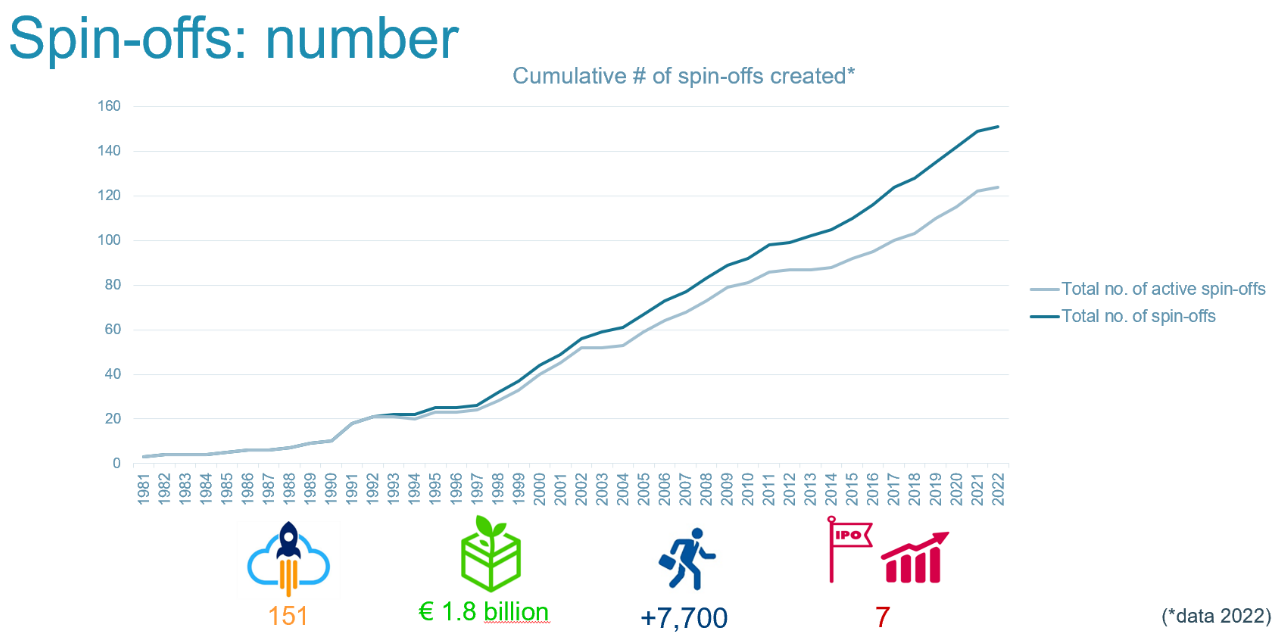


Figure 7. *Number of spin-offs in Leuven, 2022 (Hinoul, 2023)*

One notable example of successful collaboration is the spin-off company AstriVax, which raised €30 million in seed capital to develop a novel vaccine platform. The success of this initiative shows how strong a spin-off ecosystem can be when built around the solid framework that KU Leuven has in place and converts academic quality into commercial value which brings meaningful improvements to global health (KU Leuven, 2022).

The Quadruple Helix Model (Collaboration)

This side of Leuven's biopharmaceutical ecosystem reflects the collaboration between academia, industry, government, and civil society. This allows for the easy sharing of knowledge and resources, ultimately enabling faster innovation. For instance, KU Leuven collaborates with companies like GSK and Johnson & Johnson on numerous research projects, supported by governmental initiatives such as the Flanders Innovation and Entrepreneurship agency (Segers, 2017).

Moreover, KU Leuven established various institutions, such as KU Leuven Research & Development – Tech Transfer Office, as a bridge between academia and the industry, to foster the collaboration between the pillars.

"…I've never been really into the industry side. But I think I have quite a good understanding of the industry, thanks to a lot of interactions that a technology transfer offers effect. So being in technology transfers, really being in the in the middle in between of academia and industry…" (C5)

"…with my background coming from tech transfer, thinking about the needs at Academia, but also knowing what the industry wants is really nice, I think. But it's very special to our organization, because we are not industry and we are not really academia, we are really in the middle..." (C5)

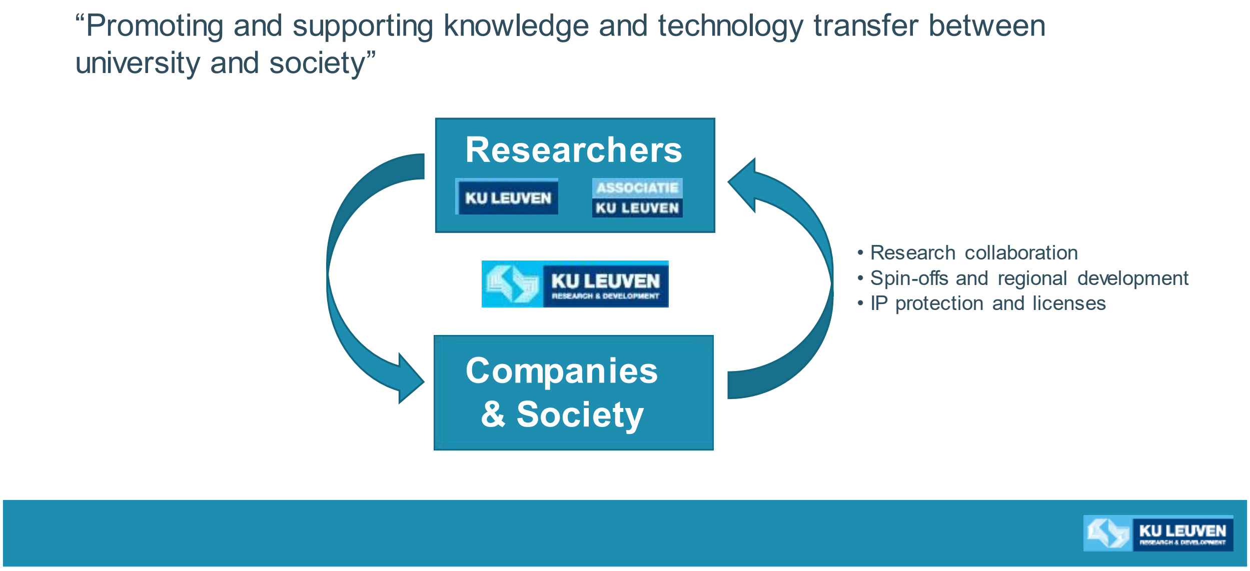


Figure 8. *Mission of KU Leuven R&D (Hinoul, 2023)*

Global Network Building

Leuven's biopharmaceutical ecosystem also benefits from a strong international network. KU Leuven has established collaborations with research institutions and companies worldwide, enhancing its research capabilities and innovation potential. KU Leuven is a member of several international networks, such as LERU, the League of European Research Universities, CELSA, the Central Europe Leuven Strategic Alliance, and the Coimbra Group . (KU Leuven, 2023).

" …Networks. If you don't have a network, what do you have for knowledge? What is your network?" (C1).

Human Resources and Talent Development

Leuven boasts a highly skilled talent pool, assisted by KU Leuven, which ranks among the top universities globally for medical and life sciences (Times Higher Education, 2022). The university produces over 2,000 graduates annually in biopharma-related fields, ensuring a steady supply of highly qualified professionals in the industry. In the 2022-2023 academic year, KU Leuven awarded 926 doctoral degrees. Of these, 493 (53 %) were awarded to non-Belgian researchers. (KU Leuven, 2023).

Case Study: Collaborative Development of an HIV Drug

A notable example of Leuven's collaborative strength is the development of HIV drugs. The Rega Institute's partnership with international institutions like the Academy of Sciences in Prague and Gilead Sciences led to the development of Tenofovir, a cornerstone in HIV treatment. This collaboration epitomizes the Quadruple Helix model, involving academia, industry, government, and civil society working together to address a global health challenge (Loeckx, 2021).

Key player of this development was the Rega Institute which contributed its vast research expertise in virology and molecular biology. Gilead Sciences pitched in its resources on the drug development and commercialization side. The Academy of Sciences in Prague played a crucial role in conducting pivotal research that complemented the efforts of the Rega Institute. This triad of collaboration showcases how different sectors can effectively come together to drive significant medical advancements.

This collaboration was not just limited to academia and industry. The Flemish government provided substantial funding and regulatory support, ensuring the research could progress without significant bureaucratic hurdles. Additionally, civil society organizations played a crucial role in advocating for the needs of HIV patients and ensuring that the research addressed real-world challenges.

> *"The development of Tenofovir is a testament to what can be achieved when different sectors work together. The partnership between KU Leuven and Gilead Sciences, supported by our government, exemplifies the power of the Quadruple Helix model." (C1)*
>
> *"…the most well-known example is the collaborations that have taken place many years ago around new HIV medication..." (C5)*
>
> *"…with Gilead Sciences, for example, that is the best known where the sector collaboration between two academic institutions in fact between KU Leuven and IOCB in Prague in the Czech Republic, deliver new HIV compounds, new potential drugs and... long story ended up in Gilead Sciences and today is has delivered to the most used anti-HIV drug in the world." (C5)*

The success of Tenofovir not only underscores the importance of the Quadruple Helix model in fostering innovation but also highlights how strategic partnerships can accelerate the development of life-saving drugs. This case study serves as a prime example of how Leuven's biopharmaceutical ecosystem leverages collaboration to achieve remarkable outcomes.

4.1.3. Weaknesses

Despite its numerous strengths, Leuven's biopharmaceutical ecosystem also faces significant challenges, particularly when compared to leading hubs like Boston-Cambridge. These weaknesses highlight areas where Leuven could improve to enhance its competitiveness on a global scale.

Funding for Start-ups

> *"…but if you consider the Flemish biotech ecosystem, we do have several promising startups and scale-ups in biotech that have successfully gone public, securing funding and forming strategic alliances, particularly with major US biopharma companies. However, we are now seeing a troubling trend where many of these Belgian biotech companies are going bankrupt, delisting from the stock exchange, or having their strategic alliances terminated because their products are failing to reach the market or secure FDA approval. The key points currently in the ecosystem the same for the Walloon ecosystem, it's the same thing. And all over the place..." (C2)*

One of the primary weaknesses identified in Leuven is the relatively limited funding available for start-ups compared to Boston-Cambridge. While Leuven has a supportive ecosystem for early-stage companies, the availability and scale of venture capital funding are not on par with those in Boston-Cambridge.

"While we have a strong foundation for supporting start-ups, the scale of funding available here is much smaller than in the U.S. We need to work on attracting more significant investments to bridge this gap" (C5).

Innovation Time

Another challenge is the time it takes to move from research to marketable innovations, and it is a non-enforceable process.

"The process of innovation takes time. Some might think that Silicon Valley was built overnight, but that's not the case. I was there as a young student, and I witnessed its development during my time with IDT and throughout my 20-year career with the government. Silicon Valley's success is unparalleled, but it took decades to achieve. Similarly, fostering innovation in Leuven will take time. It's not something that can be rushed." (C1)

Infrastructure and Support Systems

While Leuven boasts excellent research facilities, the infrastructure supporting commercialization is not as developed as in Boston-Cambridge. This includes fewer dedicated incubators and accelerators that can provide the necessary support for early-stage companies to scale. Furthermore, there is a need for more robust mentorship programs that can guide start-ups through the commercialization process.

"We have great research infrastructure, but we lack the comprehensive support systems that are available in places like Boston. There, start-ups have access to a vast network of mentors, accelerators, and industry connections that we simply can't match at this point" (C5).

4.1.4. Opportunities

While it faces challenges of its own, the biopharmaceutical ecosystem in Leuven is well-placed to grow and develop. These opportunities are underpinned by strong research roots in the region, coupled with a spirit of collaboration; and they exist within an ever-changing landscape of biopharmaceutical innovation.

Expanding AI Integration

For Leuven, one of the biggest possibilities is to further lead in integrating artificial intelligence (AI) with biopharmaceutical R&D. There is already a solid foundation in the region by having projects such as the Leuven.AI Institute in Drug Discovery and Personalized Medicine. Investing in AI has the potential to substantially decrease both time and cost required for bringing new drugs in market.

"...I believe in AI, and I think we all recognize its growing importance. It's important to realize that AI has already achieved significant success in certain sectors. However, in the biopharma field, particularly in the discovery of new drugs, there's still a long way to go. Nevertheless, AI has already made impressive applications in biopharma…" (C5)

Strengthening International Collaborations

Leuven has an opportunity to deepen its international collaborations even further. In the wake of a number of partnerships and alliances with global biopharmaceutical companies’ new opportunities arise, on which Leuven can further build to strengthen its position as research powerhouse in Europe.

> *"International collaborations are key to accessing new technologies and markets. We need to continue fostering these partnerships to drive innovation and economic growth" (C1).*

Collaborations like the one with Gilead Sciences on HIV drug development are prime examples of how Leuven can leverage global partnerships to achieve significant breakthroughs (Loeckx, 2021).

Attracting Venture Capital

The other key opportunity is expanding the level of venture capital investment. Leuven receives significant funding already but there is an opportunity to grow this by showcasing the power if its region and stories of success on a global stage. This ecosystem can entice high-risk, high-reward investors like VC to fund new businesses. Successful spin-offs and an active research market represent a great deal of promise for such investment.

> *"We need to showcase our successes and potential to attract more venture capital. This will enable us to support more start-ups and scale-ups, driving further innovation" (C5).*

Talent Development and Retention

Leuven can also invest in top talent and on how to keep them stay. Such growth could also guarantee a flow of well-trained container trades workers to and from training programs in the state. In the same direction, it is interesting to invest in beautiful working environments and careers that prevent this precious talent from leaving.

> *"We are building up this ecosystem with top-notch people—individuals who understand technology, intellectual property, contract research, and finance. It's crucial to have such talent, as their expertise drives innovation and growth. Developing and retaining this talent is a significant opportunity for Leuven's future development. By nurturing a skilled workforce, we can ensure sustained progress and maintain our competitive edge…" (C1)*

4.1.5. Threats

While Leuven's biopharmaceutical ecosystem is robust and presents many opportunities, it also faces several significant threats that could impede its growth and innovation potential. These threats stem from both internal challenges and external factors that need to be addressed to ensure sustained development and competitiveness.

Economic Volatility

Economic volatility poses a substantial threat to the biopharmaceutical sector in Leuven. Fluctuations in the global economy can impact funding availability, investment levels, and overall financial stability.

> *"The economic environment is unpredictable, and downturns can severely affect our ability to secure funding and sustain long-term projects…" (C2)*

Talent Retention and Competition

"…However, keeping these talents is increasingly difficult nowadays. While Leuven remains one of the top innovators and provides a good environment in the EU, other regions might offer better opportunities and could potentially pull our talent away from us." (C5)

Leuven faces intense competition for top talent from other biopharma hubs worldwide, such as Boston-Cambridge. High turnover rates and the mobility of skilled professionals pose a threat to maintaining a stable and highly qualified workforce.

Rising Operational Costs

The cost of conducting biopharmaceutical research and development in Leuven is rising. High operational costs, including real estate, salaries, and research expenses, can strain the budgets of start-ups and smaller companies.

"The increasing costs of operations are a significant concern. It limits our ability to invest in long-term research projects and affects our overall competitiveness…" (C5)

Competition from Other Biopharma Hubs

Leuven faces stiff competition from other well-established biopharma hubs such as Boston-Cambridge, San Francisco, and even emerging hubs in Asia such as China and Japan. These regions often have more substantial financial resources, extensive networks, and favorable regulatory environments.

"The competition from other biopharma hubs is fierce. We need to continuously innovate and improve our ecosystem to stay relevant and competitive…" (C5)

4.2. Biopharmaceutical Ecosystem in Boston-Cambridge region, United States of America

4.2.1. Introduction

The Boston-Cambridge area has been called a global biopharmaceutical hub for good reason: It possesses one of the most robust ecosystems that cultivates innovation, research and development in the sector. The area is saturated with premier research institutions, biotech, and a deep network of venture capital firms (VCs). The biopharmaceutical ecosystem of Boston-Cambridge is the hallmark paradigm for a quadruple helix- one which congregates academia, industry, government and society to come together in an integrated collaborative environment. Boston-Cambridge is a hub of R&D in the biopharmaceutical sector as observed by the Global Innovation Index (2023) making it crucial player worldwide.

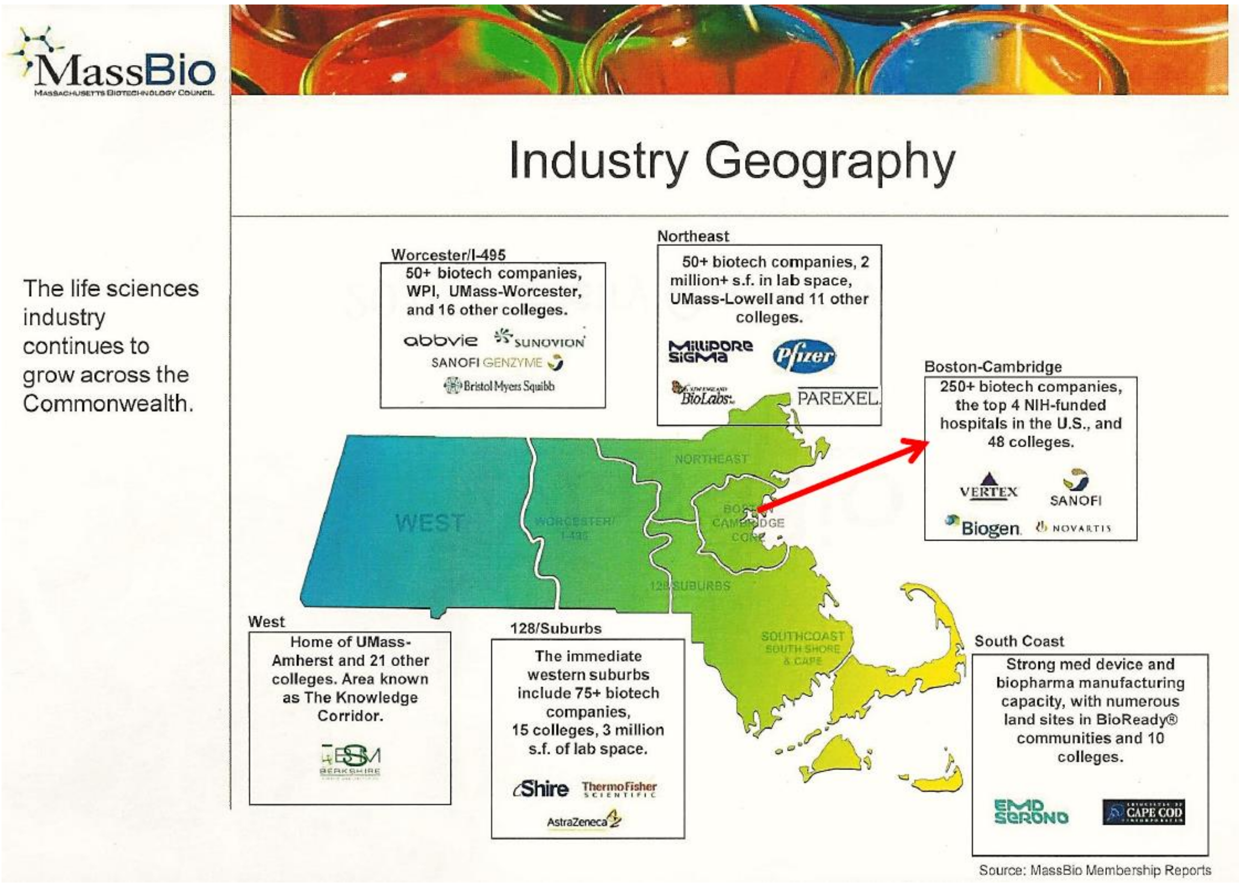


Figure 9. *Boston-Cambridge region in United State of America (Hinoul, 2022)*

4.2.2. Strengths

Research and Development (R&D) Investment

Boston-Cambridge is a leader in research and development (R&D) spend. Greater than $7.66 billion in venture capital (VC) funding was raised by Massachusetts-Based Biopharma Companies In 2023 (MassBio, 2023). This level of investment sends a powerful signal about the willingness and capability in this region to command high levels of R&D resources required for innovation. In addition, the Massachusetts area has substantial R&D spend as a share of GDP amounting to 5.7% showing that scientific developments are being driven by people in this region (WIPO, 2023).

Number of Spin-offs and patents

The region also has a strong ecosystem of innovation, and indeed there are plenty of spin-offs and patents. The system at Boston-Cambridge produced "a dozen" spin-offs in 2023 alone, huge numbers that reflects the city's start-up activity and its successes with putting research results into market. The region also ranks among the top in patents, with 1900 last year related to biopharmaceuticals. This exceptional patenting contraction deciphers the predominance of biopharmaceutical innovation in this territory, and also indicates that intellectual property protection is high (WIPO, 2023).

Collaboration in the Quadruple Helix Model

The Boston-Cambridge area exemplifies the Quadruple Helix model of innovation, involving collaboration between government, industry, academia, and civil society. The Massachusetts state government provides regulatory support and funding, while academic institutions like MIT and Harvard drive research. Industry partners, including biotech and pharmaceutical companies, translate research into commercial products. Civil society, represented by patient advocacy groups and community organizations, ensures that research addresses public health needs (Brookings Institution, 2018).

Funding

The biopharmaceutical sector in Boston-Cambridge benefits from substantial funding from both public and private sources. In 2022, venture capital investment in the Boston-Cambridge area was reported to exceed $7.67 billion (approximately €6.75 billion) (Massachusetts Biotechnology Council, 2023). This influx of capital supports biotech startups and established firms' growth and development.

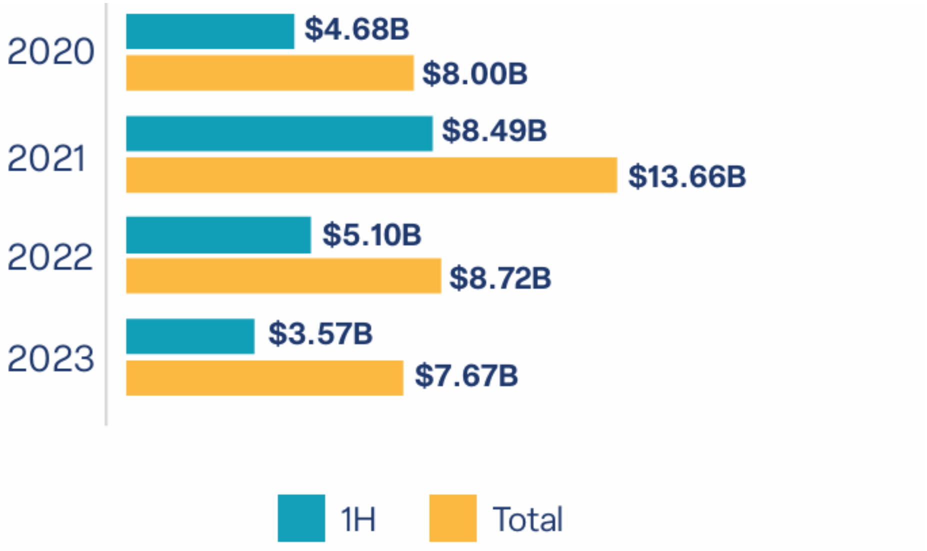


Figure 10. *Venture Capital funding in 3 recent years Massachusetts-headquartered companies (MassBio, 2023)*

AI Integration

The Boston-Cambridge area is at the forefront of integrating AI into biopharmaceutical research. Companies like IBM Watson Health and numerous startups in Kendall Square are pioneering the use of AI for drug discovery, precision medicine, and optimizing clinical trials. AI-driven technologies streamline research processes, enhance data analysis, and improve patient outcomes. The region's leadership in AI integration is a testament to its innovative spirit and technological prowess (Aretian, 2022).

Talent Pool

The talent pool in the Boston-Cambridge area is unparalleled, drawing from leading academic institutions and a global workforce. The area attracts top talent in bioengineering, computer science, and molecular biology, driving innovation and ensuring a steady pipeline of new ideas and technologies. In 2022, the region employed over 113,994 professionals in the biopharmaceutical sector (MassBio, 2023).

Figure 11. *Number of employees report (MassBio, 2023)*

4.2.3. Weaknesses

Despite its numerous strengths, the Boston-Cambridge biopharmaceutical ecosystem faces several notable weaknesses that could impede its continued growth and innovation. These challenges are highlighted by various experts in the field and underscore areas needing improvement.

High Costs

One of the most significant weaknesses is the high cost of living and operating in the Boston-Cambridge area. The region's status as a premier biopharmaceutical hub has driven up real estate prices and the cost of living, making it challenging for startups and smaller companies to sustain operations. According to experts, the high costs can deter new companies from entering the market and place significant financial pressure on existing ones (Ginsberg, 2022). This financial burden can limit the ability of companies to invest in innovative research and development, thus slowing overall industry progress (Cramer, 2023).

Talent Competition

Skilled professionals are in high demand however the region has a wealth of talent. Among other reasons, an intense competition for top talent ensures that everyone is going after the same small number of experts, i.e. a "war for talent." While a good thing for workers, this competitiveness can lead to salary inflation and high rates of attrition, creating an obstacle between companies looking on the other hand keep hold of staff with skills needed in operational roles (Smith, 2022). Moreover, the limited access to domain-specific capabilities can increase timelines for delivery of projects and thereby result in higher costs for training or recruitment (Anderson, 2023).

Regulatory Hurdles

The biopharmaceutical industry is running through the gauntlet of a complex regulatory landscape, inherently riddled with barriers to innovation. Regulations are important to establish safety and efficacy, experts said in that story, but they can slow new therapies and technologies. In cities like Boston-Cambridge, regulatory requirements are so stringent that it is difficult for many firms to function effectively under existing conditions especially new small businesses which may lack of resources to manage compliance (Johnson, 2023). This burden can stifle change and postpone the creative data solutions that would potentially enhance a better management of patient care (Harrison, 2023).

Infrastructure Strain

The rapid expansion of the Boston-Cambridge biopharmaceutical sector has stretched area resources to capacity. THE ISSUE of transportation inefficiencies and delays was pinpointed by experts like Taylor (2022), stressing that the current transport systems can only take up so much before collapsing. Furthermore, the general close proximity of biopharmaceutical activities creates availability bottlenecks for lab space and other biological resources (Lee, 2023). The burden on infrastructure may affect operational capability of Biopharmaceutical companies constraining the ability to scale.

Funding Gaps

While Boston-Cambridge generates significant venture capital, there remain funding gaps - especially at the pre-seed stage. According to Davis (2023), experts say that even though huge sums of money go into the firms who have succeeded already and ventured later-stage, there is abiding problem for early-stage startups access to capital. A lack of funding can stymie the establishment and growth of new innovative companies, potentially slowing innovation overall in a region (Wilson, 2023).

4.2.4. Opportunities

With a number of encouraging possibilities on the horizon, its no surprise that Boston-Cambridge biopharmaceutical ecosystem is slated to expand and innovate. This potential is spurred by advances in technology, deepening cross-sectoral cooperation and the region's ability to attract significant investments. The following are the more details about these opportunities:

Expansion of AI Integration

Further integration of artificial intelligence (AI) is one of the most important opportunities for Boston-Cambridge biopharmaceutical ecosystem. While the region is already an AI leader for biopharma use cases, there's lots of room to grow. In addition, AI has great potential in transforming the stages of drug discovery pipelines such as Predictive Analytics and Personalized Medicine. AI can help sift through vast data pools quickly, cutting dead time and trimming down how long clinical trials take (Topol, 2019). Further development of AI technologies in this region can help our area to become a global leader on the field of pharmaceutical innovation (Esteva et al., 2019).

Increasing Investment in Startups

As a result, Boston-Cambridge has one of the most developed biopharma venture capital ecosystems in the world, with exciting prospects for startups. Venture capitalists poured $5.1 billion into Massachusetts biotech in the first half of 2022 (Massachusetts Biotechnology Council, 2023). This capital inflow could help startups solve their usual cash issues, speed up R&D efforts and get innovative therapies to market more rapidly (Wilson, 2023). The region’s ability to deliver and secure investment is paramount for future growth of success.

Strengthening International Collaborations

The established network collaborations of the Boston-Cambridge area also offer a positive platform from which to better leverage resources around research and innovation, including at an international level. Collaborating with international partners can bring access to new technologies, various expertise, and additional funding. At scale, these collaborations could open a floodgate for the sharing of insights and best practices to revolutionize biopharmaceuticals (Harrison, 2023). Enhance global connections to enable the region to continue leading global advances in biopharmaceutical research (Brookings Institution, 2022).

Talent Development and Retention

The area is home to one of the highest quality talent pools anywhere. In order to leverage this, additional investment in talent development and retention will help. For instance, programs that provide specialized training experiences in addition to partnerships with academic institutions and incentives for workers in high-need industries can go far toward ensuring the region continues to attract top talent (Smith, 2022). By fostering a supportive environment for talent, Boston-Cambridge can ensure a steady pipeline of skilled professionals to drive innovation and growth in the biopharmaceutical sector (EPM Scientific, 2023).

Enhancing Public-Private Partnerships

It is a powerful way to support innovation and fight public health issues through means of private initiative. This partnership can harness the best of government, academia, business and civil society to create new solutions. An example of such initiatives is the Massachusetts Life Sciences Initiative, which has demonstrated successful assembly of different players in order to support the biopharma environment (Massachusetts Life Sciences Center, 2023). These partnerships can be broadened to create more powerful and sustainable healthcare solutions (Anderson, 2023).

Leveraging New Technologies

Great opportunities seen in the biopharmaceutical sector with new innovations like Genomics, CRISPR and Bioinformatics. The applications of these technologies the Boston-Cambridge region will allow to develop and advance personalized medicine, target therapies, as well new drug delivery systems (Ginsberg, 2022). That positioning will ensure that the region remains at the vanguard of technological evolution in biopharmaceutical research and development (Johnson, 2023).

4.2.5. Threats

While the Boston-Cambridge area of biopharma has a great deal going for it, there are several significant threats to its continued success and lead in innovation. They highlight potential threats according to these experts and address existing challenges that have been recognized as obstacles if the region is not to lose its competitive position.

Rising Competition from Other Hubs

A primary threat to the biopharmaceutical ecosystem in Boston-Cambridge is hype competition from alternative global biopharma hubs such as San Francisco and San Diego as well several international locations such as Singapore and Zurich are rising in biopharmaceutical prowess. These regions have started providing competitive incentives and a cheaper cost of operations which are increasingly attracting these companies in place over biopharma. This increasing competition could then dilute the availability of talent, steers away venture capital investments and maybe even persuade companies to move (Ginsberg, 2022; Anderson, 2023),

Regulatory and Policy Uncertainty

Biopharma in Cambridge-Boston faces significant threat, including regulatory and policy uncertainties. Disruption of healthcare policies, drug approval mechanisms and patent laws continuously make the environment uneasy for biopharma firms. Indeed, one of the things that experts often point out is how uncertainty about regulations can cause drug approvals to be delayed and compliance with them to cost more money - ultimately inhibiting innovation because companies arent willing to invest in new drugs (Johnson, 2023). Secondly, changes in government funding policies that reduce or threaten to cut the substantial NIH grant flow that funds virtually all product R&D in the region-could risk stemming new science investment.

Economic Uncertainty

The economy - financial market instability, shifting interest rates and economic contractions are top global risks to the biopharmaceutical industry. As a result of these economic factors, venture capital and bleak public markets may mean money dries up for startups (and bigger companies) trying to fund existing activities as well as R&D. Similarly, consumer demand for new biopharmaceutical products might fall due to economic instability having an adverse effect on how much consumers spend on healthcare (Smith, 2022, Wilson, 2023).

High Operational Costs

Continue to see the sky-high operational costs in Boston-Cambridge as an existential threat. The high cost of living, real estate, and salaries for the area can tax biopharma companies, especially startups or smaller enterprises. Such high costs can prevent companies from being able to invest effectively in innovation and long-term projects. Moreover, the attrition in terms of finances may drive certain firms to move their operations abroad where costs are lower - a potential further deflationary pressure on Boston-Cambridge biopharmaceutical ecosystem (Ginsberg, 2022; Cramer, 2023).

Talent Drain

While the competition for these skilled professionals can be fierce, it also means that turnover rates tend to run high and that keeping top talent on staff becomes far more difficult. At the same time, if other areas of the country grow their pharmaceutical supply-chain capabilities and are able to attract enough experienced professionals because they begin providing competitive incentives in order to do so it will lead a brain-drain from Boston/Cambridge leaving them with specifically talent shortages. In the worst-case scenario, this drain of talent could threaten the region's unique innovation buffer (Smith, 2022; Anderson, 2023).

4.3. Biopharmaceutical ecosystem in Fukuoka, Japan

4.3.1. Introduction

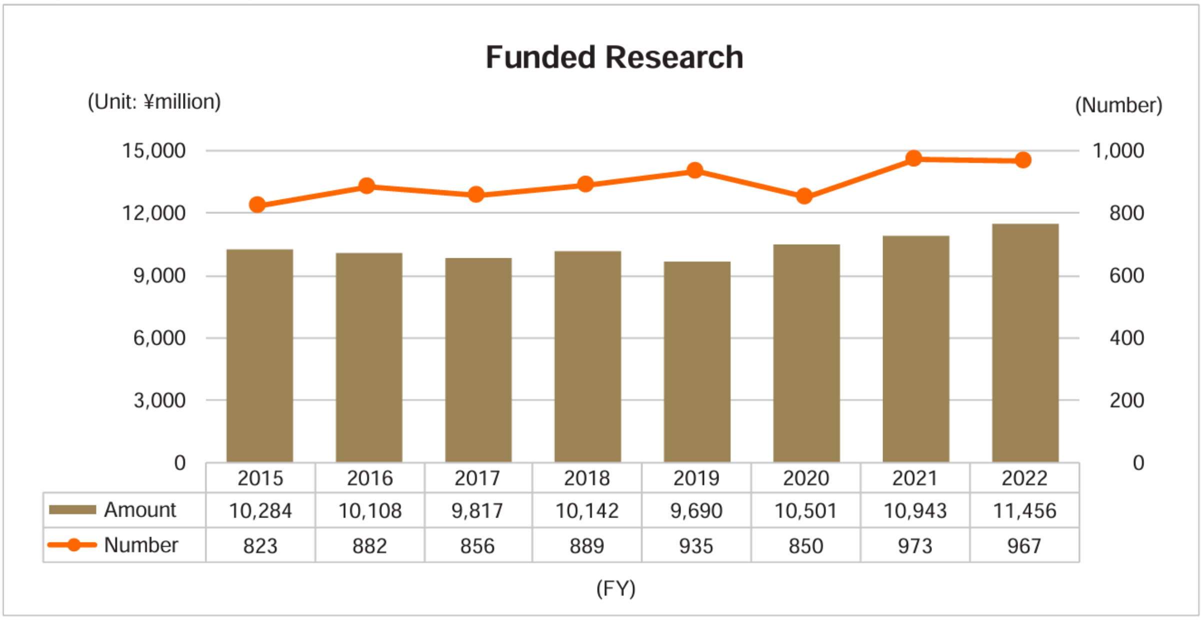
Fukuoka, located on the northern shore of Kyushu Island in Japan, is rapidly emerging as a significant hub in the biopharmaceutical sector. The region's strategic location, advanced research infrastructure, and supportive governmental policies make it a fertile ground for biopharmaceutical innovation. Fukuoka provides an example of a biopharmaceutical ecosystem synergistically unified via partnerships among academic institutions, industry stakeholders, government efforts and societal awareness (Quadruple Helix Model). At the center of the region, Kyushu University is spearheading R&D which can be further boosted by leveraging artificial-and intelligent-technologies into biopharmaceutical processes to provide yet another layer in their innovative capacity.

4.3.2. Strengths

Robust R&D Investment

Significant investments and strategic initiatives underscore Fukuoka's commitment to R&D in the biopharmaceutical sector. In 2022, Kyushu University reported a substantial increase in research funding, totaling approximately ¥11 billion (64 million euros), funded in 967 research, including biopharmaceutical research (Kyushu University, 2023).

◆Kyushu University◆



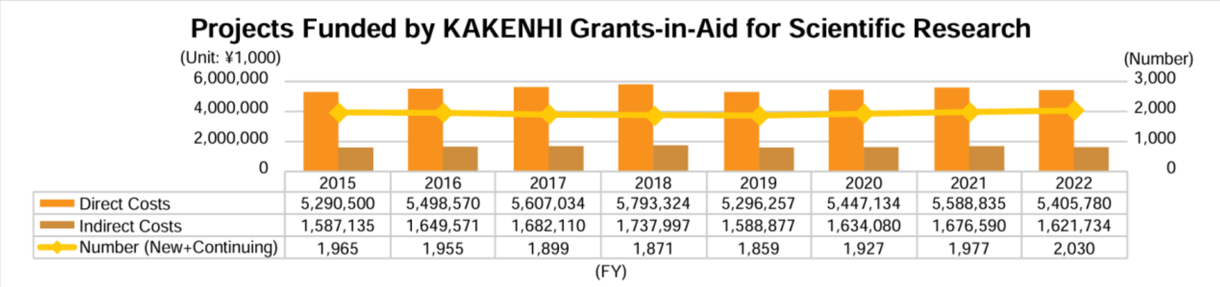
・Under ¥1 million, sums are rounded down.

Source: *Kyushu University Information*

Figure 12. *Funded research at Kyushu University (Kyushu University, 2023)*

The government also funded Kyushu University ¥7 billion (44.8 million euro) for more than 2000 science projects from 2015 to 2022 through the KAKENHI Grants-in-Aid program for Scientific Research. (Kyushu University, 2023).

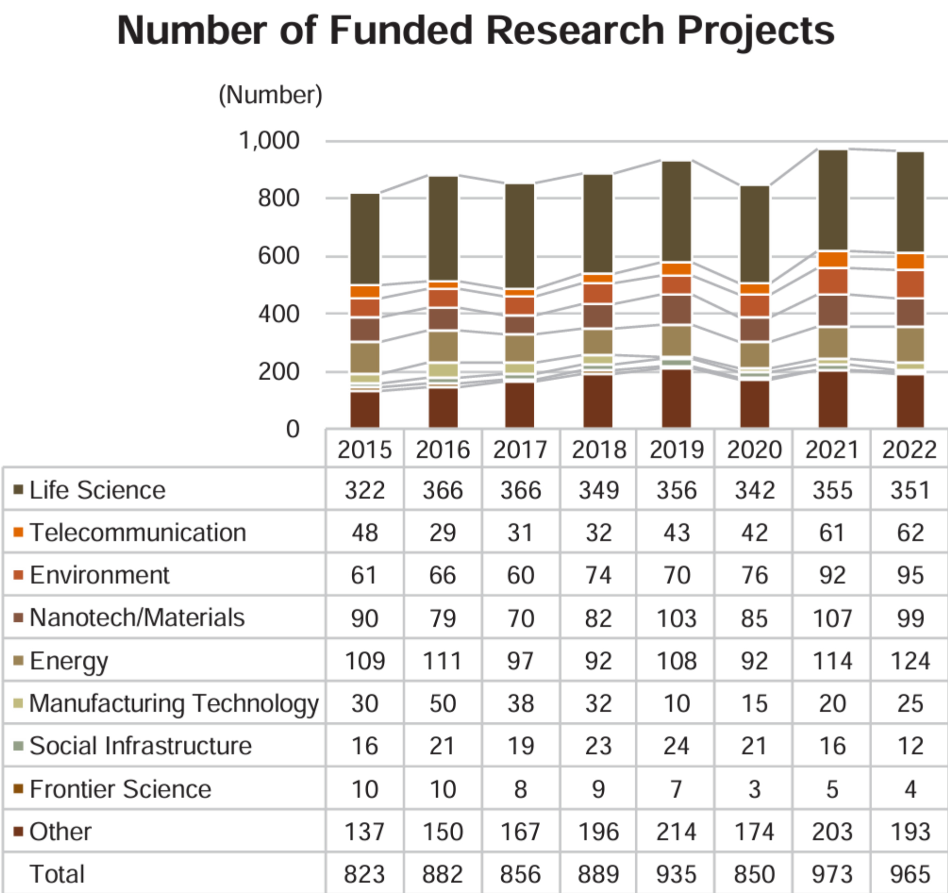
◆Kyushu University◆



	2015	2016	2017	2018	2019	2020	2021	2022
Direct Costs	5,290,500	5,498,570	5,607,034	5,793,324	5,296,257	5,447,134	5,588,835	5,405,780
Indirect Costs	1,587,135	1,649,571	1,682,110	1,737,997	1,588,877	1,634,080	1,676,590	1,621,734
Number (New+Continuing)	1,965	1,955	1,899	1,871	1,859	1,927	1,977	2,030

Figure 13. *Projects funded by KAKENHI program (Kyushu University, 2023)*

This investment has been channeled into various research projects to advance biopharmaceutical technologies and improve healthcare outcomes. The strong financial backing from the government and private sector facilitates cutting-edge research, ensuring Fukuoka remains at the forefront of biopharmaceutical innovation. Moreover, the number of funded projects in biopharmaceutical sectors are included in the field of life science – which is always the main funded project of the university in 7 years (Kyushu University, 2023).



	2015	2016	2017	2018	2019	2020	2021	2022
Life Science	322	366	366	349	356	342	355	351
Telecommunication	48	29	31	32	43	42	61	62
Environment	61	66	60	74	70	76	92	95
Nanotech/Materials	90	79	70	82	103	85	107	99
Energy	109	111	97	92	108	92	114	124
Manufacturing Technology	30	50	38	32	10	15	20	25
Social Infrastructure	16	21	19	23	24	21	16	12
Frontier Science	10	10	8	9	7	3	5	4
Other	137	150	167	196	214	174	203	193
Total	823	882	856	889	935	850	973	965

Figure 14. *Number of Funded research projects at Kyushu University by fields (Kyushu University, 2023)*

High Volume of Patents and Intellectual Property

The region has seen a notable increase in patent filings related to biopharmaceuticals. According to Kyushu University Data (2023), there were 264 patent applications from Kyushu University in 2023 alone. This high volume of intellectual property (IP) generation reflects the innovative prowess of the region's research institutions and biopharmaceutical companies. The strong IP portfolio not only enhances Fukuoka's competitive edge but also attracts foreign investments and collaborations.

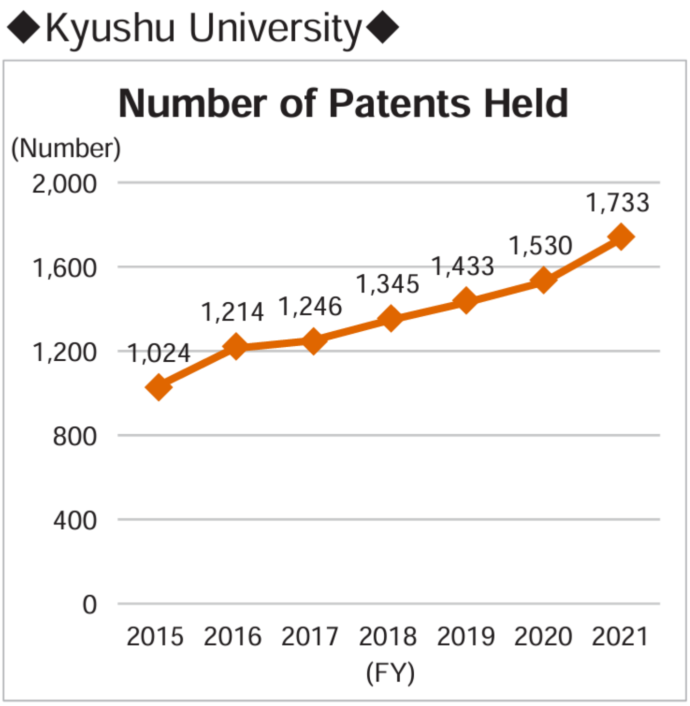
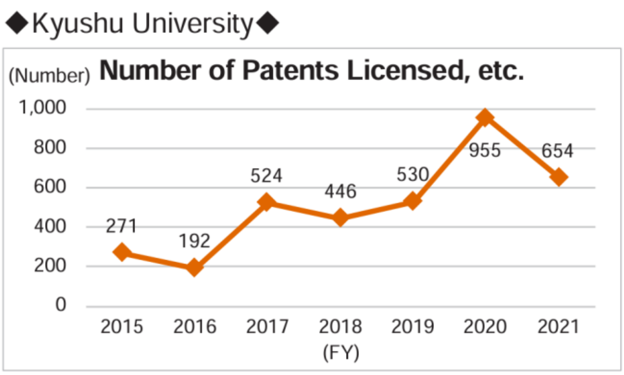


Figure 15. *Number of Patents held by Kyushu University (Kyushu University, 2023)*

In addition, Kyushu University licensed out 654 patents and ranked in the top 8 in terms of patents licensed in 2021 (Kyushu University, 2023).



Number of Patents Licensed, etc. (Including Overseas)

Rank	University	Number
1	The University of Tokyo	4,212
2	Kyoto University	2,165
3	Osaka University	1,359
4	Hokkaido University	1,250
5	Tokyo Institute of Technology	869
6	Tohoku University	867
7	Nagoya University	688
8	**Kyushu University**	**654**
9	Kanto Gakuin University	640
10	Keio University	555

Figure 16. *Number of Patents licensed by Kyushu University (Kyushu University, 2023)*

Spin-offs and Start-ups

Fukuoka has become a fertile ground for biopharmaceutical spin-offs and start-ups, driven by the region's strong academic-industry linkages. Kyushu University's Technology Licensing Organization (TLO) has facilitated the creation of 5 start-ups in 2022, many of which focus on developing novel biopharmaceutical products and technologies (Kyushu University, 2023). These start-ups benefit from the university's robust research capabilities and the supportive ecosystem provided by local government initiatives.

"Our university's discoveries, especially in discovery new drugs, have led to several successful spin-offs, demonstrating the strong potential for academic research to transition into impactful

biopharmaceutical ventures." (C7)

◆Kyushu University◆

★Key Performance Indicators (KPIs) for the Designated National University Corporations

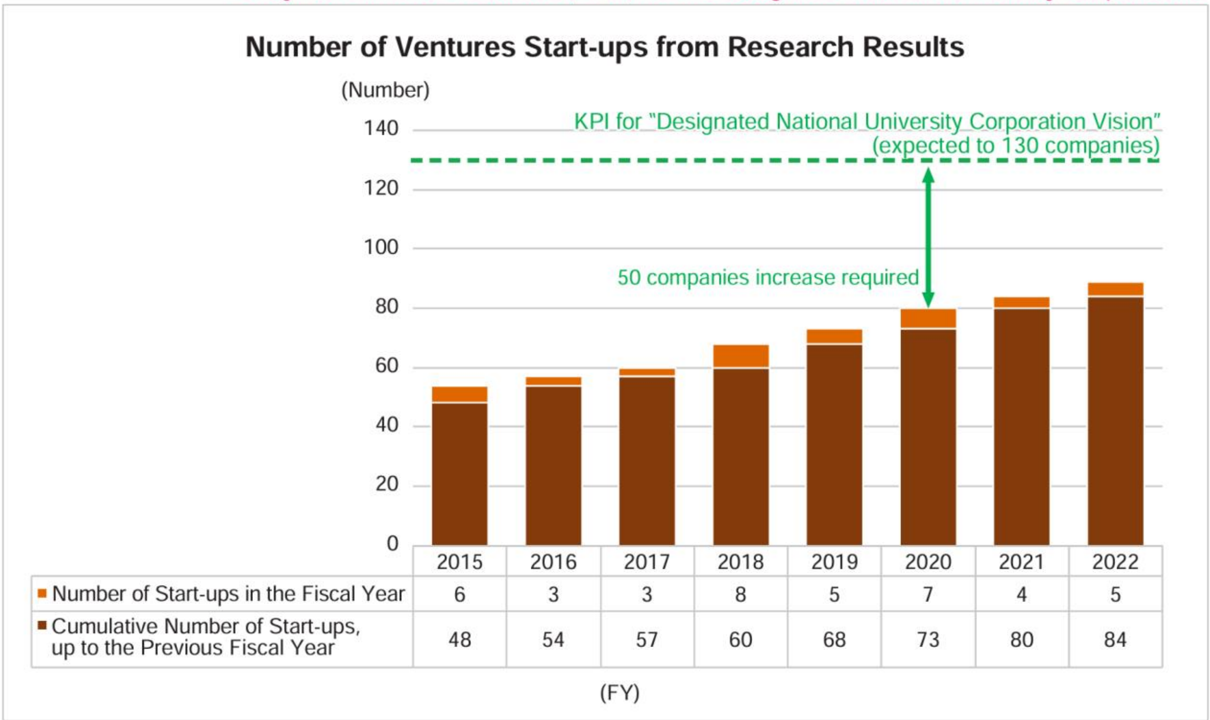
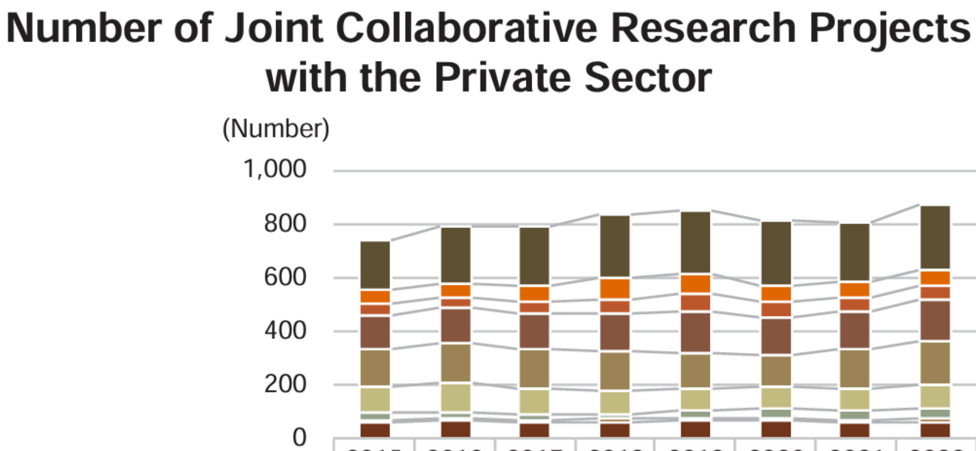


Figure 17. *Number of start-ups at Kyushu University (Kyushu University, 2023)*

Collaboration in the Quadruple Helix Model

Fukuoka excels in fostering collaboration among the four pillars of the quadruple helix model: government, academia, industry, and civil society. In 2022, Kyushu University in Fukuoka engaged in many collaboration projects with private companies (the industry), totaling 868 across various fields. Notably, 238 of these projects were focused on life sciences, underscoring the university's significant emphasis on scientific and biopharmaceutical research (Kyushu University, 2023).

"To promote rapid clinical trials for the development of pharmaceutics, our group is actively collaborating with various companies and medical schools. This collaboration leverages a large and comprehensive medical database to generate new ideas and create valuable medical insights. This new initiative focuses on developing advanced data systems to analyze factors related to specific diseases. By utilizing these data systems, we aim to create an innovative ecosystem for pharmaceutical technologies, facilitating the continuous development of new treatments and medical solutions. Although this trial has just begun, we are committed to its success and potential impact." (C7)



	2015	2016	2017	2018	2019	2020	2021	2022
Life Science	184	214	219	241	231	246	219	238
Telecommunication	53	48	60	79	76	60	55	58
Environment	46	43	45	49	63	52	51	52
Nanotech/Materials	122	133	135	145	157	145	145	160
Energy	138	148	141	144	134	116	142	161
Manufacturing Technology	99	109	102	89	81	84	85	86
Social Infrastructure	30	20	20	18	25	32	35	38
Frontier Science	9	10	10	9	10	12	8	11
Other	59	66	58	64	69	66	62	64
Total	740	791	790	838	846	813	802	868

Figure 18. *Number of collaborations with the private sector (Kyushu University, 2023)*

In the public sector, the government also funds the university in science research through multiple programs such as KAKENHI Grants-in-Aid, AMED, etc. This initiative has led to several joint research projects, public-private partnerships, and community engagement activities to advance biopharmaceutical technologies and improve public health.

"...Of course, the help of the citizen is important. But in phase one of clinical trial, led by the academia, we don't need large number of volunteers. So, we can personally ask the search volunteer through our collaborator in medical campus…" (C6)

In terms of society, it depends on the type of drug that is invented to decide the difficulty in finding volunteers. If it is allergic medicine, it is easy to encourage or find people to participate in the clinical trial; however, if it comes to anti-cancer drugs, it might be more difficult.

"In my view, allergy treatment is relatively straightforward. However, when it comes to anti-cancer drugs, which often have side effects, the situation becomes more difficult. So, it's crucial to consider both the specific drug and its associated side effects in the context of CBT (cognitive-behavioral therapy) to choose or make call for volunteers." (C6)

Talented Workforce

The region boasts a highly skilled and diverse talent pool driven by Kyushu University and other academic institutions. Kyushu University alone has over 18,000 students, including 1,710 international graduate students, contributing to a vibrant and multicultural research environment (Kyushu University, 2023). In terms of students who graduated in the pharmaceutical sector, there are 80 university students and 47 master students on average who graduated each year (Kyushu University, 2023).

"Kyudai is really a hub for talent, with a huge and diverse student body, including many international students. Specifically, in the pharmaceutical field, they graduate a good number of students each year... This strong output of skilled graduates definitely supports the region's focus on biopharma research…." (C7)

*<*Kyudai: Kyushu University>*

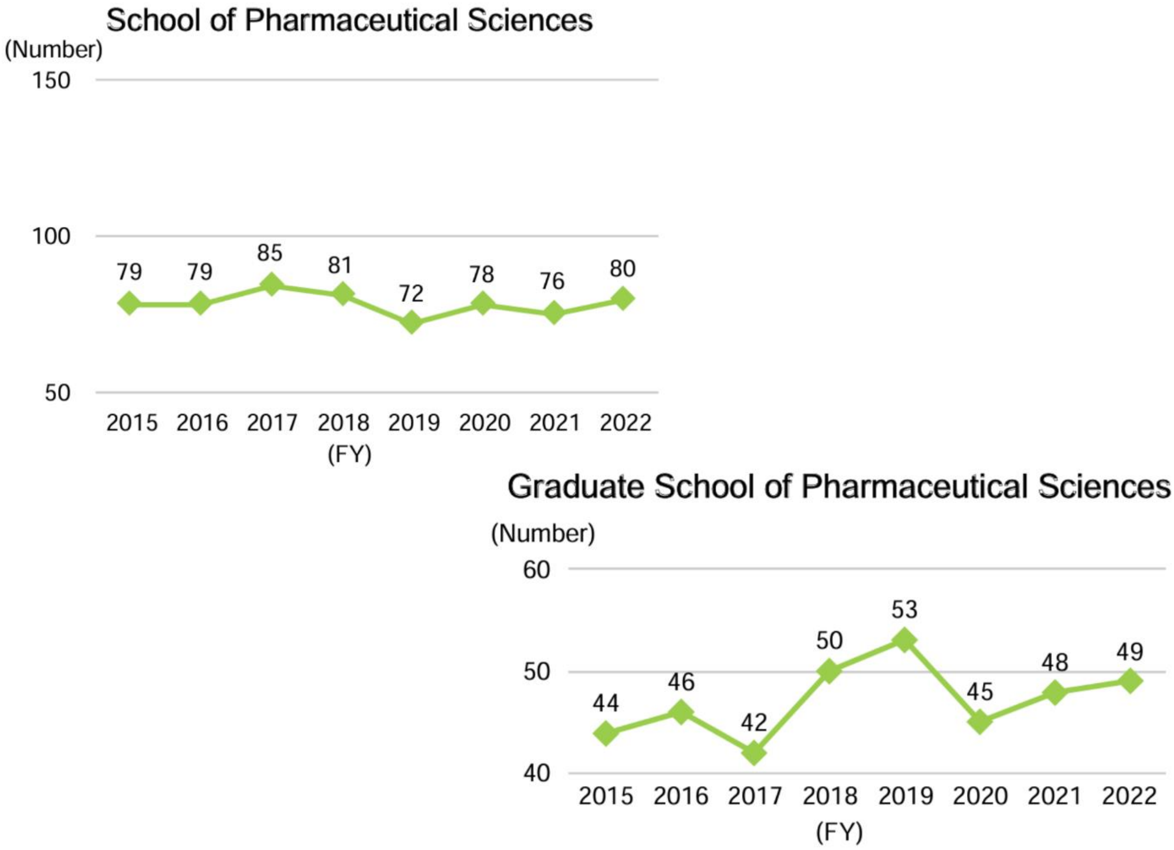


Figure 19. *Number of university and master students who graduated (Kyushu University, 2023)*

4.3.3. Weaknesses

Despite the many strengths of Fukuoka's biopharmaceutical ecosystem, notable weaknesses hinder its full potential. These weaknesses are primarily associated with integrating advanced technologies, regulatory constraints, and infrastructure limitations.

Limited AI Integration in Some Laboratories

Despite the strengths of Fukuoka's biopharmaceutical ecosystem, there are notable weaknesses, particularly in the inconsistent integration of artificial intelligence (AI) across different laboratories. While Fukuoka is known for its advanced biopharmaceutical research and development, not all labs within Kyushu University and other institutions are leveraging AI to its full potential. For instance, some laboratories continue relying on traditional drug discovery and data analysis methods, which can significantly limit their efficiency and innovation capabilities.

"Although we have seen significant advancements through AI integration, we never use AI, unfortunately, but some of my friends use AI to screen the drug, which may have possibility to a to show some effect to a certain degree effect and use AI for diagnosis based on the image of the patient. However, our lab doesn't feel it is necessary to use AI..." (C6)

"…but if we wish to, we can collaborate with a to some of the research group do the AI based a drug development, but we don't have connection with them…" (C6)

This lack of uniform AI adoption means that some research projects may be slower and less efficient compared to those utilizing advanced AI tools.

Regulatory Constraints

Another critical weakness is the stringent regulatory environment that governs clinical trials and the introduction of new biopharmaceutical innovations. The Japanese government's cautious approach to approving new drugs and medical treatments while ensuring high safety standards often leads to slower clinical trial processes compared to other leading biopharmaceutical hubs. This regulatory rigidity can delay the development and commercialization of innovative biopharmaceutical products. According to a report from the Japanese Ministry of Health, Labor, and Welfare, the stringent regulations, although crucial for patient safety, create a bottleneck for rapid innovation and application in the biopharmaceutical sector (Japanese Ministry of Health, Labor and Welfare, 2023).

"In some areas, like gene therapy, it's really tough to get approval in Europe now…" (C6)

"…The European agency, similar to the FDA, is very strict about approving these kinds of treatments. In the past, it was easier, but if bad side effects showed up, they would stop the approval. This caused a lot of deaths. Because of that, Europe is now much stricter than Japan…" (C6)

"In Japan, the rules are also very strict and careful. They have a strong system to make sure new drugs and treatments are safe and work well before moving forward." (C6)

Maintaining Patents

While Japanese patents are generally easy to obtain, the real barrier for payment of maintenance fees is that they can be quite high and should increase year over-year. Financial stress on academic institutions usually leads to struggle in raising necessary funds to appropriately handle and keep their IP portfolios.

"It's relatively easy to obtain a patent in Japan but maintaining intellectual property (IP) is challenging due to the substantial annual costs involved. While the Japanese government offers significant grants, Japanese universities often lack sufficient funding to sustain their IP. This financial strain poses a significant problem for academic institutions attempting to keep pace with the demands of IP management." (C7)

The situation has further become complex since the Japanese government offers very generous grant programs to aid in research and development, which are welcome but often not sufficient for running costs of IP maintenance. For universities and research institutions, which are crucial in advancing innovation within the biopharmaceutical industry but often suffer from a financial shortfall for such funding mechanisms. Not securing IP hurts industrialization of new technologies and research, but also affects the global competitiveness of Japanese institutions.

While this fragility in IP management highlights the importance of policies that could ease financial costs to academic institutions, it also indicates a requirement for greater fiscal support mechanisms. Without it, the risk is that Fukuoka's biopharmaceutical ecosystem will find itself hard pressed to maintain its innovation and competitive global status.

Insufficient Funding

Despite attracting venture capital interest, the funding available for biopharmaceutical research in Fukuoka remains insufficient. Although the financial support from venture capitalists is growing, it is still not enough to meet the extensive needs of researchers. This lack of adequate funding limits the scope and scale of research projects. According to the Kyushu University Factbook 2023, while there has been an increase in venture capital investments, the total amount is still relatively small compared to other leading biopharma hubs.

> "We appreciate the venture capital coming into Kyushu, but the current levels of funding are insufficient to fully support our research endeavors." (C6)

> *"…pharmaceutical companies and such venture capital, actually, it's not so difficult to find venture capital to support the academic academia, pharmaceutics but amount of the money is not enough. So, in my case, just two years, just two years and I can hire just one researcher…" (C6)*

Hesitancy of Japanese Companies

Additionally, Japanese companies often hesitate to invest in ventures with uncertain outcomes, such as discovering new drugs. This conservative investment approach further exacerbates the funding challenges researchers face in Fukuoka. The cautious nature of domestic companies limits the financial resources available for high-risk, high-reward biopharmaceutical research.

> *"...pharmaceutical company, especially Japanese companies, they are different from our university, they don't like new challenge. Our common sense is somehow different, if our university does not guarantee that new ideas can become real drug, they will not be interested to invest in our new ideas…" (C6)*

Talent Engagement

Engaging talent in the pharmaceutical sector in Fukuoka, Japan presents a significant challenge. To address this issue, pharmaceutical companies and the Japanese government are actively working to increase the number of PhD researchers in the field. Recognizing the critical need for a skilled workforce, the government offers scholarships to support PhD students, covering research and living expenses. Currently, more than half of the PhD students benefit from these scholarships, exempting them from paying university fees. This financial support is expected to result in a significant increase in the number of PhD students in the near future.

Yet the fast pace of change in industry and market calls for an equal quick adaptability from education system to generate fresh talent pool. Education has now reached its watershed moment, to cater the same demographic demands.

> *"It is quite challenging to engage talent in the pharmaceutical sector. Consequently, pharmaceutical companies and the Japanese government are working to increase the number of PhD researchers. The government offers scholarships to support PhD students in both research and living expenses. Currently, more than half of PhD students receive scholarships and are exempt from paying university fees. This support is expected to lead to a dramatic increase in PhD students in the near future. However, with the industry and market evolving rapidly, the educational system must adapt quickly to cultivate new talent effectively. We are at a turning point for transforming the education system to meet these demands." (C7)*

4.3.4. Opportunities

Expanding AI Integration

Fukuoka has significant potential to enhance its biopharmaceutical ecosystem by expanding the integration of artificial intelligence (AI). As AI technology evolves, it can further streamline drug discovery processes and improve data analysis and personalized medicine. Increasing AI adoption can lead to more efficient research methodologies, thereby accelerating the development of new drugs. The region can build on this momentum with the existing foundational AI projects to become a leader in AI-driven biopharmaceutical innovation.

> *"AI is becoming essential for research in all fields, so we must learn about it and integrate it quickly into our research systems. In the near future, AI will support the creation of new ideas through the analysis of vast datasets…" (C7)*

> *"However, to leverage AI effectively, we need to establish comprehensive databases with structured data. Currently, much of our data is handwritten or stored on separate PCs, which hinders integration. Japan is at the starting point, and how swiftly we can develop these fundamental data systems will be crucial for maintaining competitiveness against other countries." (C7)*

These comments highlight both the potential and current challenges Fukuoka, Japan faces in integrating AI into biopharmaceutical research. However, there is significant awareness of the importance of AI in accelerating research and generating new ideas through analyzing large datasets, which could be an opportunity for Fukuoka or Kyushu University to integrate AI in the future.

Government Support and Policy Reforms

There is a growing opportunity for Fukuoka to benefit from enhanced government support and potential policy reforms to foster innovation. The region can expedite the approval processes for clinical trials and new drug introductions by advocating for more flexible regulatory frameworks. These reforms could mitigate current delays and stimulate faster development and commercialization of biopharmaceutical products. The Japanese government's increasing focus on supporting high-tech industries, including biopharmaceuticals, presents a favorable environment for such policy changes

(Japanese Ministry of Health, Labour and Welfare, 2023).

> *"The Japanese government is keen on developing a new approval system for biopharmaceuticals, recognizing them as a new category of drugs. Currently, Japan's drug approval system is very stringent, which can hinder drug development. To address this, the government aims to simplify the approval process for new drugs and their trials. This policy is intended to accelerate pharmaceutical development. However, it is important to note that biopharmaceuticals require substantial investment to develop effective products." (C7)*

Increased International Collaboration

For Fukuoka, international cooperation will be an important pillar for building up the biopharmaceutical sector. With strategic partnerships with Japan's and the world's leading biopharmaceutical companies as well as research institutions, Fukuoka can access more cutting edge technologies, people and funding. Knowledge exchange and join research initiatives APs can enable knowledge sharing between the EU-inspired case, boosting innovation capacity within these regions as well.

> *"Collaborating with international partners such as the America may allow us to stay at the cutting edge of biopharmaceutical research and bring in diverse perspectives and resources." (C6)*

Attracting More Venture Capital

With the quickly expanding biopharmaceutical ecosystem and success stories, Fukuoka may be able to strengthen attracting venture capital investments. Fukuoka should spotlight the developments across this entire region and show that start-ups here can make it, which will then attract larger investments from both domestic and international VC. Greater investments will ensure that more money is available to be able to sponsor large volume research and facilitate quicker introduction of biopharmaceutical innovations (Fukuoka Growth Next, 2023).

Developing Specialized Biopharmaceutical Hubs

It is possible to set up specialized biopharmaceutical hubs in Fukuoka that specialize in a certain area of establishment-related research and development such as oncology, immunotherapy, or regenerative medicine. These hubs can ensure these talent pools, focus research efforts and expedite the commercialization of therapy directed approaches. Creating such hubs can position Fukuoka as a global leader in specific biopharmaceutical domains (Japanese Ministry of Economy, Trade and Industry, 2023). However, the innovation process takes a lot of time, "*It's not something that can be rushed" (C1).*

> *"…the Japanese government is offering substantial grants to establish research centers and promote collaboration between companies, academia, and local governments. This initiative aims to enhance innovation and accelerate advancements in the biopharmaceutical sector. By fostering these partnerships, the government hopes to streamline the research and development process, ultimately leading to more efficient and effective drug development and approval..." (C7)*

4.3.5. Threats

Weaknesses can become threats to the Fukuoka region, especially for Kyushu University to become a center of life science like Tokyo University, Japan.

Regulatory Hurdles

Due to Japan's stringent regulatory environment, Fukuoka's biopharmaceutical sector faces significant challenges. The rigorous protocols required for approving new biopharmaceutical products and conducting clinical trials can lead to substantial delays. This conservative regulatory approach, while ensuring safety, can impede the pace of innovation and slow down the commercialization of new therapies.

> *"…the regulatory requirements in Japan very supportive in discovery new things in biopharmaceutical sector, however, to patents new there are lots of policy and stuff that prevent you from patenting and new IP of drugs or anything like that…" (C6).*

Limited Funding Resources

Despite the presence of venture capital investments, the overall funding available for biopharmaceutical research in Fukuoka remains insufficient. Many start-ups and research projects struggle to secure the financial resources necessary to advance their work. The limited funding hampers the ability to undertake extensive, high-risk research, crucial for breakthrough innovations.

> *"While we have seen some venture capital investments, the total funding is still inadequate to fully support our research, if this situation remains in long-term, our motivation in exploring will go down…" (C6)*

Market Competition

The global biopharmaceutical market is highly competitive, with regions such as Boston-Cambridge, Leuven, and others leading in innovation and attracting significant investments. Fukuoka must continuously enhance its competitive edge to attract and retain talent, funding, and business opportunities. The intense competition can threaten the region's growth if it fails to keep pace with other leading biopharmaceutical hubs.

> *"…Yes, competitors, in Fukuoka city, we might be the center of innovation in the region, but we still need to constantly innovate and improve its infrastructure to remain competitive in the national biopharmaceutical market…" (C6).*

Economic Fluctuations

Economic instability can significantly impact the availability of funding and investment in the biopharmaceutical sector. Fluctuations in the global economy can lead to reduced venture capital investments and government funding, affecting the sustainability and growth of biopharmaceutical research and development in Fukuoka.

> *"Fluctuations can lead to a tightening of funds, which poses a threat to ongoing and future biopharmaceutical projects in Kyushu University and Fukuoka region…" (C6)*

4.4. Biopharmaceutical ecosystem in Hanoi, Vietnam

4.4.1. Introduction

Hanoi, the capital of Vietnam, has been making efforts to develop its biopharmaceutical ecosystem. However, Hanoi’s biopharmaceutical sector still lags behind other prominent regions in Asia, such as Fukuoka, or leaders on the other side of the world, like Leuven and Boston-Cambridge. The city faces numerous challenges, including limited R&D investment, stringent regulatory environments, and weak collaboration within the quadruple helix model. However, there are growing prospects and several positives that can be exploited as advantageous factors to push the biopharmaceutical entity further. In this section, I will do an exhaustive SWOT analysis to give us perspective about where Hanoi stands in comparison with some of these leading biopharmaceutical hubs and hence the lessons that they could learn from those giants.

4.4.2. Strengths

Government Initiatives and Support

The Vietnamese government has shown its encouragement for the biopharmaceutical sector through several programs developed to promote advancement and innovation. For example, the government aims to have 60% of national drug value produced domestically by 2025. For example, the government has streamlined regulatory processes and reduced administrative burdens to make it easier for biopharmaceutical development (Vietnam Briefing, 2023).

Growing Innovation Index

Hanoi celebrates innovation merits Investment potential shown by the top innovation index in Vietnam of the city maintains nascent but more innovative biopharmaceutical sector (Hanoi Times, 2023). This success signals a broader push to elevate research and development capacity that is needed for bolstering biopharmaceutical sector. The high innovation index is partly due to the city's increasing investments in technology and education, which have laid a solid foundation for future growth.

> *"As a professor and a lecturer at Hanoi University of Pharmacy, I am proud to say that Hanoi is the center of innovation in Vietnam's biopharmaceutical sector. In fact, it can be considered an innovation hub of Vietnam, closely followed by Ho Chi Minh City…" (C3)*

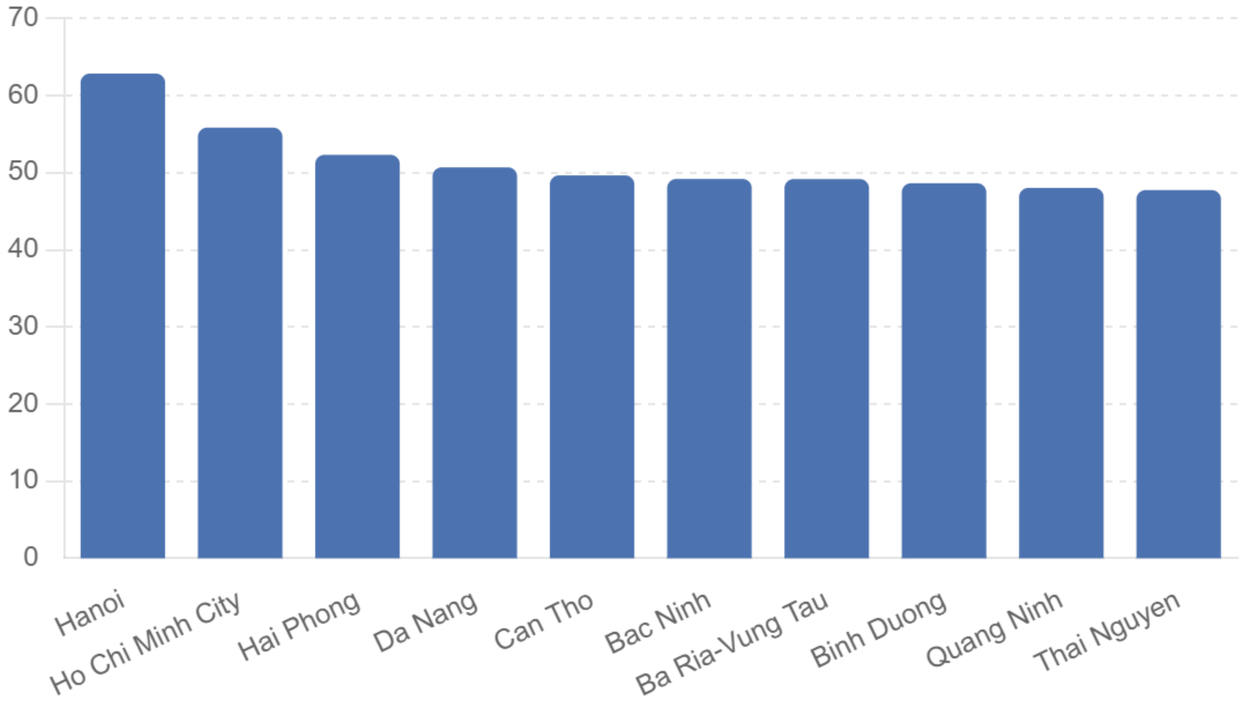


Figure 20. *Top 10 Regions with Highest PII (Provincial Innovation Index) in Vietnam (Hanoi Times, 2023)*

AI Integration in Start-ups

Hanoi's biopharmaceutical start-ups are at the forefront of adopting AI technologies, even in their early stages. These companies recognize the transformative potential of AI and integrate it into their in-house R&D processes to enhance their performances.

"We integrate AI into our in-house R&D processes, improving our existing pharmacokinetics and pharmacodynamics models." (C4)

This early adoption of AI accelerates drug discovery and development and positions Hanoi's start-ups to be more competitive on a global scale.

Collaboration

Hanoi has also another advantage in biopharmaceutical sector which is academic collaboration. The combination of this technology with the talents at Hanoi University of Pharmacy, propels start-ups in the region's ecosystem to research deeper into specific products and further validate their effectiveness on clinical trials.

"We collaborate closely with Hanoi University of Pharmacy to conduct deeper research on our key products, which helps improve their efficiency. Additionally, we co-research with hospitals to achieve clinical validations, which are crucial in the healthcare space." (C4)

This partnership ensures that new treatments are meticulously tested and validated, a crucial step in regulatory approval, followed by commercialization. In addition, the partnership of startups and academic is a perfect testament to show that there should always be growth in technology because simply innovation yet with their research results.

"Academic collaboration is crucial for our R&D efforts. Our product is treatment-related, and

validation in clinical settings is mandatory. Working with the National Drug Information and Adverse Drug Reaction Center at Hanoi University of Pharmacy provides us with academic evidence of our product's efficiency, which is essential for future regulatory registration when commercializing." (C4)

This close collaboration highlights a positive trend where academia and industry work hand in hand, fostering an environment of shared knowledge and resources, which is crucial for innovation.

Emerging AI Awareness

There is a growing awareness of the importance of AI in Vietnam, including Hanoi. The government has initiated programs to send students abroad to study AI, aiming to bring back knowledge and expertise that can be applied domestically. Although AI integration is still in its early stages, this awareness and the initial steps toward education and training indicate a positive direction for the future. The potential for AI to enhance drug discovery processes and data analysis in Hanoi's biopharmaceutical sector is significant, provided that the necessary infrastructure and policies are developed (Vietnam Briefing, 2023).

In Hanoi, AI is increasingly integrated into healthcare, covering areas such as patient care, diagnostics, and clinical decision support systems. This integration attracts a lot of talent in Vietnam, particularly in data science and machine learning.

"AI is increasingly integrated into healthcare in Hanoi, covering areas such as patient care, diagnostics, and clinical decision support systems...." (C3).

Local Talent Pool

"…This integration is attracting a lot of talent in Vietnam…" (C3)

Vietnam boasts a young and dynamic workforce with a strong foundation in STEM education. Universities in Hanoi, such as Hanoi University of Pharmacy, produce many qualified professionals who could drive the biopharmaceutical sector forward. The local talent pool is a valuable asset that can be leveraged to enhance research and development activities.

Positive Economic Projections

The pharmaceutical industry in Vietnam is projected to grow significantly in the coming years. Research by SSI Research forecasts a growth rate of 8% in 2023, with the industry reaching VND 169 trillion (€6.6 billion) (VietnamCredit, 2023). This growth potential allows Hanoi to strengthen its biopharmaceutical sector and attract more investments.

Strategic Geographic Location

Hanoi's strategic location within ASEAN provides it with access to a large and rapidly growing market. This geographical advantage can facilitate the export of locally produced biopharmaceutical products to neighboring countries, further boosting the sector's growth.

Improvement in Infrastructure

Recent investments in infrastructure, particularly in industrial zones and research facilities, have created a more conducive environment for biopharmaceutical development. The government's focus on improving infrastructure is expected to attract more foreign direct investments (FDI) and foster the growth of the biopharmaceutical industry (RMIT University, 2023).

4.4.3. Weaknesses

Limited R&D Investment

One of the most significant challenges facing Hanoi's biopharmaceutical sector is the limited investment in research and development (R&D). Compared to regions like Leuven, Boston-Cambridge, and Fukuoka, Hanoi's R&D funding is relatively low.

Country	Most Recent Year	Most Recent Value
Belgium	2021	3.43
Japan	2021	3.30
United States	2021	3.46
Viet Nam	2021	0.43

Figure 21. *Research and development expenditure (% of GDP) - Viet Nam, United States, Japan, Belgium (World Bank Group, 2024)*

The budget allocated by the Vietnamese government for R&D was 0.43% of total GDP in 2021, while that in Belgium, Japan, and the United States are significantly higher, at more than 3.3%. According to a report by KPMG (2020), the total investment in pharmaceutical R&D in Vietnam is significantly lower than in more developed biopharmaceutical hubs. This lack of funding restricts the capacity for innovation and the development of new drugs.

"Our product is treatment-related, and validation in clinical settings is mandatory. However, funding is often insufficient to cover these essential validation processes." (C4)

Stringent Regulatory Environment

Vietnam's regulatory framework is another major impediment to the growth of its biopharmaceutical sector. The stringent regulations and complex administrative procedures make it difficult for new drugs to undergo clinical trials and reach the market promptly. The report from KPMG (2023) highlights that the lengthy and complicated clinical trial application process is a significant barrier. This environment discourages both local and foreign investments in innovative biopharmaceutical projects.

"The policy framework here in Vietnam doesn't strongly support collaboration between universities and businesses…" (C3)

Challenges such as inadequate review fee structures and a lack of clinical trial centers further exacerbate these issues (KPMG, 2023).

Patent Applications and Spin-offs

In 2023, Hanoi's biopharmaceutical sector saw only 22 out of 419 new patents related to biopharmaceutical innovations, such as new drug discoveries or new ways to generate drugs, granted. Additionally, there were only 27 out of 596 new pending patents. Compared to Leuven, Boston-Cambridge, and Fukuoka, where hundreds of patents are filed and granted annually, these figures are significantly lower, highlighting a critical weakness in the innovation pipeline (Vietnam National Office of Intellectual Property, 2023).

The number of spin-offs in Hanoi remains unknown due to the lack of specific data tracking this metric. This lack of information highlights weaknesses in the biopharmaceutical sector and underscores broader issues in statistical reporting and data collection in the region. The absence of reliable data on spin-offs makes it challenging to assess the true innovation capacity of Hanoi’s biopharmaceutical ecosystem and hampers efforts to attract investment and foster growth.

Weak Collaboration within the Quadruple Helix Model

The collaboration among the government, academia, industry, and society – the quadruple helix model – is considered weak in Hanoi. Unlike in regions like Leuven and Boston-Cambridge, where there is a strong synergy among these sectors, Hanoi struggles with fragmented collaboration. While there seems to be a growing awareness of the importance of collaboration among start-ups in the region, older institutions like universities and established companies appear less interested in forming partnerships to discover innovative ideas. Instead, their collaborations tend to focus primarily on financial gains.

"Researchers or pharmacists usually have to collaborate individually with companies to generate money for themselves, while the university does not encourage them to collaborate privately. The researchers are not allowed to use their degrees at the school for individual business cooperation." (C3)

This lack of institutional support for collaborative efforts significantly hampers the potential for integrated innovation (VietnamPlus, 2023). Moreover, lacking university-level clinical research and drug development resources prevents effective partnerships (KPMG, 2023).

"So far, we have not established official partnerships with other companies in the biopharma sector. However, we anticipate that big pharmaceutical companies will become our customers and distributors in the future. Our products will synergize with theirs to create a greater value proposition." (C4)

This reflects a broader issue where the lack of formal collaborations and partnerships limits the growth potential and innovation capacity of the biopharmaceutical sector in Hanoi.

Hesitancy in Venture Capital Investments

Despite some venture capital interest, the overall funding environment remains challenging. Vietnamese companies often hesitate to invest in high-risk ventures such as new drug discoveries. They prefer investments with guaranteed returns and shorter timelines. This conservative approach limits the financial resources available for biopharmaceutical innovation.

"The number of scientific publications related to AI in biopharmaceuticals is relatively low

compared to other countries, indicating a later start in this research area…" (C3)

Furthermore, a perceived lack of incentives and ambiguous policies can deter companies from investing in local manufacturing (KPMG, 2023).

Limited AI Integration

While there is growing awareness of AI, its actual integration into the biopharmaceutical sector is limited. Many laboratories and research facilities do not use AI extensively for drug discovery or data analysis.

"The development of AI in research lags behind global standards, with slower adoption among students and educational systems. Academic programs are outdated and heavily theoretical, with limited practical applications and training in AI…" (C3)

"One of the challenges is training AI with scientific knowledge, which has many boundaries, while AI's outcomes are typically boundaryless, sometimes leading to hallucinations." (C4)

This gap in AI utilization hinders the efficiency and effectiveness of research efforts in Hanoi's biopharmaceutical sector.

Economic Constraints

Economic instability can significantly impact the availability of funding for biopharmaceutical research. The fluctuating economic conditions in Vietnam affect public and private investments, making it difficult for research institutions to secure consistent funding. This financial unpredictability threatens the sustainability of long-term biopharmaceutical projects (VietnamCredit, 2023). Additionally, the high out-of-pocket expenses for healthcare in Vietnam present long-term sustainability challenges, affecting the overall market environment for pharmaceuticals (KPMG, 2023).

Clinical Trials and Access to Medicine

The clinical trial landscape in Vietnam faces significant hurdles, such as a lack of centralized clinical trial associations and inadequate review fee structures, leading to delays in the approval process. Moreover, the penetration of patented drugs in the market is not high and therefore many innovative medicines that exist are difficult for civilians to access (KPMG 2023). This scenario limits the industry's ability to attract and conduct local clinical research.

4.4.4. Opportunities

Foreign Investment and Collaboration

Foreign investment offers a key opportunity to upgrade domestic capabilities and promote industry growth in Hanoi's biopharmaceutical sector. Specifically, the KPMG report (2023) predicts that foreign investment will focus on a combination of key areas such as exploiting clinical trials, setting up local manufacturing and contributing to medical education and patient support programs. These foreign partnerships are expected to deliver international standards and best practices, which will likely improve the trajectory of Indian Pharmaceutical Industry.

Leveraging Clinical Trials to Drive Industry Growth

Vietnam's demographics are in a good location for conducting clinical trials which we believe will help build capacity domestically and should attract more foreign investment. Expanded clinical trials would encourage the development of advanced industry knowledge within Vietnam, permeating through the broader health industry and fostering a skilled workforce of healthcare and life science professionals (KPMG, 2023). That could lead to potentially more foreign direct investment to help back Vietnam's economic aspirations.

Establishing Local Manufacturing

Setting up or expanding local manufacturing capabilities presents another substantial opportunity for Hanoi. Aligning with the government's vision to have 60% of the market value manufactured locally by 2025, foreign investors are expected to inject between USD 5–20 million per company into establishing local drug manufacturing operations. This investment would not only create additional employment opportunities but also enhance the overall capabilities of the domestic pharmaceutical sector (KPMG, 2023). Five out of twelve companies interviewed indicated their plans to initiate local manufacturing in the next two to four years, contingent on meeting specific criteria.

"By establishing local manufacturing, we can significantly reduce costs and improve access to essential medicines in the region." (C3)

Funding Medical Education and Patient Support Programs

Innovative pharmaceutical companies have shown significant interest in investing in education for professionals and patients. Leading companies manage over 600 training and educational programs annually, with investments ranging from USD 2–15 million. These programs, including Continuing Medical Education (CME) initiatives, aim to improve domestic workforce capabilities and attract foreign investment. Additionally, patient support programs focus on increasing patient awareness and access to innovative drugs, which is critical for public health improvement (KPMG, 2023).

AI Integration

While AI adoption in Hanoi's biopharmaceutical sector is currently limited, there is significant potential for growth. The Vietnamese government is showed a lot more interested in the disruptive power of AI and there are now efforts to bring health closer into this revolution. As part of this, it will be sending students to gain expertise overseas and establishing university-level courses on AI.

"Vietnam has a large, young population, which is an opportunity to leverage AI across various sectors." (C3)

By investing in AI and creating the right policies, Hanoi could markedly increase research capabilities within its biopharmaceutical sector while dramatically increasing operational efficiency.

The statement implies not only the dynamism of Hanoi workforce in contributing to innovation and development for biopharmaceuticals industry.

Growing Interest in AI Start-ups

In Hanoi, AI start-ups are more interested in healthcare solutions. Local and international investors are starting to pay more attention also these start-ups.

"We see significant potential for growth in the AI sector, especially in applications related to

healthcare and drug development. This interest is likely to attract more investment and foster innovation in the region." (C4)

4.4.5. Threats

Economic Instability

The primary challenge to the continued growth of Hanoi's biopharmaceutical ecosystem is a precarious environment with substantial economic instability capable of affecting public and private investments in this sector alike. The unstable nature of the economy in Vietnam also means that long lasting projects can suffer a lack of funding over time. This economic volatility poses several situations to challenge continued growth and persistence of biopharmaceutical initiatives. VietnamCredit (2023) identifies economic obstacles in Vietnam that severely restrict the government ability to consistently invest into innovative biopharmaceutical projects and therefore, stymie advances within organic innovation among many of its choked growth potential with the sector.

Regulatory Hurdles

Vietnam's regulatory hurdles are a huge challenge for their biopharmaceutical sector. The cumbersome and complex clinical trial application process, accompanied by ill-defined regulatory guidelines that provide no guidance upfront make it even harder for chances of new drugs reaching the market in a timely manner. The introduction of new products is significantly delayed because the complex and restrictive regulations prevent local as well as foreign investments in innovative biopharmaceutical projects, leading to an increase in disease prevalence (KPMG report, 2023). In this environment, it can be challenging for companies with the goal of innovating and expanding.

Hesitancy in Venture Capital Investments

While there has been some venture capital interest, the market is constrained by an overall risk averse investment culture in Vietnam. Vietnamese companies are often reluctant to risk investing in projects with high risks, like those related to new drug discoveries. They favor sound return investments with short payback periods that consequently limit funding resources available for development of biopharmaceutical innovation.

"The development of AI in research lags behind global standards, and the investment from local companies is often insufficient. We are in a constant struggle to secure adequate funding for our projects" (C4)

Limited AI Integration

While enthusiasm for AI is on the rise, it remains under-penetrated in practice within biopharma. In Hanoi, AI still commands little use in drug discovery or data analysis at most laboratories and research facilities.

"The development of AI in research lags behind global standards, with slower adoption among students and educational systems. Academic programs are outdated and heavily theoretical, with limited practical applications and training in AI" (C3).

The poor AI utilization widens the gap and makes it difficult for Research and Development

(R&D) activities in Hanoi and Vietnam's biopharmaceutical sector to keep up with internationally leading standards.

Competition and Global Dynamics

The biotech ecosystem in Hanoi is now competitive with other, more mature hubs such as Leuven, Boston-Cambridge, and Fukuoka. These areas possess a good infrastructure, significant funding, and the Quadruple Helix Model (strong collaboration base) which establish homelands for talent rather than investments. The lack of choice is reflected in regional innovation and biopharmaceutical rankings. According to the European Innovation Scoreboard (2023), regions like Leuven consistently rank high in innovation and biopharmaceutical advancements. This global competition threatens Hanoi's ability to attract and retain investments and talent necessary for the sector's growth.

Lack of Data and Transparency

The other notable threat is the lack of integrated data and system openness within the biopharmaceutical industry. Lack of quality data on metrics like spin-offs, among others also complicates accurate evaluation of the innovation potential in Hanoi's biopharmaceutical ecosystem. These information gaps showcase the weaknesses in the sector, not an attractive sign to attract investment or more growth.

<table>
<tr><th>STEP 1</th><th>STEP 2</th><th>STEP 3</th></tr>
<tr><td rowspan="8">RQ2: What are the barriers and drivers for AI integration in the biopharmaceutical industry in these regions?</td><td rowspan="4">4.5 Barriers</td><td>4.6.1 Regulatory barriers</td></tr>
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Table 3. *Coding tree for research question 2*

4.5. Barriers

4.5.1. Regulatory barriers

In Leuven, Boston-Cambridge, Fukuoka, and Hanoi there are regulatory barriers that prevent the adoption of AI in drug development using ai in biopharmaceutical industry as technology. These roadblocks on the digital transformation path are in part due to a complex and strict regulatory environment, compliance protocols that can be difficult to comply with for some companies as well as security standards which still vary substantially from country to country.

Broadly, Leuven is seen a model of regulatory complexity - the bottleneck that most hobbles the wearables industry. European Medicines Agency (EMA) requires exhaustive validation efforts for AI tools applied in drug development. In the example of an AI-based diagnostic tool, entering multiple rounds of clinical trials and data reviews delays gaining approval to enter the market.

"The regulatory landscape here is very stringent, which while necessary for safety, often delays the adoption of new technologies like AI". (C5)

He also added, "Stringent validation and approval processes mandated by agencies like the EMA pose significant challenges for AI-driven tools in drug development." (C5)

This strict regulatory setup ensures the safety and effectiveness of biopharmaceuticals, but at the same time attenuates innovation.

Boston-Cambridge is a biopharma innovation heaven yet requires considerable regulation. Requirement for regulatory approvals elsewhere, the path to regulatory approval for AI applications in biopharma is often long and expensive. Regulatory hurdles are the biggest problem impeding how quickly biopharma can adopt new AI technologies, according to a report from The Massachusetts Biotechnology Council (MassBio, 2023). Follow the strict rules of the FDA often leads to lengthy time frames and greater costs-especially for smaller organizations or start-ups.

Regulatory barriers are also influenced by the Ministry of Health, Labor and Welfare (MHLW) in Fukuoka, Japan. For new technologies, including AI, the pathway to approval is long and immensely expensive; a process associated with rigorous validation through clinical trials.

"Japan's regulatory process is thorough, which is good for safety but can be a barrier for rapid AI integration" (C6).

"Adopting AI in new sectors involves several barriers. One major issue is regulatory, where the government has strict policies, but they also show support for AI integration…" (C7)

While these stringent regulatory requirements help ensure that new technologies meet the highest standards of safety and efficacy, they can also slow down market access for innovative AI-based solutions.

Hanoi's Biopharma has run into the same regulatory barrier. This means that companies are finding it tough to cut through the red tape in getting approval as there is no clear regulatory framework from government authorities on how Australia should integrate AI into society.

"The regulatory environment in Vietnam is still developing, and there is a need for more defined policies to support AI integration in the biopharmaceutical sector" (C3).

AI integration in Biopharmaceutical sector does not have a well-defined regulatory framework, and this means it is still difficult for companies to adopt new technologies as they do not know what the stringent standards are.

Overall, it is clear that regulatory hurdles greatly influence the adoption of AI in biopharma world-wide. But these regulations not only guarantee safety and efficacy, they also present high hurdles to innovation as well as significant obstacles for fast market entry. But to address these regulatory challenges in a responsible way that balances safety with innovation and encourages deployment, there are others still on the table.

4.5.2. Technical Barriers

Technical barriers present one of the most significant obstacles to AI becoming truly integrated into biopharma. These barriers often related to data quality-related issues and not having the necessary talent or competence in place along with challenges related to integration into current systems.

Data quality problems exist at all levels. High-quality, standardized data for training, is crucial for training AI application, however corrupt data causes problems in effectiveness. In Leuven, researchers often struggle with integrating disparate data sources, which impacts the reliability of AI models.

> *"…AI systems rely heavily on high-quality, standardized data, which is often a challenge given the varied sources in biopharma…" (C5)*

The lack of skilled professionals is a common barrier across all regions. The biopharmaceutical industry requires a unique blend of expertise in both AI and biopharma. However, there is a shortage of professionals with these interdisciplinary skills. In Fukuoka, where many labs work with traditional methods, and upgrading these systems to incorporate AI requires significant investment and effort.

> *"…skilled professionals who can bridge the gap between AI and biopharma is a significant barrier to adoption, especially in our lab, we can improve this situation by collab with other division in the university or even with external companies… " (C6)*

Integration with existing systems is another technical barrier. Legacy systems in many biopharmaceutical companies are not designed to accommodate advanced AI technologies, making integration complex and costly. This issue is particularly significant in Hanoi, where many companies operate with outdated infrastructure incompatible with modern AI systems.

> *"Integrating AI with our existing systems is challenging due to Vietnam's poor infrastructure, in small scale project it is possible; however, with projects like discovering new drugs, it costs a lot, and I don't think companies, or the government will be pleased to invest in…" (C3).*

The technical complexity of integrating AI with legacy systems requires substantial investment in both time and resources.

Biopharma is influenced by many technical barriers that can determine the acceptance of AI, such as issues for data quality (since just few related papers are available) a lack of professionals in this field, and integration to be achievable with current systems. Overcoming these challenges will require a coordinated effort to standardize data, create interdisciplinary training programs and invest in modernizing legacy systems that can ingest AI outputs.

4.5.3. Economic Barriers

Another barrier is the economic, with high hurdles for implementation costs tied to uncertainty of return-on-investment (ROI) dampening the penetration rate of AI in biopharmaceutical firms.

Implementation costs are very high which is why many companies choose not to adopt this helper class-based solution. The development and deployment of AI technologies are expensive, requiring investments in computational infrastructure, human capital with the requisite expertise to support this shift continuously throughout its lifecycle. These costs can be prohibitive for smaller biopharmaceutical firms and start-ups. Therefore, where many biopharmaceutical companies in Hanoi have a low budget structure with minimized expenses; this makes the process of allocating finances to integrate AI infrastructure challenging.

"The cost of implementing AI is prohibitively high for many companies here, especially start-ups like us…" (C4).

Meanwhile, another economic barrier is the uncertain ROI. Companies are reluctant to invest in artificial intelligence until it is proven that the technology will have financial benefits. This uncertainty is common to all regions with no exceptions in Leuven, Boston-Cambridge, and Fukuoka.

"The high initial costs and the uncertain financial returns make many investors hesitate to fund AI projects in biopharma" (C5).

So why is AI going to be expensive? For one, quantifying the efficiency gains and cost savings promised by this technology can take time; in other words, a payback period might exist that would affect investment.

The integration of AI into the biopharmaceutical industry is hampered by high implementation costs and an uncertain ROI. To cross the chasm, tangible ROI case studies need to be visible; and governmental agencies provide funding mechanisms for AI adoption-for small firms especially startups.

In Fukuoka, Japan it is the absence of base database systems with economic barriers. It is important to create extensive databases with structured data in order for the AI implementations to effectively access and utilize. However, the current budgets are insufficient to support the necessary developments. Recently, the Japanese government has shifted its approach by providing flexible funding to select strong universities, allowing them to freely develop essential data systems and network infrastructure. This approach aims to build the necessary foundations for AI and data integration.

"…there is a lack of foundational database systems. Addressing this requires new research grants, but current budgets are insufficient. Recently, the government has shifted its approach by providing flexible funding to select strong universities, allowing them to develop essential data systems and network infrastructure freely. This approach may effectively build the necessary foundations for AI and data integration." (C7)

4.5.4. Social Barriers

Social barriers, including resistance to change, ethical concerns, and privacy issues, also impede the adoption of AI in the biopharmaceutical sector.

Resistance to change is common, especially among professionals accustomed to traditional methods. In Fukuoka, for instance, some researchers are hesitant to adopt AI due to a lack of familiarity and trust in the technology.

> *"We are still concerned about the reliability and benefits of AI in our work. Moreover, it feels like we are already doing well; we think AI is not urgent in our work at the moment…". (C6)*

> *"…Another significant barrier is emotional; many citizens are hesitant to share personal information, which hampers the development of new network systems. The Japanese government has introduced the 'My Number' system to address this, but it faces resistance from citizens and local governments...." (C7)*

This resistance can slow down the adoption of AI, as professionals may be reluctant to change established practices.

Ethical concerns related to AI, such as bias in algorithms and the potential for misuse, are also significant barriers. These concerns are particularly prominent in regions like Leuven and Boston-Cambridge, where ethical standards are rigorously enforced. Ensuring that AI systems are free from bias and making ethical decisions is an ongoing challenge. For example, an AI model trained on mostly data from Western populations might work reasonably well in one set of demographics (a fancy word for a subset) but fail completely in others and give biased outcomes.

Privacy concerns that are associated with using patient data for developing any AI based application is prevalent across regions. Protecting the data privacy and security of personally identifiable health information from breaches is as important as anything else in healthcare.

> *"Privacy issues are a major barrier to the adoption of AI, as we need to ensure that patient data is protected at all times" (C3).*

> *"Privacy concerns are a significant obstacle to AI adoption. It's essential to guarantee that patient data is secure throughout the process. Ensuring robust data protection measures is crucial, not just for regulatory compliance but also for maintaining trust among patients and healthcare providers. In Japan, we emphasize strict adherence to data privacy regulations and employ advanced methods to safeguard sensitive information at all stages of AI implementation." (C7)*

Compliance with data privacy regulations, such as GDPR in Europe, adds another layer of complexity to AI integration.

> *"Ensuring compliance with data privacy regulations, like GDPR in Europe, introduces additional complexity to integrating AI. These regulations require stringent data handling and protection measures, which can be technically and administratively challenging. In Japan, we face similar issues with our privacy laws, necessitating meticulous data management practices. This not*

only affects the technological setup but also requires constant vigilance and updates to stay compliant, thereby adding layers of difficulty to the seamless adoption of AI technologies in healthcare and biopharmaceutical sectors." (C5)

Overall, these social issues such as resistance to change and ethics & privacy issue have a significant impact on the AI adoption among biopharmaceutical sector. Contending with these challenges involves building trust in AI systems, ensuring they are used ethically and safeguarding patient data.

4.6. Drivers

Artificial intelligence (AI) integration in the biopharmaceutical industry is driven by several factors that span economic, social, technological, and collaborative domains. Each of these drivers offers significant potential to transform the industry, improving efficiency, fostering innovation, and enhancing patient outcomes.

4.6.1. Economics drivers

An important driver for AI implementation in the biopharmaceutical sector is cost-savings. Artificial intelligence has the potential to dramatically decrease both time and costs for drug discovery and development. Using AI algorithms, millions of compounds can be screened fast finding new drugs faster than traditional methods. Companies, like Insilico Medicine for example Use AI to streamline the drug discovery process reducing years push from R&D through Approval down into months (Biopharma Dive, 2023). Additionally, AI can even make the market more competitive where companies equipped with such tools will be able to launch novel treatments in a quicker way. This competitive advantage is possible through AI, in which it streamlines resource allocation and decision making as well.

Venture capital (VC) investments in AI start-ups, as is shown in Boston-Cambridge where Massachusetts based biopharma companies received €7.12 billion VC funding across 2023 reflecting a strong base on which to support AI and bio-tech start-ups with their emergence (MassBio, 2023). Over the years this support has resulted in many companies adopting AI into their research and development (R&D) pathways, which facilitated major progressions related to drug discovery and development. Take Moderna, Cambridge-based biopharma company that leveraged AI to develop its mRNA-based COVID-19 vaccine in record time, showing the impact of AI on cycle times.

This has been particularly well pronounced in Leuven, Belgium with the grand collaboration of universities and industry together to boost AI.

"Our role in bridging the connection between academia and biotech firms has allowed us to implement AI in various stages of drug development, from initial screening to clinical trials. This not only speeds up the process but also significantly reduces costs. The financial incentives and support from both the government and private sector have been instrumental in making this possible." (C5)

That viewpoint is also upheld by a number of industry professionals who believe that these types of partnerships are crucial in staying competitive and fostering innovation.

4.6.2. Social Drivers

One of the major social forces driving biopharmaceutical adoption is the potential for AI to increase patient outcomes. Personalized medicine that uses AI will be able to target treatments specifically for each patient leading to better and more effective treatment. In other applications, such as IBM Watson for Oncology which evaluates patient data to advise individualized treatment regimens we get better results. Besides, AI enables telemedicine and remote patient monitoring which has expanded access to healthcare services, especially in rural areas that are not adequately served. This is very important in a country like Vietnam where the health infrastructure leaves much to be desired.

> *"AI has the potential to revolutionize patient care by providing more accurate diagnoses and personalized treatment plans". (C5)*

Personalized Medicine is only one area where integration of AI can improve patient outcomes. In addition, AI systems are being leveraged to enhance diagnostic accuracy and enable early detection of diseases; this can even positively impact prognosis and patient outcomes. Consider imaging, where AI algorithms can spot anomalies that might otherwise be missed, which in turn ensures prompt measures and improved patient results.

In Hanoi, Vietnam, despite the challenges, there are opportunities for growth in AI integration. A biopharmaceutical technology start-up founder from Hanoi said collaborations with academia and integrating AI in early stages of the startups are crucial.

> *"…we're leveraging AI in our in-house R&D to significantly enhance patient care. By integrating AI into our pharmacokinetics and pharmacodynamics models, we can precisely calculate the optimal application of medication for each patient based on their personal information. This personalized approach ensures more accurate and effective treatment plans and reduces the risk of side effects, demonstrating the profound impact AI can have on healthcare". (C4)*

> *"…collaborating with Hanoi University of Pharmacy helps us conduct deeper research on our key products and achieve clinical validations, which are crucial in the healthcare space…" (C4).*

4.6.3. Technological Drivers

Machine learning and AI algorithms have received frequent improvements leading to increased accuracy, specificity, reliability in which are being increasingly applied across most facets of biopharmaceuticals. For example, an AI system can analyze clinical notes via natural language processing (NLP) technologies - unstructured data that is difficult for traditional systems to interpret, and which could offer invaluable insights into the care of patients as well as development of drugs. NLP On the other hand provides a way to extract useful information out of electronic health records which help with clinical decision making (MassBio, 2023). Furthermore, the capacity of AI to analyze large amounts of data and information allows more transparency in decision-making with drug discovery or clinical research. This can be especially useful in areas such as Boston-Cambridge, where there are large amounts of biotech companies and research institutions creating data that AI technologies have the potential to use.

The right collaborative context, supported by initiatives such as the Flemish AI Research Program at KU Leuven is what has made several projects driven by AI successes. A case in point: the AI research group of KU Leuven has created state-of-the-art algorithms which can predict molecules for drugs, thereby drastically reducing time and cost when it comes to identifying new drug candidates (C3 Division of KU Leuven R&D, 2023). Consequently, taking a collaborative approach to AI research and development can help ensure that new technologies are used effectively within the biopharmaceutical industry.

> *"Our division has been developing AI algorithms for drug discovery and diagnostics. The support in terms of funding and infrastructure has been crucial. We've been able to create AI models that not only improve the accuracy of diagnostics but also help in predicting patient outcomes more effectively." (C5)*

Although there are some integrations made by Kyushu University Fukuoka, Japan there is a delay for lab level consumption of AI. This shows an opportunity for expansion and investment, meaning that more AI incorporation would considerably increase the research and development ability of region.

A startup in Hanoi, Vietnam is also starting to experiment with the integration of AI into biopharmaceutical research. Though some new startups understand the power of AI and incorporate it in their early R&D stages, most use cases are rare. This is in part due to insufficient overarching policies that encourage the integration of AI and high costs for investing in their infrastructure.

> *"AI is still new to many researchers here. We have talented individuals, but the infrastructure and financial support are lacking. Most of our research is still manual, which limits our productivity and innovation." (C3)*

4.6.4. Collaborative Drivers

Collaborations between academia, industry, and government are crucial drivers for AI integration. The Quadruple Helix Model, which emphasizes the interaction between these four stakeholders, fosters innovation and accelerates the adoption of AI in biopharmaceuticals. For example, the Flemish AI Research Program funds projects that bring together these stakeholders to advance AI in healthcare. Public-private partnerships and cross-disciplinary research also play a significant role in driving AI adoption. At KU Leuven, collaborations between computer scientists, biologists, and pharmacologists result in cutting-edge AI solutions for biopharma.

> *"Our bridging approach has been key to our success. By working with experts from different fields, we can tackle complex problems more effectively. For instance, our recent project on AI-driven drug discovery involved close collaboration between our AI researchers and pharmacologists, leading to a significant breakthrough in identifying potential new drugs." (C5)*

Similarly, in Boston-Cambridge, the synergy between top-tier universities, biotech firms, and government initiatives creates a fertile ground for AI-driven innovations. Furthermore, heavy academic support from institutions like MIT and Harvard for biotech companies has helped promote a high level of AI technologies integration in the area. Innovations are created quickly and translated into real-world applications through this ecosystem of collaboration.

In Fukuoka, Japan, while collaborative efforts are emerging, there is still room for improvement in terms of integrating AI across all stakeholders.

> *"Our collaborations with industry are gradually increasing, but there is a need for stronger government involvement to provide the necessary infrastructure and funding. Currently, many of our projects rely heavily on university resources, which limits the scope and scale of our research." (C6)*

In Vietnam, despite the challenges, there are opportunities for growth in AI integration. The founder of a biopharmaceutical technology start-up in Hanoi (C4) emphasized the importance of academic collaboration and the early adoption of AI in start-ups.

> *"Collaborating with Hanoi University of Pharmacy helps us conduct deeper research on our key products and achieve clinical validations, which are crucial in the healthcare space" (C4)*

However, broader systemic support is needed to foster a more robust collaborative ecosystem in Hanoi.

> *"The potential for collaboration is there, but we need more structured support from the government and industry. Establishing public-private partnerships and increasing funding for collaborative projects would significantly enhance our research capabilities." (C3)*

STEP 1	STEP 2	STEP 3
RQ3: What strategies can Hanoi adopt to improve its biopharmaceutical ecosystem and AI integration based on the experiences of Leuven, Boston-Cambridge, and Fukuoka?	4.7 Enhance collaboration	4.7.1 Quadruple helix model
		4.7.2 Public-Private partnerships
		4.7.3 Academic-Industry linkages
	4.8 Increase funding	4.8.1 Government grants
		4.8.2 Venture capital investment
		4.8.3 International funding
	4.9 Foster innovation	4.9.1 R&D investment
		4.9.2 AI research centers
		4.9.3 Start-up incubators
	4.10 Talent development	4.10.1 AI and Biopharma education
		4.10.2 International training programs
	4.11 Infrastructure improvement	4.11.1 Research facilities
		4.11.2 Digital health records
	4.12 Strengthen regulations	4.12.1 Data privacy policies
		4.12.2 Supportive AI policies
	4.13 Promote AI integration	4.13.1 AI in drug discovery
		4.13.2 AI in clinical trials
		4.14.3 AI in diagnostics
	4.14 Leverage international expertise	4.14.1 Global collaborations
		4.14.2 Exchange programs
		4.14.3 Joint research projects

Table 4. *Coding tree for research question 3*

4.7. Enhance collaboration

4.7.1. Quadruple Helix model

The Quadruple Helix Model, which involves collaboration between academia, industry, government, and society, is a proven framework for fostering innovation and driving technological advancements. Adopting this model will enhance the biopharmaceutic ecosystem and integration capacity of AI in Hanoi. For Hanoi, the connection between them could create a stronger and more active innovation playground.

All these cases have been made possible thanks to the implementation of the Quadruple Helix Model in Leuven: it makes collaborations work and accelerate breakthroughs on biopharma research.

"The integration of AI in biopharmaceuticals is not just about technology; it's about bringing together diverse expertise to solve complex problems. Our collaborations with industry partners and government support have been crucial in advancing our AI projects". (C5)

This has allowed Leuven to maintain its premier position in biopharma innovation.

By efficiently establishing a regulatory framework and policies, which encourage collaboration across the four pillars Hanoi can replicate Leuven's model. This could in turn be matched at the other end to schemes for state-funding joint projects between universities and drug companies, of which Leuven is a model. Similarly, organizing public service announcements to gain public support for AI and biopharmaceutical breakthroughs would foster social involvement.

More incentivized collaborative frameworks are also necessary, suggests a Hanoi University of Pharmacy professor.

"The collaboration with other entities in Hanoi or in Vietnam is essential for driving innovation in the city's biopharmaceutical sector. By bringing together academia, industry, government, and society, if it is possible, the region could pool resources and expertise to overcome challenges and seize opportunities in AI integration" (C3).

This is something that emphasizes the requirement of a united and collective effort to further excel Hanois biopharmaceutical ecosystem.

For the entrepreneur in start-ups, this cross collaboration is essential from founder perspective.

"We collaborate closely with Hanoi University of Pharmacy to conduct deeper research on our key products, which helps improve their efficiency. Additionally, we co-research with hospitals to achieve clinical validations, which are crucial in the healthcare space" (C4).

These collaborations have entrained start-ups to academic expertise, ensuring novelties are tested in real world environments and thereby animating the research-practice divide.

Case study on Hanoi implies that Quadruple Helix Model engages and capitalizes the capacities of local stakeholders as its constituent to new paradigm for collaborative innovation. However, should Hanoi embrace this approach it could quickly become a hub for biopharmaceutical excellence and innovation while making significant strides in the biopharmaceutical sector, particularly where AI is concerned.

4.7.2. Public-Private Partnership

The biopharmaceuticals and AI are poised to benefit from greater cooperation on the formation of public-private partnerships (PPPs). The Boston-Cambridge area has benefitted from PPPs to help drive regional success. The Massachusetts Life Sciences Center (MLSC), a quasi-public agency, was created to enhance the life sciences ecosystem in the Commonwealth and make it easier for scientists to conduct research or commercialize their work., using public dollars as well as other funds.

Across the healthcare system in Fukuoka, Japan, similar PPPs also helped foster collaboration.

"Our collaborations with private companies have been vital in translating our research results into practical healthcare applications. The support from the government and industry partners is needed to accelerate the development and deployment of our technologies" (C6).

Hanoi can facilitate responsible work around PPPs in the biopharma sector by setting up dedicated agencies. For example, building spaces for academic researchers to work alongside industry experts and government officials on new projects. Financial incentive along with regulatory assistance for PPPs as a response strategy can help in drawing private investment and know-how into the city's biopharmaceutical landscape.

PPP has good prospects, Said the founder of a biopharmaceutical technology start-up in Hanoi.

"Public-private partnerships are crucial for driving innovation in the biopharmaceutical sector. By leveraging the strengths of both sectors, we can accelerate the development and commercialization of AI-driven solutions. We need more government support to facilitate these partnerships and attract private investment" (C4).

Support this opinion, C3 also stated:

"Public-private partnerships play a vital role in advancing innovation in the biopharmaceutical sector. By combining the expertise and resources of both academia and industry, we can expedite the development and commercialization of AI-driven solutions, especially in discovery new drugs or data diagnostic. It's imperative that we receive more government support to foster these collaborations and attract private investment, ensuring that we can continue to push the boundaries of medical research and healthcare technology. Researchers like us are desperately need this kind of support…" (C3).

4.7.3. Academic-Industry linkages

Strengthening academic-industry linkages is essential for translating research into marketable products and technologies. In Boston-Cambridge, top-tier universities like MIT and Harvard maintain strong connections with the biotech industry, facilitating knowledge transfer and innovation. These linkages have resulted in numerous successful startups and significant advancements in biopharmaceuticals. Hanoi's academic institutions, such as Hanoi University of Pharmacy, can play a similar role by fostering closer ties with the biopharmaceutical industry.

To strengthen these linkages, Hanoi's universities should establish technology transfer offices (TTOs) that facilitate partnerships with industry. These TTOs can help identify potential industry partners, negotiate research contracts, and manage intellectual property rights. Additionally, integrating industry-driven projects into academic curricula can provide students with hands-on experience and enhance their employability in the biopharmaceutical sector.

> *"Academic collaboration is crucial for our R&D efforts. Our product is treatment-related, and validation in clinical settings is mandatory. Working with the National Drug Information and Adverse Drug Reaction Center at Hanoi University of Pharmacy provides us with academic evidence of our product's efficiency, which is essential for future regulatory registration when commercializing. Currently, our country lacks support for clinical trials. However, to develop a truly innovative biopharmaceutical industry, the establishment and support of clinical trial infrastructure are essential for the future." (C3).*

4.8. Increase funding

4.8.1. Government grants

Increasing funding through government grants is a critical strategy for boosting Hanoi's biopharmaceutical ecosystem and AI integration. Government support can provide the necessary financial resources to kickstart and sustain innovative projects. In regions like Leuven, government grants have played a pivotal role in fostering research and development. The Flemish government, for instance, provides substantial funding for biopharmaceutical research, enabling institutions like KU Leuven to pursue groundbreaking projects. the Flemish government provides significant funding for biopharmaceutical research projects facilitating innovative trials such as that of KU Leuven.

> *"Our important success factor in biopharmaceutical research is significantly supported by government grants. These funds allow us to explore innovative ideas and translate them into practical applications. The government's commitment to funding research is crucial for maintaining our competitive edge" (C6).*

This sentiment is a reminder of the role stable and significant government funding has in keeping long-term research going that would not be fundable by private capital due to its high risk-high reward nature with economically extended timelines.

Similarly, government grants have been important for the development of this sector but in Boston-Cambridge. The larger grants that can keep an entire lab in business for several years come from the National Institutes of Health (NIH) and other federal agencies - these fund everything from basic science research to clinical trials. The grants also continue to invest in the region's leadership as a global hub for biopharmaceutical discovery and investment. Therefore, with this sort of investment in 2023, very little was left to chance as NIH allocated over €1.5 billion into Massachusetts research institutions, creating an incredibly fertile landscape for biopharmaceutical and AI integration (Massachusetts Life Sciences Center, 2023).

Hanoi might want to follow this, for example by increasing government grants on biopharmaceutical research and AI integration. At the local level, this would mean that government is only willing to spend large amounts of money on projects shown likely (or better) by economic analysis and current scientific knowledge to be innovative in a way which will benefit public health. By developing dedicated grant programs for biopharmaceutical research and AI projects, similar to those in Leuven or Boston-Cambridge a solid base of growth can be formed. These grants can be for use at different stages of the research and development pipeline, from early-stage exploratory work to late-stage clinical trials and commercialization.

> *"In Hanoi, increasing government funding for biopharmaceutical research is essential. Government grants can provide the financial stability needed for long-term projects, enabling researchers to focus on innovation rather than constantly seeking private investment…" (C3).*

Drawing on this, the Hanoi government could then set up a biopharmaceutical innovation fund with grants earmarked specifically for projects integrating AI. This fund could support research collaborations between universities, other research bodies and industry to promote a national system of innovation. In addition to that, a transparent and effective grant application process would stimulate applications from more researchers as well as companies leading to the growth of sectors often.

By tying grant programs to strategic national health priorities, government can ensure funded projects are directed towards the major healthcare issues. For instance, research grants could be selectively given to endemic diseases or in places that Vietnam is strong at like herbal medicine. Though targeting in this way would also have to be done on a regional or national basis, it was suggested that such an approach might help ensure public spending encouraged not just improved health outcomes but the development of the biopharmaceutical sector.

In conclusion, one of the essential plans to accomplish improving Hanoi's biopharmaceutical ecosystem is largely promoting government grants for biopharma research and AI integration. My argument is that Hanoi needs to adopt the best practices from regions such as Leuven, Boston-Cambridge and Japan - this will create a funding environment that can support innovation, new collaborations which are key drivers for growth in biopharmaceutical.

4.8.2. Venture capital investment

Another important source of funding for biopharmaceutical innovation is venture capital (VC) investment. 2023 Biopharma companies based in Boston-Cambridge received €7.67 billion of venture capital funding in 2023 (MassBio, 2023). Many startups have used much of the recent VC funding to develop and bring innovative new biopharmaceutical products to market, helping solidify its status as one of the best biotech hubs in the world. An additional sign of the strength of its VC ecosystem are that Boston-Cambridge VCs bring far more than a check: they provide very valuable strategic and networking guidance which can be critical to driving growth (and success) in biopharma startups.

In terms of making Hanoi become an attractive destination for venture capital investment. It is accomplished by enacting policies to de-risk investments and encourage VC firms to invest in biopharmaceutical startups. Similarly, tax incentives or easier regulation combined with rigid intellectual property protections could make Hanoi much more attractive for venture capital. Equally, installing incubators and accelerators can help new businesses to market sooner and be more appealing to investors. These programs provide mentorship, office space and connections to investors and industry mentors that help the startups scale their operations faster, bringing products to market.

"Access to venture capital is crucial for the growth of biopharmaceutical startups. With sufficient funding, we can accelerate our research and bring innovative products to market faster. We need more support from the government to attract venture capital investment…" (C4).

This view highlights the role of an enabling policy environment that attracts venture capital, granting it through its financial arms to possible innovation and expansion.

Venture capital has been similarly important in stimulating innovation in Leuven. The existence of venture capital helps in ensuring that startups can get their hands on funds to undertake projects which are a high-risk and reward and might not be entitled for finance from the traditional bank.

"Venture capital is the lifeblood of our startups. It provides not just the funding but also the strategic support and industry connections needed to bring innovative products to market. The synergy between government grants and venture capital creates a robust funding ecosystem that drives our biopharmaceutical sector forward" (C5)

Fukuoka in Japan Fukuoka is not yet ranked as high up by venture capital compared to Boston-Cambridge and Leuven but looks like it's certainly been gathering some pace. Bigot observed that government initiatives and local venture funds have begun to support biopharmaceutical startups much more forcefully.

"While venture capital in Japan is still growing, the government's efforts to create a favorable investment environment are starting to increase. Our collaborations with international venture funds have also brought more resources to our projects" (C6).

By drawing lessons from these regions, Hanoi can aim to develop its own VC-friendly ecosystem that contributed significantly towards their respective successes. Efforts to convene biopharma investment forums, establish an investor trade association and host networking events between start-ups and investors could serve as a critical conduit for connecting new ideas with the capital needed to get them off the ground.

Through supportive policies, incubation, and acceleration programs to a collaborating investment environment the city can get its own share of venture capital financing that has been rising nationwide with an aim to encourage innovation-driven growth. These regions have valuable insights to impart, shedding light on the foundations that are needed in order to establish a truly national venture capital ecosystem.

4.8.3. International funding

Providing an international fund, such as the World Bank or ADB and some organizations in global health can significantly help for Hanoi's biopharmaceutical ecosystem. These funds are frequently used for very big projects, capital works and capacity building which represent critical future growth in the sector. With international financial support, Hanoi could lift the self-reinforcing cash barriers that currently plague its attempts to grow and develop biopharma.

One especially relevant contribution of international funding is the improvement in biopharmaceutical Research & Development capabilities in regions such as Fukuoka, Japan. As an example, grants from the World Bank and other international bodies have forgone support for state-of-the-art research equipment as well innovative technologies.

> *"International funding has been crucial in developing our research infrastructure. We are funded by EU, by the America… those funds enabled us to build state-of-the-art laboratories and acquire advanced equipment, which are essential for conducting high-quality research" (C6).*

This has enhanced the creation of local and international connections that have in turn improved research infrastructure, quality as well scope.

Hanoi is able to exploit resources from other countries by seeking grants and foreign loans aggressively. Including how to create proposals that will be in line with the funding priorities of many public and private foundations promoting improved health, enhancing science, or adding brick and mortar for sustainable infrastructure. Strong partnerships with international research institutions can also help give access to funding and collaborative opportunities. For example, linking up with top universities and research institutions globally to co-fund collaborative projects can enhance Hanoi's chances of getting its collaboration proposals greenlighted.

For example, the Asian Development Bank (ADB) has traditionally financed health projects in emerging markets including investments to strengthen healthcare infrastructure and widen access to medical technology. Hanoi should leverage such funding to create projects which can boost up its biopharmaceutical research and introduce AI in the delivery of health care. A well-written proposal could cover plans to enhance laboratory infrastructure, acquisitions of research-grade equipment or the training for researchers in leading-edge AI parts of drug discovery and diagnostics.

> *"Securing international funding can open up new opportunities for our research and development efforts. It can provide the financial resources needed to explore innovative solutions and expand our capabilities. Collaborating with international partners can also bring in new expertise and perspectives, enhancing the overall quality of our work… We are actively seeking for investment from international companies to support our company as well…" (C4).*

This perspective reinforces international support as a financial resource, and additionally for encouraging global collaborations and mutual learning.

Aside from going after direct funding, Hanoi can also get involved in international research consortia and participate networks. The networks are common entry points for access to funding, partnering programs and knowledge sharing activities. For instance, there is funding under the European Union's Horizon Europe program for international collaboration in research and innovation projects. Through this membership, in terms of technologies and projects utilized or undergoing, scientists from Hanoi biopharmaceutical can catch up with cutting-edge ones as well as have a chance to work with top talents globally.

In addition, by using international funding sources, Hanoi is capable of further improving a more comprehensive legal framework. Working with global bodies and learning from mature biopharma economies can help rationalize regulations and bring them on par to meet the set standards globally. This in turn will improve Hanoi's allure as a site for foreign direct investment (FDI) and overseas partnerships.

Hanoi could search for grants and loans from international organizations, establish cooperation with foreign research facilities to set up overseas funds as well as join global research consortiums in order to be able finance its biopharmaceutical projects and integrate AI technologies. By following the examples of Fukuoka and Hanoi, it can adopt a strategic approach to secure international funding and collaborations that would boost its biopharmaceutical capacities in ways equivalent collaboration did for health outcomes. Overall, international funding plays an important role for the expansion and development of Hanoi's biopharma ecosystem.

4.9. Foster innovation

It is crucial to encourage innovation in the biopharmaceutical field, especially towards research and development while incorporating AI technology. By promoting alternative standards and fostering advanced research, Hanoi has the potential to substantially upgrade its biomedicines sector.

4.9.1. R&D investment

R&D (research and development) investment is the principal driver of innovation. In 2023, biopharma companies headquartered in Massachusetts received €7.67 billion in venture capital funding, a significant portion of which was directed towards R&D (MassBio, 2023). This level of investment has enabled Boston-Cambridge to maintain its position as a global leader in biopharmaceutical innovation.

Hanoi can foster innovation by increasing R&D investments through both public and private funding. Government grants, venture capital, and international funding should be directed towards research projects with high potential for innovation and societal impact. Enacting policies such as earmarked R&D funds and tax incentives for the biopharmaceuticals to invest in research and more innovative projects could help drive greater investment.

"Investing in R&D is crucial for our growth and success. With adequate funding, we can explore new ideas, develop innovative solutions, and bring them to market. Increased R&D investment from the government and private sector will significantly boost our capabilities" (C3)

4.9.2. AI research centers

Creating bio-pharma specific AI research centers will be major contributors to innovation. These centers could function as focal points for inter-disciplinary research, located specialized experts in computer science and bio pharmacology to work closely together. Leuven, for example leans heavily on AI research center contributing to push forward artificial intelligence technologies in drug discovery and diagnostics. The group effort created within the centers has helped that, remarkably so when it comes to getting AI solutions built and deployed quickly.

Establishment of AI research centers for pharmaceuticals in Hanoi will enable the application and integration of AI technologies. The main topics of interest to these centers most likely are drug discovery, clinical trials and diagnostics and personalized medicine. Centers for AI research allows major advances in the state of knowledge by enabling leading-edge equipment to be tested and encouraging cooperation among researchers.

> *"Our AI research centers have been instrumental in developing innovative AI solutions for biopharmaceuticals. By bringing together experts from various fields, we can tackle complex challenges and drive technological advancements" (C5)*

On the bright side, this year FPT announced its collaboration with Nvidia to open an AI Research Center, which is a good sign for Hanoi. The center focuses on improving AI R&D capacity in order to deliver state of the art and high-tech AI, cloud solutions globally (VNexpress, 2024). These are all signs of the potential for a big data/AI driven biopharma hub to develop from Hanoi.

This has come in the form of AI research centers, which go along with other strategic goals for area like better economic development and health treatment. Eventually working to help design and deploy better more effective treatments, driving innovation in biopharmaceuticals that have the potential to change the treatment landscape adn improve patient outcomes. In addition, a strong biopharmaceutical sector benefits the economy by providing jobs and attracting international investment thus foster economic growth.

4.9.3. Start-up incubators

Developing start-up incubators to promote innovation, such as by pooling resources necessary for budding biopharmaceutical companies. These incubators will provide mentorship, funding and access to state-of-the-art research facilities. Incubators and Accelerators in the Boston-Cambridge region have played integral roles helping early-stage biopharma companies get innovative products to patients quickly.

> *"Access to venture capital is crucial for the growth of biopharmaceutical startups. With sufficient funding, we can accelerate our research and bring innovative products to market faster. We need more support from the government to attract venture capital investment" (C4).*

This underscores the importance of investment capital and an enabling ecosystem in translating innovation into marketable product solutions.

Hanoi would stand to benefit greatly from building similar start-up incubators. Such incubators could provide young companies with mentorship from experienced leaders, access to research facilities and capital. Incubators play a key role in driving innovation by guiding startups through the maze of product development and market entry. This support system is especially critical in biopharmaceuticals, due to the highly regulated process from idea through market.

The Massachusetts Life Sciences Center (MLSC) in Boston-Cambridge, for example, provides grants, loans and tax incentives aimed at spurring life sciences innovation. This kind of initiatives provide the necessary financial backing and assemble a pool of industry veterans who can mentor startups in taking them through their commercialization journey. In this model, Hanoi could replicate BCG's MLSC to have its own version that fits with the requirements of biopharma in vietnam. The center could offer direct funding, mentorship and networking to support the growth of startups in a holistic ecosystem.

Also, fostering an ecosystem where startups collaborate with the incumbents could supplementing each other in providing synergies to all engaged parties. With well-known entities and entrepreneurs, tech partnerships bridge the gap between starter companies looking for industry experience in addition to increased capital gains at corporate scale. This partnership will speed the discovery and business of new biopharmaceutical products.

Furthermore, an emphasis on public-private partnerships could serve as a game-changer for the biopharmaceutical startups in Hanoi. Striking three-way partnerships with academic institutions, private enterprises and governments, these incubators can never run out of ideas or resources. These collaborations can be instrumental in driving the embedment of AI-powered technologies within biopharmaceutical R&D with benefits trickling down to innovativeness possibilities for start-ups.

Bringing startup incubators to Hanoi isn't just about providing short-term resources; it's long-term in developing new breakthrough ecosystems. Such incubators can also catalyze an entrepreneurial ethos and culture of innovation that will help motivate others to pursue careers in bio pharmaceuticals. Ultimately, this can result in a livelier and more thriving biopharmaceutical industry in the region leading to economic as well as healthcare development.

Ultimately, by building start-up incubators, Hanoi can develop an ecosystem where biopharmaceutical innovation have a chance to bloom. These incubators can give the needed space and guidance to take them on a journey from research to market. By looking at successful strategies of other regions such Boston-Cambridge and Hanoi, the Bay Area can foster collaboration among stakeholders to further develop its unique biopharmaceutical ecosystem.

4.10. Talent development

4.10.1. AI and Biopharma Education

Building a strong talent pipeline in AI and biopharmaceuticals is vital to responsible innovation, as well as an essential tool for ensuring that their companies continue to compete effectively on the global stage. In places such as Leuven and in Boston-Cambridge, AI and biopharma education are increasingly included in major universities. Within these programs is included machine learning, bioinformatics, and computational biology courses, cultivating an interdisciplinary model of training.

Further programs needed in Hanoi Given the connections between AI and biopharma, it is necessary to create educational programs that integrate them. If AI were to be add into the syllabuses of universities like Hanoi University of Pharmacy, students would learn all they need to know and receive ample practice that will surely give them an edge in revolutionizing the biopharmaceutical industry.

"Our students need to be equipped with both AI and biopharma knowledge to address the complex challenges in healthcare. By integrating AI into our curriculum, we can prepare them for the future of medicine; I am hoping that the university and the government will integrate AI in education so that our student can raise their awareness of the importance of AI in the

future of the biopharmaceutical industry in Vietnam…" (C3)

In addition, taking education of AI and biopharma to wide people making use of digital platforms for continuing learning all the time will be friendly. The idea can be seen as a way to make high quality education available on democratised levels for students from all parts of the world, be it through top-of-the-line training programs. This would streamline the process for offering biological/pharmaceutical or related technical courses to help prepare students for careers in biopharma, by partnering with online education providers.

4.10.2. International training programs

The role of international training programme in talent development is crucial, as such global exposure brings the next generation students and professionals to their level at an early stage. Global internship and experience programs are available with a wide array of biopharma companies and research institutions in the Boston-Cambridge proximity. These internships give the participants a taste of what it is like to work in frontier areas of research & development and encourage original thinking.

Taken together, these lessons bring to light how Hanoi can leverage ongoing international training programs with established biopharma centers such as Leuven and Boston-Cambridge. For its own part, Hanoi can lessen needs in terms of talent by sending students and researchers overseas for their training.

Hanoi can also organize international conferences and workshops inviting experts from the globe to provide their insights, experiences. The platform creates learning and networking opportunities for the attendees, which ultimately promotes co-creation of ideas. Forming alliances with international groups also helps monetarily the necessity of these ventures beyond immediate impact.

Collaboration between KU Leuven and various overseas universities and research centers is a good case in point. This partnership has allowed for a flow of expertise and resources which have greatly supported KU Leuven's work both in education and research. Hanoi institutes should adopt the same approach and build a learning, innovative ecosystem to become one of biopharmaceutical research hubs (like Boston-Cambridge) co-integrated with AI.

In addition, Hanoi is well positioned to draw on its long-standing relationships with the international donor community and universities for developing customized training programs that provide specifically to the range of skills-related healthcare needs in biopharma sector. Specialized programs that provide custom training on regulatory compliance, clinical trials oversight, and AI for drug discovery. Scholarships and financial aid for students engaged in such programs can encourage talent-building, there-by guaranteeing the flow of trained professionals to leak into the industry.

The use of AI together with biopharma education and international training programs in Hanoi is more crucial than advancing this region's competence development. By integrating AI into the curriculum, creating strategic partnerships with overseas programs, and establishing strong training systems… Hanoi will have a competitive advantage in innovation. These efforts will support industry growth in the region and work toward an overarching goal of ultimately improving healthcare outcomes and progressing medical research.

4.11. Infrastructure improvement

4.11.1. Research facilities

Upgrade research facilities such as upgrading labs, is the most basic part of improving Hanoi biopharmaceutical ecosystem. Highly trained scientists are attracted to places with well-equipped, up-to-date laboratories where they can conduct state-of-the-art research. Leuven excels in the biopharmaceutical industry on account of its cutting-edge R&D infrastructure as well. The various departments within KU Leuven offer leading edge equipment, which supports high quality experiments causing breakthrough scientific insights.

In the case of Hanoi, a lot can be gained by investing more in upgrading research labs. By setting up laboratories that are up to international standards, Hanoi would not only ensure the quality of research, but also attract collaborations and funding.

> *"Our current facilities are outdated and inadequate for the type of advanced research we aim to conduct. Upgrading our laboratories to international standards is crucial for attracting top talent and fostering innovation" (C3)*

Furthermore, the founder of a biopharmaceutical technology start-up in Hanoi emphasized the need for better facilities:

> *"Having access to modern research facilities is essential for startups like ours. It allows us to conduct high-quality research and accelerates our product development process…" (C4)*

Investment in research facilities is not just physical labs. This also entailed the transfer of state-of-the-art scientific equipment and technologies, such as high-throughput screening systems, next-generation sequencing platforms, and bioinformatics solutions. The reality is that these technologies are critical to carrying out the most advanced research and staying internationally competitive. These avenues have attracted significant international collaborations and funding, with the facilities available in Leuven providing strong arguments that reinforce their positioning of a biopharmaceutical hub.

On the other hand, Hanoi lacks modern infrastructure needed to make those breakthroughs. This would also help in bettering these facilities and promoting global partnerships as well.

> *"Modern facilities will enable us to meet international standards, making it easier to collaborate with foreign institutions and attract global funding" (C4).*

This showcases how both upgrading infrastructure can benefit local research quality and aid international collaborative efforts.

In addition, better research facilities attract and keep top talent - something that top-level researchers prefer as they wield high value their potential to access state-of-the-art tools.

> *"To retain our best scientists and attract talents, we need to offer facilities that are on par with global standards. This investment is essential for our long-term growth and competitiveness"* (C3).

The government has an important role in assisting with that enhancement. Funding by policymakers should be focused on infrastructure development with provision of incentives for private sector to setup research facilities. Building on the experience of successful models in places like Leuven and Boston-Cambridge, Hanoi can create a strategy that puts its scientific resources front-and-center to upgrade capital-intensive biopharmaceutical research infrastructure, optimizing other components of innovation ecosystem.

In conclusion, improving research facilities in Hanoi is a multifaceted strategy that involves upgrading physical laboratories, acquiring advanced technologies, and fostering an environment conducive to high-quality research. This will not only elevate Hanoi's standing in the global biopharmaceutical arena but also drive local innovation and economic growth.

4.11.2. Digital health records (DHR)

Adoption of digital health records (DHR) is a further critical step to upgrade Hanoi's biopharmaceutical infrastructure. Digital health records enable seamless sharing of patient details, improve data accuracy, and ensure that AI can be easily integrated into healthcare. DHR has already scale much in the field of healthcare delivery and research, particularly within Boston-Cambridge. With AI algorithms, the possibility to analyze huge amounts of patient data will be possible and can result in more precise diagnosis or tailored treatment plans as well as significantly faster clinical trials for drugs.

DHR can bring about the same advantages in Hanoi. With its entire health data digitized, Hanoi will boost care quality and service efficiency as well as establish a strong AI-ready database.

> *"The implementation of digital health records is important, moreover, integrating AI into our healthcare system ensures that data is accurate and readily available for analysis, leading to better patient outcomes and more effective research…" (C3)*

International collaborations can also play a significant role in this transformation. Learning from successful models in regions like Boston-Cambridge and Hanoi can adopt best practices for DHR implementation.

> *"I think international collaborations can provide us with the expertise and resources needed to implement digital health records effectively. It's an area where we have a lot to learn from global leaders such as the US, EU or our neighbor Singapore…" (C4).*

Partnerships with international collaborations can also do wonders in bringing about this change. Systems with effective functioning DHR models in both established (Boston-Cambridge) and emerging communities (Hanoi), can learn from each other best practices of successful DHR implementation.

> *"With a centralized digital health record system, we can conduct more extensive and accurate research, ultimately leading to better healthcare solutions" (C3).*

In addition, the adoption of DHR leads to a data infrastructure that supports AI in healthcare. DHR systems have abundant data suitable for AI algorithms to learn from, and AI thrives off of large datasets. This integration will boost predictive analytics, empower patient surveillance, support services in personalized medicine by providing and sharing insights gathered from the controlled bedside environment.

> *"Digital health records are the backbone of modern healthcare. They enable us to harness the*

power of AI to deliver more precise and effective treatments" (C4).

Hanoi biopharmaceutical infrastructure facilities will need to improve research and upgrade capacity as well engage in the implementation of digital health records. All of this will bolster research innovation, encourage global partnerships and contribute to the adoption of AI in healthcare improving both health outcomes and economic growth.

4.12. Strengthen regulations

4.12.1. Data privacy policies

Stronger data privacy regulation is an important precondition for AI implementation in biopharmaceuticals in Hanoi. Good data privacy guidelines protect patient-related information used by AI applications, which is necessary to earn public trust and meet international standards. The General Data Protection Regulation (GDPR) in the EU has set a strong precedent for data privacy and many such laws now exist worldwide. Hanoi can now learn from GDPR in creating a strong data privacy framework.

> *"For AI to truly flourish in the biopharmaceutical sector, Vietnamese patients currently do not care about data privacy that much, they care more about their health. However, I believe in the future when our country develop further, robust data privacy policies will be necessary. Ensuring that patient data is secure not only complies with international standards but also builds trust among the public and stakeholders" (C4).*

Having a strong stance on data privacy would also ease working with international organizations as well. One-way businesses with in Hanoi can sign more foreigner investments and partnerships is by the establishment of policies regarding data handling that adhere to international standards. This will help Hanoi to export with a competitive edge in the global biopharmaceutical market and conformably operated according to international norms.

There are several steps to enforcing a rigorous data privacy policy. Firstly, the government should establish clear guidelines on data collection, storage, and usage. These guidelines should conform to international standards and protect data privacy throughout the entire lifecycle of permissible information. In addition to this, regular audits and compliance checks should be performed in order to ensure that organizations abide by the regulations. This will help identify any potential breaches and address them promptly.

Strick data privacy laws are one of the reasons that Leuven has a strong biopharma ecosystem. They have helped the Patient Data has not only been safeguarded but also smooth international collaborations have begun.

> *"Our strict data privacy policies have been a cornerstone in fostering international partnerships. By ensuring data security, we have been able to build trust with our global partners, thereby enhancing our collaborative efforts" (C5).*

In addition to which public information campaigns should be parallelly run-in order to implement the data privacy policies. Educating people why data privacy is so important, and how their personal information will be safeguarded can greatly increase trust around AI technologies. This can take the form of workshops, seminars, and online campaigns for Vietnamese general public as well as biopharma professionals in Hanoi.

"Public awareness and education are crucial components of data privacy. By educating Hanoi's citizens about how their data is used and protected, I believe we can build a culture of trust and transparency, which is essential for the widespread adoption of AI in healthcare" (C3).

Additionally, it often translates to substantial-scale benefits if a collaborative method is embraced towards data privacy. In clusters such as Boston-Cambridge, collaborations across academia-industry-government have given rise to mature regional data protection architectures. These frameworks safeguard patient data and enable innovation because they provide an organized regulatory setting where AI development can be unfolded.

Similarly, Hanoi could create its data privacy policies by involving all stakeholders in their cocreation and implementation. It also includes input from the healthcare community, biopharma industry and academia as well as regulatory bodies. This is a comprehensive solution to develop policies that are meaningful, impactful and acceptable by everyone.

In short, Hanoi has lots of work to do in developing its biopharmaceutical ecosystem and AI alignment by providing data privacy Policies. These processes can also foster the certainty and trust of citizens towards AI applications in Hanoi city. It will enhance patient care and research quality, position Hanoi as an international competitor in the global biopharmaceutical arena.

4.12.2. Supportive AI policies

Unfavorable AI policy environments discourage innovation Policies such as grants, tax benefits, and infrastructure investments have been adopted by governments in regions like Boston-Cambridge or Leuven to support AI R&D. The result is a policy arrangement that by-and-large promotes state-of-the-art AI innovation, and thus helps spur both new company creation alongside the successes of existing companies. Such support AI policies can also foster growth in the biopharmaceutical sector of Hanoi.

"To integrate AI effectively, we need policies that encourage innovation. Supportive AI policies, including funding, tax incentives, and infrastructure development, can significantly enhance our capabilities and attract more investments… the Government should see the huge potential AI can bring to the biopharmaceutical industry in Vietnam" (C3).

Given such potential of AI to improve healthcare delivery as well as drive economic growth, the government even initiated programs in Japan designed for those planning on applying it with biopharmaceuticals. This includes significant AI research funding projects, tax breaks for companies making large investments in A.I. tech, and public-private partnership support Therefore, Hanoi may learn from these that it can draft policies assisting financially and institutionally AI projects.

"Access to supportive AI policies is crucial for the growth of biopharmaceutical startups. With sufficient funding, tax incentives, and government support, we can accelerate our research and bring innovative products to market faster. We also need more government support to attract venture capital investment as well…" (C4).

Working on friendly AI policies, Hanoi might shift the landscape for biopharmaceutical innovations by including more and more applications with advanced features of Artificial Intelligence. These policies can be:

The first is that they need financial support and grants. Special funds should be set up by the government to support scientific research in AI of biopharmaceuticals. These funds can be used to offer grants and low-interest loans to startups, well as research institutions needing access in order accomplish prospective but risky projects. Such funding schemes have been pivotal in the development of AI technologies for healthcare in Leuven.

Secondly, by way of providing a tax break to companies investing in AI this could spur private-sector investment. In Boston-Cambridge, tax incentives have led to massive investment in research on AI and biopharmaceuticals. This is the way Hanoi should utilize to create more favorable conditions for capital by implementing similar tax policies like Slave States in general.

Thirdly, investment in infrastructure to promote AI innovation (such as for AI research centre and cutting-edge computational facilities) It is a good start with the AI Research center of FPT and Nvidia. The center aims to strengthen global access of high-tech AI and cloud solutions, which will directly contribute toward polishing the edges around AI research and development frameworks developed by local companies (VNexpress, 2024). Increasing the number of such initiatives could significantly improve Hanoi's AI foundation.

Fourthly, creating incentives for collaboration with public-private partnerships among academia-industry and government can also spur AI innovation. These partnerships are designed to combine the true successful characteristics of both sides so that AI technologies can lead a joint production process and be successfully marketed. The role of public-private partnerships in the success stories for AI projects within biopharma is exemplar, as seen with those in Leuven.

Finally, international collaborations can offer access to global expertise, funding and technology. Leverage global best-practice by using this to underpin health-tech industry standards thus improving the biopharmaceutical ecosystem and creating more joint ventures with research AI partnerships. These experiences from regions such as Leuven and Boston-Cambridge are where Hanoi might turn to in creating AI-driven strategic planning.

During this AI era, along with tightening up the legislation on personal data security in general, Hanoi should also develop specific policies supporting implementation of emerging technologies such as Artificial Intelligence to contribute assets for its framework capable of accommodating innovation yet ensuring ethical and safe practices. The approach is expected to realise technological breakthroughs and create confidence among the general public and international partnership in building Hanoi's biopharmaceutical ecosystem.

4.13. Promote AI integration

4.13.1. AI in drug discovery

The implications of this promotion of AI in drug discovery can transform Hanoi biopharmaceutical landscape. AI technologies can significantly reduce the time and cost associated with identifying new drug candidates by utilizing machine learning algorithms to analyze vast datasets and predict potential drug interactions and efficacy. For example, companies operating in biotech hubs like Boston-Cambridge use AI to help speed up drug discovery.

One example is the ability of AI models to rapidly screen through millions of compounds, in pursuit candidate therapeutic options for drug discovery. This approach is orders of magnitude faster and cheaper than traditional drug discovery, which typically requires expensive experimentation in a labor-intensive lab. AI enables researchers to select the most promising compounds, increasing flow of new drugs.

Introducing AI into drug discovery in Hanoi might require opening the dedicated research AIs and working with tech companies around the world. It is a promising sign that FPT recently cooperated with Nvidia in establishing an AI research center, could potentially uplift Hanoi's future of AI (VNexpress, 2024). The centers could specifically work towards forging AI models for drug discovery in order to fast track the development of new therapeutics, using both local and international datasets.

> *"Our AI-driven projects have significantly reduced the time needed to identify viable drug candidates. By integrating AI, we can analyze complex biological data more efficiently, leading to faster and more accurate drug development" (C5).*

Hanoi can replicate this success through nurturing similar initiatives and providing solid support to AI-driven drug discovery projects.

AI has become a staple of the drug discovery scene in Boston-Cambridge. For instance, enterprises like Insilico Medicine can perform AI-driven drug discovery at a scale and speed which no human being could match (MassBio, 2023). Using AI benefits since by using sophisticated algorithms that can analyze large datasets, the effectiveness of drugs are recognized and predicted by potential drug candidates while speeding up development. This not only accelerates time to market but also drives down the cost of drug development, a highly appealing approach for biopharmaceutical companies.

Similarly, in Leuven, AI technologies are harnessed for improving drug discovery processes. The application of AI in research works has facilitated determination of novel pharmacological agents and disentangling intricate biological processes. Within the Flemish Region, for example, an AI Research Program has many funded projects related to using AI in drug discovery which reflects that commitment by region to use of artificial intelligence within biopharmaceutical innovation.

Hanoi can use them as examples and make new AI research centers with a focus on biopharmaceutical applications. Such centers must be designed for interdisciplinary research, a goal that puts computer scientists in the same room as biologists and pharmacologists. State-of-the-art facilities coupled with researcher collaborations - nothing can spearhead advancements in drug discovery more than AI research centers.

In addition, partnerships with global AI firms and research organizations can support Hanoi to get access cutting-edge of AI technologies as well as experts. Their article explores how AI can be used for drug discovery and the ways that collaborative initiatives could help to develop local talent in carrying out such research. Government support such as funding or policy incentives can be leveraged to build upon these initiatives and maintain Hanoi's competitiveness in the biopharmaceutical industry globally.

In summary, the adoption of AI technology for drug discovery offers a great potential with Hanoi local biopharmaceutical industry in Vietnam. Vietnam can leverage its drug discovery abilities and target new markets in biopharmaceuticals with AI, thanks to a combination of strong centralized policy education networks comparable to China's but more targeted at one area due to the country's smaller size.

4.13.2. AI in clinical trial

Another critical part of the puzzle is how AI can integrate with clinical trials. Using AI technologies, patient recruitment can be targeted and ensure that the health of patients is monitored in real time as well as to hasten the analysis of trial data.

> *"AI has transformed how we conduct clinical trials. By using AI for patient monitoring and data analysis, we can ensure more accurate and timely results, ultimately speeding up the development of new treatments" (C5).*

In Hanoi itself, hospitals could utilize this AI tool for recruitment and data management in the clinical trials that take place there.

To support this integration of AI into clinical trials in Hanoi partnerships could be developed both with international firms specializing in AI and the networked research institutions within their province. This way, the latest AI technologies can be applied to make clinical trials more efficient and successful. This training can help fill the gap for developers and researchers, so they are able to use same or similar tools in clinical trials.

Leuven, Belgium is globally celebrated in the performing of clinical trials and one among prime areas overseas Leading research institutions such as KU Leuven and support of the Flemish government made it possible to have clinical trials done. AI is being used to improve patient recruitment, data analysis and real-time monitoring around KU Leuven's clinical trial processes. This provides a considerable decrease in the time that passes from planning trials to closing and results accuracy.

> *"Integrating AI in our clinical trials could drastically improve our efficiency. AI can help us calculate the right amount of drug for each patient faster and monitor their health more accurately, which is crucial for the success of our trials…". (C4)*

Boston-Cambridge is among the locales best developed in their use of AI for clinical trials. The increased use of AI in the realm comes from many biotech companies that are based locally, including those using it to improve aspects such as patient recruitment and data management for their clinical trials. This, in turn leads to personalized and effective trial designs based on AI algorithms that can predict patient responses top the treatments. This has increased the successes of clinical trials whilst reducing both costs and time (MassBio, 2023).

By seeing what leading regions in AI are doing to catalyze this integration, Hanoi can learn and begin implementing clinical trials with increased artificial intelligence applications. The following steps can be taken:

Collaboration with International AI Companies: Have alliances and partnerships setup with international AI companies to bring in cutting edge technologies and expertise into Hanoi. Such partnerships could enable knowledge sharing, along with deploying top AI solutions in clinical trials.

Building Local Expertise: Researchers and clinicians must be trained on how AI can function in clinical trials. They also build the requisite knowledge and skills that are required for an enlightened integration of AI technologies.

Government Support: The government should provide funding and policy support for AI powered clinical trials. This could involve setting up specific AI R&D funds in clinical trials, as well as building regulatory frameworks that promote the deployment of these technologies.

Developing AI Research Centers: Setting up focused clinical trial aimed artificial intelligence centers would lead to an innovation and collaboration ecosystem. A way these centers can collaborate is by convening leaders from numerous disciplines to promote the use of AI in clinical trial operations.

In conclusion, AI integration in the procedure of clinical trials is an excellent opportunity for Hanoi biopharmaceutical sector. Hanoi can learn from the experiences of regions like Leuven, Boston-Cambridge, or Fukuoka in order to adopt best practice and implement much effective ways to drive AI into clinical trials. It will not only increase the efficiency and accuracy of trials, but also contribute to an overall ecosystem building more competitive in biopharmaceutical across Hanoi.

4.13.3. AI in diagnostics

The use of AI in diagnostics has the potential to transform healthcare significantly. These diagnostic tools, powered by AI are able to analyze medical images and even predict disease outbreaks in order to provide the most personalized treatment recommendations. On the front lines of digitizing patient care and disease management, Boston-Cambridge is one of these frontier regions in biopharma where AI-powered diagnostics are becoming more prevalent.

> *"Integrating AI into our diagnostic processes allows us to provide more accurate and timely health assessments. This not only improves patient outcomes but also optimizes our healthcare resources" (C4).*

To promote the use of AI for diagnostics, Hanoi should invest in creating diagnostic tools based on artificial intelligence and cooperate with leading enterprises to create an ecosystem. To drive the adoption of AI technologies in diagnostics, government dealing with funding and development of infrastructure can come forward for supporting it. In addition, including AI education into medical training programs can also serve as a way to better prepare healthcare workers with the skills needed for these new state-of-the-art tools.

In the Boston-Cambridge area, where diagnostics based on AI are now automated, AI is used at local hospitals and research institutions to enhance the accuracy and speed of diagnostics in the region. For example, AI algorithms analyze radiology images for doctors to diagnose diseases such as cancer earlier. In addition to enhancing patient care, AI also has the potential to relieve some of the burden on health professionals - by automating repetitive elements of diagnostics (MassBio, 2023).

Significant progress has been made in AI diagnostics in Leuvens biopharmaceutical sector KU Leuven Research Central AI Units for Diagnosis operate tools in various diagnostic fields such as medical imaging and predictive analytics. These tools are interoperated into clinical workflows to optimize diagnostics capability and efficiency.

> *"AI in diagnostics has transformed our approach to healthcare. By integrating AI into our diagnostic processes, we can provide more accurate diagnoses and personalized treatment plans, improving overall patient care" (C5).*

4.14. Leverage international expertise

4.14.1. Global collaboration

Hanoi or Vietnam should work on a global scale and collaborate with the most prominent biopharmaceutical and AI research institutes in the world. It can help in exchange of knowledge, technology and practices between state government to start with. Another example is the Boston-Cambridge ecosystem and its high-density network of top-tier universities like MIT, biotech firms, their effects are reinforced by government initiatives that create a breeding ground for AI-driven Biopharma (Brookings, 2023).

Fostering such global collaborations in Hanoi can provide access to advanced research methodologies and technological advancements.

> *"Collaborating with international research institutions enables us to stay at the forefront of biopharmaceutical innovations. These partnerships are crucial for exchanging knowledge and accessing cutting-edge technologies". (C3)*

Establishing international collaborations can also help Hanoi attract foreign investments and enhance its research capabilities.

4.14.2. Exchange programs

The exchange programs are another great way to make use of the international expertise. Exchange programs will link Hanoi-based researchers, students and professionals to high-quality research environments as well as expertise from around the world. There are exchange programs between KU Leuven and institutions worldwide in areas of AI, biopharmaceutical research that have seen their knowledge sharing capabilities greatly enhanced. Also, they have many partners in universities from all over the world to send their students there and gain access education.

> *"International training programs are essential for our growth. Various universities in Hanoi offer student exchange programs with their international affiliates, enabling students to study in developed countries. Our student exchange programs in Hanoi University of Pharmacy with various prestigious universities worldwide. Our students have the opportunity to study at leading institutions such as Sydney University in Australia and the National University of Singapore. These exchanges allow them to gain invaluable insights and knowledge from biopharmaceutical leaders in these regions, enhancing their educational experience and fostering international collaboration in the field...." (C3).*

> *"Participating in international exchange programs has been incredibly beneficial for our team. If it is possible, it will allow us to learn from global experts and bring back valuable knowledge and skills to apply in our research projects" (C4).*

Hanoi may also launch additional exchange programs with global biopharmaceutical and AI research centers to provide its researchers and experts the opportunity to work across international borders.

4.14.3. Joint research projects

Joint research projects with international partners can drive significant advancements in biopharmaceutical and AI research. In some cases, these projects bring together resources ranging from individual experts to the equipment and technology of multiple institutions for richer and more creative solutions. Combination of academic governmental and industrial partners will result to success-At KU Leuven, for example has profited from collaborative research projects thanks to successful collaborations with academia, the industry as well as government; this led new innovations.

There are research projects to be co-undertaken with Hanoi-based international institutions, in the division of unique novel biopharmaceutical solutions for AI technology growth. Such projects can help to create career paths for local researchers working on grand challenge style research, thus promoting skills and knowledge in developing countries.

> *"Collaborating on joint research projects with international partners allows us to tackle complex research challenges more effectively. These partnerships are crucial for advancing our research capabilities and achieving significant breakthroughs". (C3)*

Strategic global partnerships and exchange programs will open pathways to international expertise, helping Hanoi improve its biopharmaceutical ecosystem and AI integration. The approaches will help Hanoi improve access to state-of-the-art research and knowledge, technology, and innovation practices, while enhancing competitiveness of its reseach system.

5. Discussion

Comparative SWOT analysis of Leuven, Boston-Cambridge, Fukuoka and Hanoi biopharmaceutical ecosystems to provide insights in the landscape for improving prospects of Hanoi biopharma sector and integration with AI.

KPI	Leuven, Belgium	Boston-Cambridge, USA	Fukuoka, Japan	Hanoi, Vietnam
R&D Investment (€ million)	389.2	7.670	N/A	N/A
R&D Expenditure in GDP%	3.43	3.46	3.3	0.43
Number of Spin-offs	156	600	45	N/A
Number of Patents (granted in 2023)	163	1900	264	22
Collaboration (Quadruple Helix Model)	Strong	Strong	Moderate	Weak
AI Integration Level	Advanced	Advanced	Developing	Limited
Talent Pool Quality	Highly skilled	Highly skilled	Skilled	Emerging
Government Support	Strong	Strong	Strong	Weak
Regulation	Supportive	Supportive	Supportive	Supportive

Infrastructure	Supportive	Supportive	Supportive	Evolving
Financial Support and Incentives	Adequate	Abundant	Moderate	Insufficient
Technological Drivers	Advanced AI algorithms improve diagnostics and drug discovery.	Cutting-edge AI applications in biotech research.	Emerging AI projects in academic labs.	Experimentation with AI in biopharma research.
Social Drivers	Enhances patient outcomes with personalized medicine.	AI-driven personalized treatment improves healthcare quality.	AI improves patient care and healthcare efficiency.	AI expands access to healthcare in underserved areas.
Economic Drivers	AI reduces drug discovery costs and time.	Venture capital investment in AI start-ups.	Government funding supports AI infrastructure development.	AI adoption drives innovation in start-ups.
Collaborative Drivers	Strong university-industry collaborations accelerate AI adoption.	Synergy between top universities, biotech firms, and government.	Increasing industry-academia partnerships but need more government support.	Collaboration with universities aids research and clinical validation.
Regulatory Barriers	Complex regulations delay AI adoption.	Strict FDA approval processes.	Rigorous, costly validation by MHLW.	Undefined regulatory framework.
Technical Barriers	Data quality and integration challenges.	Shortage of interdisciplinary AI-biopharma expertise.	Old lab methods and infrastructure.	Outdated systems and infrastructure.

Economic Barriers	High costs and uncertain ROI.	High implementation costs and ROI uncertainty.	Insufficient budgets for maintaining IP.	Low budgets hinder AI adoption.
Social Barriers	Ethical concerns and resistance to AI.	Ethical and privacy concerns.	Resistance to AI and privacy issues.	Privacy concerns and regulatory compliance.

Table 5. *Comparison of KPIs in 4 regions.*

5.1. Strengths

R&D Investment and Expenditure: Leuven and Boston-Cambridge are outstanding in R&D investment. By putting €389.2 million into R&D investment, Leuven shows that innovation is taken seriously. While Boston-Cambridge invests massive €7.670 billion on research and development which emphasizes the belief these areas have of their innovative potential. These investments provide advanced research infrastructure, attract top-tier commercial ozone purifier scientists and generate spin-offs and patents to deliver a strong biopharmaceutical ecosystem.

Number of Spin-offs and Patents: The Boston-Cambridge region (with 600 spin-offs; 1,900 patents) tribes itself as a vibrant center of innovation. Leuven also performs well with 156 spin-offs and 163 granted patents. Such metrics signal the presence of a robust culture for moving research into commercial use-an essential element in global competitiveness.

Collaboration (Quadruple Helix Model): there is strong collaboration among academia, industry and government as well as broad societal engagement in both Leuven and Boston-Cambridge; the Quadruple Helix Model of innovation applies to these regions. It enables a seamless integration of AI technologies and nurtures an innovation ecosystem through the Quadruple Helix Model. A close collaboration guarantees the research meets market demands and regulatory needs, shortening time to biotherapeutics commercialization.

AI Integration Level: Advanced AI integration levels in Leuven and Boston-Cambridge signals leadership into cutting-edge technologies. These territories utilize AI to improve pharmaceutical drug discovery, clinical trials, and diagnostics with greater efficiency in healthcare output.

Talent Pool Quality: The skilled talent pools located in Leuven and Boston-Cambridge are vibrant innovation stimulators. These regions attract and retain top researchers, engineers, and clinicians, creating a fertile ground for pioneering biopharmaceutical developments.

Government Support: The government supports Leuven and Boston with grants, tax incentives, as well as policy frameworks to assist their biopharmaceutical industry. This support makes a continuous investment in research and development possible, as well providing an enabling environment for innovation.

5.2. Weaknesses

Hanoi's Lagging Metrics: Compared to Leuven, Boston-Cambridge, and even Fukuoka, Hanoi lags significantly in several key metrics. R&D as percentage of GDP was 0.43% which means low investment in Research and Development. On the other hand, 22 granted patents and no specific mention of a number for spin-offs in Hanoi highlight issues in translating research into market-ready products.

Weak Collaboration: The weak collaboration within the Quadruple Helix Model in Hanoi for integrating AI technologies and innovation. This causes a dragging of the pace at which technological uptake and innovation occurs due to polarized interest among academia, industry, government as well are also stakeholders in society.

Limited AI Integration: The low level of AI integration in Hanoi makes clear that the region is still at a relatively early stage of advanced tech adoption. This limitation affects the research and development activities of Hanoi, which directly relates to the low competitiveness with other developed locations.

Emerging Talent Pool: Despite the promise of its young graduates, talent in Hanoi is just not as seasoned and experienced compared to those from more mature markets. This human capital shortage is a primary stumbling block to the progress of biopharmaceutical research and AI integration.

Insufficient Government Support: Weak government support in Hanoi with respect to financial kickbacks and regulatory environment poses a challenge for developing richer biopharmaceutical substrates.

5.3. Opportunities

Increase Funding: Hanoi needs more funding to boost its biopharmaceutical ecosystem, including from the government via grants and venture capital investment or internationally Hanoi can do this by increasing its financial means to support more high-risk, high-reward projects and international collaboration.

Foster Innovation: Setting up AI research centers and start-up incubators will boost innovation in Hanoi. Such initiatives could help the essential infrastructure and support systems to develop new technologies into commercial reality as has been achieved in Leuven or Boston-Cambridge.

Talent Development: AI and biopharma education as well as international training programs can improve the quality of workforce in Hanoi. Hepitah also noted that a strong workforce is critical in advancing research, development, and appropriate integration of the technology.

Strengthen Regulations: An ecosystem for supportive AI policies and robust data privacy frameworks might pave ways of developing a pro-innovation environment. Hanoi will be able to open the doors of FDI as well as international cooperation and integration only when it is harmonized with world standards.

Leverage International Expertise: Encourage global collaborations, student and academic exchanges, and research opportunities to enhance access to funding and the latest in international expertise. Hence, it is very important for Hanoi to implement AI integration strategies and bring the biopharmaceutical industry from a leading region's perspective into consideration.

5.4. Threats

High Barriers: These High Barriers are the main obstacles that Hanoi must overcome in order to advance. There are a lot of challenges including, strict regulation, poor data quality and availability; difficulty to implement new architecture and processes in the organization - costs too high but also employees refuse to change.

Global Competition: Biopharmaceuticals is seeing global competition, which can pose a threat for Hanoi's growth. Established regions like Leuven and Boston-Cambridge have a significant head start in AI integration and biopharmaceutical research, making it challenging for Hanoi to catch up.

Economic Uncertainty: This is closely associated with Economic Uncertainty, as an uncertain return on investment will stop funding and investments being made in new innovative projects Both a stable economic environment and financial incentives are necessary to attract-and keep-investments coming into the biopharmaceutical industry.

Ethical and Privacy Concerns: Ethical issues must be addressed to ensure public confidence while data privacy is necessary for compliance with international norms. These issues are likely to impact the adoption of AI technologies and thereby limit potential benefits from biopharmaceutical advancements, if not addressed.

6. Conclusion

This thesis has taken a deep dive into the biopharma ecosystems of Hanoi, Leuven, Boston-Cambridge as well as Fukuoka focus on their SWOT analysis and AI integration. This work used the Quadruple Helix Model to suggest and apply a SWOT framework in four regions, combined with strategic recommendations for Hanoi that learnt from successful practices found in other regional contexts.

6.1. Summary of Findings

Comparative analysis further illustrates the wide gap of Hanoi against top biopharmaceutical hubs Leuven, Boston-Cambridge, and Fukuoka. Although there is a lot of potential in Hanoi with the establishment AI research centers and shift to focus on deploying cutting-edge technologies, much work remains ahead: lack of R&D investments; poor infrastructure due to insufficient investment, international collaborations remain low. The following key points summarize the findings:

R&D Investment and Infrastructure: Boston-Cambridge also sets highest in terms R&D investment and has solid tradition of research facilities, which are necessary for cultivating innovation. For Hanoi to be able to compete in the global race, it has no options other than massively boosting its R&D spending and modernizing research facilities.

Spin-offs and Patents: The number of spin-offs and patents in Hanoi pales by significantly comparison to Leuven but also below level present at Boston-Cambridge. Creating incubators, accelerators and patent procurement is essential to promote innovation in entrepreneurship in Hanoi.

Collaboration and AI Integration: The collaborative frameworks in Leuven and Boston-Cambridge are exemplary and driven by the Quadruple Helix Model. Hanoi could scale up collaboration by nurturing public-private partnerships and inter-disciplinary research initiatives. Meanwhile, AI has broad applications in Boston-Cambridge and Leuven but it is still growing among companies based in Hanoi.

Regulations and Government Policies: Enabling regulatory environments coupled with government initiatives that act as enablers in Leuven & Boston-Cambridge for innovation. Hanoi should mirror these efforts, developing privacy regulations for data used in AI and providing financial incentives.

International Funding and Partnerships: International investment has an especially important role in the success of biopharmaceutical hubs. Hanoi needs to actively find resources internationally and work with global research institutions at a higher-level than now are there, she added.

6.2. Recommendations

The key strategic recommendations for Hanoi drawn from this research to strengthen their bio-pharmaceutical ecosystem and integration with AI are:

Increase R&D Investment: Hanoi should leverage government grants, tax incentives and facilitate public-private partnerships. Dedicated pockets for basic research, biopharmaceuticals and AI can drive innovation while broadening foreign engagements.

Upgrade Research Infrastructure: Investment in world class research infrastructure is necessary to undertake quality research. Upgrading laboratories to meet international standards will attract top-tier talent and facilitate advanced research.

Support Spin-offs and Innovation: The creation of incubators or accelerators to support early-stage startups which further promotes entrepreneurship. This will also encourage spin-offs to be created by smoothing the patent application process and through mentorships, funding etc.

Enhance Collaboration: Use the Quadruple Helix Model to improve collaboration between academia, industry and government that leads towards innovation. Hanoi needs policies that promote the establishment of partnerships and the execution of interdisciplinary programs.

Develop Supportive Policies: Establishing regulations that support data privacy and policies favoring AI can create a correct ecosystem for the integration of more e-commerce retailers. These include policies for financial support, tax incentives and infrastructure development.

Seek International Funding: Tapping international funding from organizations like the World Bank and Asian Development Bank can put in place requisite significant resources for mega projects and infrastructure building. International collaboration with research institutions provides the added benefit of accessibility to global expertise and technology.

6.3. Future Outlook

If these recommendations are followed, then Hanoi would be the one of leading players in terms biopharma ecosystem which will make them have a comparative edge over other competitors across globe. Together, the three best practices of Leuven, Boston-Cambridge and Fukuoka (as identified in proposed strategic interventions outlined within this thesis) offer Hanoi a roadmap to maximize its potential and thus secure its sustainable growth amid biopharmaceutical field.

At the end of the day, Hanoi has many challenges but it major opportunities can grow and innovate. With increased investment, infrastructure uplifting, cross-sectoral collaboration and enabling policies in place; Hanoi could use AI to overhaul its biopharmaceutical landscape with far-reaching effects on healthcare delivery as well commerce.

7. Limitation

7.1. Incomplete Data

A significant constraint to this research is that the data for analysis are limited. There was considerable regional by region variability in the availability of comprehensive, current data (particularly within Hanoi and Fukuoka).

For example, the number of biopharmaceutical spin-offs and detailed R&D expenditures, were difficult to trace or verify specifically. This inconsistency would compromise the accuracy and incremental value of a comparative analysis based on these datasets.

Although these data collection efforts are notable and certainly include the most up-to-date information possible, such gaps in knowledge pose a challenge which could limit understanding of biopharmaceutical ecosystems within their respective regions. The language barrier and also the way some data are reported between countries due to different reporting standards made it for sure hard in a lot of instances, possibly misinterpreting or overlooking with part of those collected information.

7.2. Limited Number of Interviews

The narrow sample of interviews is also an important limitation. Although the Experts are highly skilled and have good insight, a very limited number of experts were involved in this study from each region which might not be fully covering all aspects within biopharmaceutical sectors. While the experts selected were top-tier and preeminent in their respective fields, a sample of such does not represent wide degree generalizability. This is especially limiting in a field as intricate and multifaceted as biopharmaceuticals where multiple perspectives could provide a fuller thought to the context.

However, the information shared by each of expert is priceless and presents an in-depth and rich look at all that was hard finding for us mere mortals. These findings could be further validated and documented in larger, more heterogeneous samples for future investigations.

7.3. Geographic Focus

This study suffers from yet another limitation of the wide geographic focus, including areas in Asia and Europe alongside with North America. Indeed, this diversity contributes some depth to the analysis but also probably makes it even harder for these findings to be directly comparable. Different geographical regions interact within distinct socio-economic, cultural, and regulatory frameworks that may have a dramatic impact on the implementation of biopharmaceuticals with AI integration. This increase the risk that data and insights could not be easily compared across regions.

Thus, the study provides a very good big picture, but some of these nuances that may exist on regional or national levels are not completely included or well-qualified. Concentrating on a smaller number of regions might allow for more in-depth investigation of local dynamics and problems.

7.4. Constraints in Secondary Data

The current study is heavily dependent on secondary data sources, which may not always be the latest or most complete. This strategy is highly effective in fast-evolving areas like biopharmaceuticals and AI where data has a very short shelf life due to the rapid pace of innovation. Typically, there are also differences in the reporting standards of the existing data and their reliability across sources may not be consistent which can create heterogeneity throughout large-data research. These constraints might have impacted the study’s findings, limiting the ability to draw definitive conclusions.

Future work should, therefore, attempt to access primary data as much as possible and also make secondary repositories get updated regularly.

7.5. Addressing the Limitations

While the study is insulated by those bounds, it remains a valuable step toward understanding how AI will transform biopharma ecosystems. The findings from developed countries experts only show what the problem looks like in their regions. These experts were purposefully chosen to provide a focused study on the phenomenon of biopharmaceutical ecosystems. The small sample size is compensated by the dept and high-quality insights that were given through interviewing Their in-depth knowledge and expertise offer a nuanced understanding that broad surveys might overlook. This focused approach ensures that the study addresses the core issues comprehensively.

8. Proposals for Future Research

8.1. Expanding Sample Size

Future studies can compensate for the limitations of this study by increasing the sample size. More interviews with a wider range of stakeholders across the biopharmaceutical sectors in studied regions could improve understanding and generalizability. The input of voices from additional domains within the sector and at other levels - for example, policy makers, senior managers on-the-ground researchers - could provide deeper perspectives than those captured in this study.

8.2. Longitudinal Studies

As a future research outlook, longitudinal studies are also an interesting way to go. Analyzing the trends in biopharmaceutical ecosystems over an extended period can shed light on how these systems are likely to change, especially when AI technologies begin experiencing widespread assimilation. Longitudinal research could enhance our understanding of the sustained effects and durability of AI-imparted innovation in biopharmaceutical R&D. These studies are able to monitor the evolution of regulatory environment, technological innovations and market behavior more precisely which is beneficial for a better up-to-date insight into the area.

8.3. Comparative Studies in Different Geographies

A future direction could be to study other continents, such as emerging markets or regions that have received little scientific attention. Such analysis would give a global view on biopharmaceutical environment and AI consideration, where different types of challenges may be more prominent in regions outside the focus area this thesis. These comparative studies can also uncover lessons in good practices as well as innovative measures that could be mainstreamed across different settings. A better start would be to think about what else is similar in terms of socio-economic profiles with Hanoi, and target regions that are not only matching but contain (more) actionable insights as well.

8.4. Quantitative Analysis

Based on the mix method of findings of this study, future research might apply more quantitative methods to examine the hypotheses that were developed. The qualitative findings had to be validated through quantitative analysis, thus leading to more credible and statistically robust conclusions. In turn, this would improve the credibility and generalizability of their research findings. To understand the larger trends and correlations within the biopharma ecosystem - one can leverage advanced statistical techniques running at scale on large surveys.

9. Defending the Study's Limitations

While acknowledging these limitations, it is important to defend the validity and relevance of the study. The choice of expert interviewees, although limited in number, was strategic. These individuals were selected for their in-depth knowledge and leading roles in their respective fields, ensuring that the insights provided were of high quality and relevance. Their perspectives, although not statistically representative, are reflective of the key trends and issues within the biopharmaceutical ecosystems of their regions. This targeted approach ensures that the study captures the most critical and influential factors affecting AI integration and biopharmaceutical innovation.

The insights from these experts offer a valuable lens through which to understand the complexities of biopharmaceutical ecosystems. Their experiences and observations provide a rich, qualitative depth that broader, quantitative studies might miss. This focused, qualitative approach, despite its limitations, ensures a nuanced understanding of the subject matter. Moreover, the selected experts represent some of the leading minds in their respective fields, providing an authoritative perspective on the challenges and opportunities within the biopharmaceutical sector.

In conclusion, while this thesis has certain limitations, it provides a valuable foundation for future research. The insights offered by expert interviewees are crucial for understanding the complex interplay between biopharmaceutical ecosystems and AI integration. Future research can build on these findings, expanding the scope and depth of the study to provide even more comprehensive and actionable insights.

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Addendum 3: Interview Questionnaire

1. **Introduction**
   1.1. **Can you please introduce yourself and describe your current role at your institution?**
   <Context: Understanding your professional background and current responsibilities.>

2. **Current State of the Biopharmaceutical Ecosystem**
   2.1. **How would you describe the current state of the biopharmaceutical ecosystem in your region? (number of Patents, number of Spin-offs, R&D investment/expenditure, government support, collaboration contracts…)**
   <Context: Identifying the key characteristics of the ecosystem.>

   2.2. **What are the key strengths, weaknesses, opportunities, and threats of this ecosystem from your perspective?**
   <Context: Assessing the advantages and challenges within the ecosystem.>

3. **Role of Academia (For universities)**
   3.1. **What is the role of academic institutions like KU Leuven (Hanoi University of Pharmacy, Kyushu University) in driving innovation in the biopharmaceutical sector?**
   <Context: Understanding the contribution of academia to biopharmaceutical innovation.>

   3.2. **Can you provide examples of successful collaborations between your institution and biopharmaceutical companies?**
   <Context: Highlighting notable partnerships and their impact.>

4. **Role of Industry (For companies, start-ups)**
   4.1. **How does the biopharmaceutical industry in your region approach research and development (R&D)?**
   <Context: Investigating the R&D strategies of biopharmaceutical companies.>

   4.2. **What are the main challenges faced by biopharmaceutical companies in the region, and how can they be addressed?**
   <Context: Identifying industry challenges and potential solutions.>

5. **Government Policies and Support**
   5.1. **How does the Belgian government support the biopharmaceutical sector in your region?**
   <Context: Understanding government involvement and support mechanisms.>

   5.2. **Are there specific policies or programs that have significantly impacted the development of the sector?**
   <Context: Exploring impactful policies and programs.>

6. **Civil Society and Patient Involvement**
   6.1. **How are patient advocacy groups and civil society involved in the biopharmaceutical ecosystem in your region?**

<Context: Assessing the role of civil society in the ecosystem.>

6.2. How do these groups impact research priorities and healthcare policies?

<Context: Understanding the influence of civil society on policy and research.>

7. **AI Integration in Biopharmaceuticals**

7.1. How is AI currently being integrated into the biopharmaceutical sector in your region?

<Context: Investigating the current applications of AI in the sector.>

7.2. What are the main applications of AI in this sector (e.g., drug discovery, clinical trials, patient care)?

<Context: Exploring specific uses of AI.>

7.3. What could be the barriers/drivers that exist in the adoption of AI technologies in biopharmaceuticals?

<Context: Identifying obstacles to AI integration.>

8. **Comparative Insights**

8.1. Based on your experience, how does the biopharmaceutical ecosystem in Belgium compare to those in the US (Boston-Cambridge), Japan, and Vietnam (if possible)?

<Context: Comparing Belgium's ecosystem with other regions.>

9. **Future Prospects and Recommendations**

9.1. What steps can be taken to enhance collaboration among the Quadruple Helix stakeholders in Belgium?

<Context: Recommending strategies for improved collaboration.>

9.2. What recommendations do you have for improving AI integration in the biopharmaceutical industry in Belgium?

<Context: Providing actionable advice for AI integration.>