

The Digital Health Startup Ecosystem in Vietnam: From Technological Applications to Sustainable Policy Design

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Article History	Abstract
Original Research Article	<p><i>Amidst the accelerating wave of global digital transformation, digital health startups are emerging as key pioneers driving innovation in healthcare systems, particularly in developing countries. In Vietnam, the convergence of rapid digitalization, proactive innovation policies, and increasing demand for personalized healthcare services has created a favorable environment for the growth of a vibrant digital health startup ecosystem. However, the ecosystem remains constrained by fragmented data governance, underdeveloped legal frameworks, and a lack of targeted investment mechanisms. This study examines the Vietnamese digital health startup landscape using a policy innovation perspective grounded in the Health Innovation System (HIS) model. Drawing from global best practices such as Singapore's HealthTech regulatory sandbox, Israel's unified digital health infrastructure, and the European Union's approach to data governance, the paper proposes a three-pillar policy framework to catalyze systemic growth. The proposed framework includes: (1) establishing a regulatory sandbox for healthtech to enable experimentation; (2) creating a standardized, interoperable, and secure health data infrastructure aligned with international standards such as HL7 FHIR and GDPR; and (3) designing fiscal incentives and co-investment mechanisms to support clinical validation and scalability. Through qualitative document analysis and international benchmarking, this research provides actionable insights for Vietnamese policymakers and ecosystem stakeholders. By addressing the structural and institutional challenges impeding innovation, Vietnam can accelerate the development of a resilient, inclusive, and future-ready digital health ecosystem that meets both domestic and regional healthcare needs.</i></p> <p>Keywords: Digital health, healthtech startup, policy design, AI in healthcare, innovation ecosystem.</p>
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1. INTRODUCTION

The global healthcare sector is undergoing a profound transformation, driven by the convergence of digital technologies and the urgent demand for accessible, affordable, and efficient health services. Digital health innovations, including telemedicine, mobile health (mHealth), artificial intelligence (AI), wearable technologies, and blockchain-based medical records, are gaining increasing attention worldwide. These technologies have the potential to revolutionize traditional healthcare systems, particularly in low- and middle-income countries where inefficiencies and resource limitations persist. As noted by the World Health Organization [1], digital health involves the use of information and communication technologies (ICTs) to improve health and

healthcare delivery, which can substantially contribute to achieving universal health coverage.

In Vietnam, digital health is emerging as a key strategic approach to addressing long-standing systemic challenges such as hospital overcrowding, shortages of qualified health professionals in rural areas, and uneven access to healthcare. With a population exceeding 100 million people and a rapidly growing digital economy, Vietnam offers a promising landscape for health technology adoption. The increase in smartphone penetration, rising consumer awareness of preventive care, and the Vietnamese government's national digital transformation agenda have collectively supported this

trend. Initiatives such as the National Digital Transformation Program to 2025 with a vision toward 2030 [2] and the e-Government Development Plan are laying the groundwork for systemic digitization, including in the health sector. Furthermore, the COVID-19 pandemic acted as a catalyst for digital health adoption, accelerating the implementation of remote medical consultations, digital diagnostics, and mobile-based disease tracking systems [3].

In response to these evolving needs, Vietnam has seen the rise of numerous digital health startups that aim to disrupt traditional healthcare delivery models. Companies such as Jio Health, Med247, and eDoctor are offering online consultations, home-based healthcare services, digital prescriptions, and chronic disease monitoring solutions. These ventures leverage AI and cloud-based platforms to deliver more personalized, timely, and patient-centered care. However, despite their potential, the digital health startup ecosystem in Vietnam remains fragmented and constrained by institutional, legal, and financial barriers. Key challenges include the absence of a formal regulatory sandbox for health technology innovation, the lack of interoperability and standardization across health data systems, legal ambiguities concerning telemedicine responsibilities, and limited access to venture capital tailored to health technology startups.

Health innovation is inherently complex due to its direct impact on human lives and its interface with ethical, legal, and clinical concerns. Unlike the fintech or e-commerce sectors, digital health startups must navigate rigorous compliance protocols related to patient safety, clinical validation, and data privacy. Although the revised Law on Medical Examination and Treatment (2023) introduced legal recognition of telemedicine in Vietnam [4], it does not yet address critical components such as AI-based diagnostics, cross-border health data flow, or the assignment of liability in digital care environments. Additionally, existing innovation policies and startup funding programs in Vietnam do not adequately account for the unique regulatory needs of health technology ventures, thereby limiting their scalability and long-term viability [5].

This paper aims to examine and assess the digital health startup ecosystem in Vietnam through a comprehensive, interdisciplinary lens that integrates insights from public health, technology governance, and innovation policy. The primary research objectives are threefold: to map the landscape of digital health startups in Vietnam, including key stakeholders, focus areas, and systemic challenges; to analyze how current national policies have supported or hindered the development of digital health innovation; and to propose a sustainable, scalable, and inclusive policy framework tailored to the needs of digital health entrepreneurship in Vietnam. To achieve these objectives, the study employs a qualitative methodology based on secondary policy and legal document analysis, complemented by international comparative benchmarks.

The analytical framework draws upon the Health Innovation System (HIS) model, which conceptualizes innovation as the result of dynamic interactions among various actors including entrepreneurs, universities, regulators, funders, and end-users within an institutional context [6]. This systems-based approach enables the identification of structural bottlenecks, missing policy links, and collaborative opportunities that can shape the evolution of digital health entrepreneurship. Furthermore, comparative insights are drawn from selected international models such as Singapore's HealthTech Sandbox [7], Israel's national digital health initiative [8], and the European Union's GDPR-compliant digital infrastructure for health data [9], all of which provide valuable benchmarks for reforming Vietnam's policy environment.

The remainder of this paper is structured as follows. Section 2 reviews the global and regional literature on digital health entrepreneurship and ecosystem development. Section 3 outlines the research methodology and data sources. Section 4 presents findings on the status, challenges, and dynamics of Vietnam's digital health startup ecosystem. Section 5 analyzes the existing policy and legal framework, identifying key constraints and areas for reform. Section 6 proposes a three-pillar sustainable policy framework that includes regulatory sandboxes, medical data infrastructure, and financial incentives. Section 7 concludes with key recommendations for policymakers, stakeholders, and researchers.

2. LITERATURE REVIEW

This section provides a comprehensive review of the global and theoretical foundations of digital health innovation, followed by an assessment of international best practices and their relevance to the Vietnamese context. The review is structured into four key areas: (1) global trends and developments in digital health, (2) the conceptual frameworks guiding health innovation systems, (3) comparative policy models from leading countries, and (4) the challenges and gaps within Vietnam's digital health landscape.

2.1. Global Developments in Digital Health

Digital health has emerged as one of the most dynamic sectors in the global healthcare industry. Driven by advancements in mobile connectivity, artificial intelligence (AI), cloud computing, and wearable technologies, digital health innovations are transforming how care is delivered, monitored, and managed. According to the World Health Organization [1], digital health interventions can significantly enhance health system efficiency, expand access to care, and improve health outcomes. These benefits are particularly crucial in low- and middle-income countries, where infrastructure constraints often limit traditional service delivery.

The COVID-19 pandemic marked a pivotal moment in the global uptake of digital health technologies. Governments and healthcare providers turned to telemedicine, digital triage tools, remote monitoring platforms, and contact tracing applications to ensure care continuity and contain viral spread.

McKinsey & Company reports that digital health adoption accelerated by several years during the pandemic, with telehealth usage increasing significantly across regions. Moreover, the global digital health market was valued at over 200 billion USD in 2022 and is projected to grow at a compound annual growth rate (CAGR) of 15 percent, fueled by rising demand for virtual care and AI-enabled diagnostics [3], [18].

Investment trends mirror this momentum. In 2021, venture capital funding in digital health reached an all-time high, with significant investments in telemedicine, digital therapeutics, mental health platforms, and clinical decision support tools. Countries like the United States, United Kingdom, India, and China have launched national digital health initiatives aimed at creating interoperable data systems, promoting innovation, and fostering public-private partnerships.

2.2. Health Innovation Systems and Ecosystem Theory

To understand the dynamics of digital health development, it is essential to consider the conceptual frameworks that define innovation in health systems. One of the most widely adopted models is the Health Innovation System (HIS) framework, which conceptualizes innovation as a result of interactions among various stakeholders including government agencies, private firms, academic institutions, civil society organizations, and end users within an enabling policy and institutional environment [6].

Unlike linear models of innovation, HIS emphasizes feedback loops, co-creation, and institutional learning. Key components of a well-functioning HIS include regulatory clarity, access to infrastructure, financing mechanisms, stakeholder trust, and coordination platforms. These elements interact within a broader context shaped by national priorities, global standards, and technological readiness.

The Quadruple Helix model complements the HIS framework by incorporating the role of civil society and users into the traditional triple helix of government, academia, and industry. In the context of digital health, patient engagement, societal acceptance, and ethical considerations play critical roles in shaping innovation outcomes. For example, the success of telemedicine depends not only on technical capacity but also on public trust, clinician acceptance, and legal protection [10].

Health innovation ecosystems thrive where institutions align their strategies, share data securely, and develop platforms for collaboration. This approach is particularly relevant for emerging economies like Vietnam, where policy fragmentation and resource constraints can impede the scaling of digital solutions. Understanding the structure and function of health innovation systems provides a basis for diagnosing gaps and identifying opportunities for systemic reform.

2.3. Global Regulatory and Policy Benchmarks

Several countries have developed pioneering models for supporting digital health innovation, each offering lessons for

policy design, data infrastructure, and ecosystem development. Three prominent benchmarks are Singapore, Israel, and the European Union.

Singapore's HealthTech Regulatory Sandbox, administered by the Infocomm Media Development Authority (IMDA), enables startups to test new digital health technologies in a controlled and guided environment [7]. The sandbox facilitates innovation while ensuring patient safety and regulatory compliance. Participating companies receive support from regulators, gain access to public health institutions, and benefit from streamlined feedback mechanisms. The sandbox has been instrumental in accelerating the adoption of AI diagnostics, blockchain-based health records, and teleconsultation platforms.

Israel offers a unique model of health data integration. Its national healthcare system comprises four health maintenance organizations (HMOs) that operate under a unified digital infrastructure. Every citizen has an electronic health record accessible across providers, enabling longitudinal data analysis, AI applications, and large-scale clinical research. The Israeli government has invested heavily in data anonymization, cybersecurity, and partnerships with international firms, creating a globally recognized hub for digital health research and development [8].

The European Union provides a robust legal and technical framework for cross-border health data exchange. Through the General Data Protection Regulation (GDPR), the EU enforces stringent standards for data privacy, consent, and portability. Building on this foundation, the European Health Data Space initiative seeks to establish a common governance model for sharing health data across member states, supporting research, innovation, and public health policy [9].

Each of these benchmarks illustrates the importance of integrated strategies, regulatory flexibility, and data governance. While their institutional contexts differ, they share core features: (1) government leadership in defining priorities, (2) investment in health data systems, (3) engagement with private innovators, and (4) protection of individual rights. These lessons offer valuable insights for Vietnam as it seeks to modernize its digital health ecosystem.

2.4. Relevance and Gaps in the Vietnamese Context

Vietnam has made commendable progress in promoting digital transformation through national programs such as the National Digital Transformation Strategy to 2025 with a vision to 2030 [2]. Healthcare is identified as a key sector, and initiatives such as eHealth, telemedicine, and electronic prescriptions have gained visibility. However, a closer examination reveals significant institutional, regulatory, and infrastructural gaps that hinder innovation.

One of the most pressing issues is the fragmentation of governance. Responsibility for digital health is divided among the Ministry of Health, the Ministry of Information and Communications, and provincial health departments. This

results in overlapping mandates, inconsistent implementation, and regulatory uncertainty. For instance, while the revised Law on Medical Examination and Treatment (2023) formally recognizes telemedicine [4], it lacks detailed provisions for AI-based diagnostics, cross-border data flow, or liability assignment in digital care environments.

Health data infrastructure is also underdeveloped. Many hospitals continue to operate with paper-based records or standalone digital systems that are not interoperable. There is no national mandate for adopting unified data standards such as HL7 FHIR, and cybersecurity protocols vary widely. As a result, startups face challenges integrating with hospital information systems, accessing anonymized datasets, or demonstrating clinical effectiveness [9].

Financial barriers further constrain ecosystem growth. Most healthtech startups in Vietnam are self-funded or rely on small-scale angel investors. Venture capital firms tend to prioritize fintech, e-commerce, or logistics sectors. Public innovation grants are general-purpose and do not account for the specific needs of digital health ventures, which often require regulatory approvals, medical device certification, and extended product development cycles [5].

Another key challenge is the limited collaboration between academic institutions, research hospitals, and private innovators. Vietnam lacks dedicated translational research centers or health innovation hubs that bridge science and entrepreneurship. Medical universities rarely engage with startups, and regulatory bodies are not equipped to evaluate novel digital therapies. This disconnect weakens the pipeline of evidence-based solutions and delays adoption [6].

Despite these challenges, Vietnam has strong foundations for building a vibrant digital health ecosystem. The country has high internet penetration, a young tech-savvy population, and growing demand for patient-centered care. Government interest in digital transformation is evident, and lessons from international models can inform a coordinated strategy. What is needed is a systemic approach that aligns regulation, infrastructure, financing, and collaboration under a shared vision for digital health.

In summary, the literature underscores the transformative potential of digital health and the importance of system-wide innovation strategies. Vietnam's path forward depends on addressing current bottlenecks and leveraging global best practices to design a coherent and inclusive ecosystem for health innovation.

3. METHODOLOGY

This study adopts a qualitative research design aimed at understanding the structural and policy-related factors shaping the digital health startup ecosystem in Vietnam. It is grounded in the Health Innovation System (HIS) conceptual framework, which enables a systems-based analysis of how innovation emerges, is governed, and diffused within the healthcare sector [10]. In addition, the study draws on comparative policy

benchmarking to identify enabling institutional models from other countries that may offer relevant insights for Vietnam [11].

The methodology comprises three core components: document-based content analysis of legal, strategic, and regulatory texts; comparative review of international models and case studies; and interpretation of findings within a systems-innovation policy framework.

3.1. Data Sources

The analysis relies entirely on secondary data, which includes a combination of Vietnamese government documents, global policy papers, and institutional reports from multilateral organizations. Vietnamese sources include the revised Law on Medical Examination and Treatment [4], the National Digital Transformation Program to 2025 with a vision to 2030 [2], and selected government decrees, circulars, and strategy plans issued by the Ministry of Health and the Ministry of Information and Communications.

International documents were selected based on their relevance to digital health innovation and governance. These include reports from the World Health Organization [1], the Organisation for Economic Co-operation and Development [10], the European Commission [13], and government publications from Singapore [11] and Israel [14]. Supporting literature was drawn from academic and industry sources such as McKinsey & Company to contextualize investment and ecosystem trends.

3.2. Analytical Procedure

All documents were analyzed using a qualitative content analysis method. This process involved identifying keywords, thematic patterns, and institutional linkages that signal how digital health innovation is conceptualized, regulated, and promoted [15]. Themes were categorized into five analytical dimensions: regulatory framework, data infrastructure, investment environment, stakeholder coordination, and public-private partnerships.

The comparative analysis was performed by mapping these five dimensions against selected international benchmarks. The HealthTech regulatory sandbox in Singapore [11], Israel's integrated digital health infrastructure [14], and the European Union's GDPR-compliant governance model [13] were examined in detail to identify transferable components and context-specific adaptations.

3.3. Conceptual Framework

The Health Innovation System (HIS) framework was used to guide interpretation. HIS emphasizes the importance of interactions among various actors including governments, innovators, universities, health professionals, and end users and the institutional settings that facilitate or hinder innovation [10]. This approach enables the identification of both structural enablers and systemic bottlenecks. It also highlights

the role of adaptive governance in responding to technological disruption.

To enrich the systems perspective, the Quadruple Helix model was employed to include civil society and user communities as critical actors in innovation ecosystems [12]. This dimension was particularly important when assessing public trust, data ethics, and societal readiness for technologies such as AI-driven diagnostics and remote care delivery.

3.4. Limitations

As a document-based study, the research is constrained by the availability and reliability of public records. Although government strategy documents and legal texts offer authoritative insights, they do not always reflect real-time implementation or on-the-ground practices. Similarly, while international comparisons provide valuable learning opportunities, direct transplantation of policy models without contextual adaptation may be impractical due to institutional and cultural differences [16].

Despite these limitations, the methodology provides a robust foundation for identifying gaps and opportunities in Vietnam’s digital health ecosystem. It also enables a policy-oriented synthesis that is grounded in comparative evidence and responsive to the unique challenges of a rapidly transforming healthcare landscape.

4. FINDINGS AND ANALYSIS

This section presents detailed findings derived from documentary analysis and comparative benchmarking. It is organized around four thematic domains: (1) stakeholder

landscape and ecosystem mapping, (2) regulatory environment and legal clarity, (3) infrastructure for digital health data, and (4) financing and institutional collaboration. Where appropriate, data are summarized in tabular form and references are cited at the point of analysis.

4.1. Stakeholder Landscape and Ecosystem Mapping

Vietnam's digital health ecosystem involves multiple actors with overlapping but insufficiently coordinated roles. Government ministries, especially the Ministry of Health and the Ministry of Information and Communications, provide strategic direction and regulatory authority. However, these roles are often fragmented, with inconsistent interpretations of telemedicine implementation and data protection measures. Private startups like Jio Health, Med247, and eDoctor are offering integrated care, home-based services, and AI-powered symptom checkers, but they face scalability issues due to the lack of systemic integration with hospitals and public infrastructure.

Hospitals, both central and provincial, are critical to the ecosystem as potential adopters and validators of innovation. Yet many public hospitals are reluctant to partner with startups due to concerns about compliance, liability, and technical incompatibility. Universities have emerging capabilities in biomedical informatics and telehealth, but these capacities remain siloed, with limited engagement in entrepreneurial ecosystems. Investors and donors, especially those focusing on healthtech, are still rare, and most early-stage funding comes from general-purpose technology investors unfamiliar with the clinical and regulatory risks involved [3].

Table 1. Stakeholder Landscape in Vietnam’s Digital Health Ecosystem

Stakeholder Type	Representative Actors	Role in Ecosystem
Government Ministries	Ministry of Health, Ministry of Information and Communications	Policy formulation, regulation, digital infrastructure
Digital Health Startups	Jio Health, Med247, eDoctor	Service delivery, product innovation, platform design
Hospitals and Clinics	Central and provincial general hospitals, specialized facilities	Care integration, pilot testing, clinical partnerships
Academic Institutions	Hanoi Medical University, University of Medicine and Pharmacy HCMC	Training, research and development, health IT education
Investors and Donors	Venture capital firms, angel investors, public innovation funds	Capital mobilization, startup acceleration

Vietnam lacks cross-sectoral innovation platforms that allow these actors to co-develop, test, and scale technologies. The current approach is reactive and bilateral, rather than systemic [11].

4.2. Regulatory Environment and Legal Clarity

Vietnam has made progress in defining legal status for telemedicine through the revised Law on Medical Examination and Treatment (Vietnam Ministry of Health,

2023) [4]. However, there is no enabling legal environment for AI-based diagnostics, cross-border consultations, mobile health apps that manage chronic disease, or blockchain technologies. The absence of sandbox mechanisms makes it difficult for both regulators and innovators to safely trial and adapt new digital interventions. Additionally, the lack of comprehensive health data privacy legislation means that health information is not always protected under consistent standards.

Table 2. Regulatory Scope: Comparison Between Vietnam and Selected International Models

Regulatory Domain	Vietnam (2023)	Singapore (2023)	European Union (2023)
Telemedicine	Legally recognized	Regulatory sandbox in operation	Fully integrated and scaled
Artificial Intelligence	Not defined	Provisional regulatory pathways	Covered under MDR and AI Act
Data Portability	Absent	Consent-based pilot policies	Mandatory under GDPR
Blockchain in Health Records	Not addressed	Approved in sandbox environments	Permitted under national laws

The lack of granularity in Vietnam’s digital health laws increases risk aversion among both public institutions and private companies, limiting pilot project development (IMDA Singapore, 2023) [6]; (European Commission, 2023) [8].

4.3. Digital Health Data Infrastructure

Vietnam's hospital information systems remain fragmented and heterogeneous. There is no national health information exchange (HIE) framework that would allow patient records to move securely and seamlessly across providers. This is a significant impediment to continuity of care and clinical

analytics. The 2023 MOH IT Department report shows only partial digitization, with limited cloud adoption and no mandated standard for interoperability (Vietnam Ministry of Health, 2023) [4].

Further, data is often stored in closed systems that do not communicate across hospitals or with third-party applications. Many startups report that integrating with hospital infrastructure requires costly one-off interfaces, creating barriers to scale and discouraging innovation.

Table 3. Status of Digital Health Data Infrastructure in Vietnam

Facility Type	Electronic Medical Record Adoption (%)	Cloud-Based Storage Usage (%)	Interoperability Level
Central Hospitals	75	45	Limited (non-standard formats)
Provincial Hospitals	38	9	Minimal integration capacity
Private Clinics	54	27	Low, mostly proprietary platforms

Without a national strategy for interoperable health data aligned with international standards like HL7 FHIR, system-wide integration will remain unachievable (European Commission, 2023); (OECD, 2021); (Gartner, 2019).

4.4. Financing and Institutional Collaboration

Most digital health ventures in Vietnam are self-funded or operate with short-term grants. Healthtech-specific venture capital is virtually absent. Investors cite the lack of transparent clinical validation processes and limited exit opportunities as key deterrents (McKinsey & Company, 2023) [3]; (OECD, 2020) [5]. Furthermore, existing innovation funding schemes such as those under the National Technology Innovation Fund do not adequately address the extended

development timelines or regulatory risks inherent in health technology (Vietnam National Technology Innovation Fund, 2023) [12].

From an institutional perspective, Vietnam lacks formalized innovation clusters or hubs specifically focused on digital health. Academic institutions and teaching hospitals do not have structured pathways for partnering with private companies or testing digital solutions. In contrast, countries like Israel and Singapore have national digital innovation strategies supported by translational research centers and joint testing environments (Gartner, 2019) [7]; (World Health Organization, 2019) [1].

Table 4. Key Institutional Gaps Identified in Vietnam’s Digital Health Ecosystem

Domain	Institutional Gap Identified	Source Reference
Legal Framework	No sandbox, no AI-specific regulation	IMDA Singapore, 2023; Vietnam MOH, 2023
Digital Infrastructure	No national HIE, fragmented EMR systems	Vietnam MOH, 2023
Financing and Investment	No targeted health innovation fund or tax incentive	OECD, 2020; McKinsey & Company, 2023
Cross-sector Collaboration	Lack of translational research hubs or pilot networks	Gartner, 2019; WHO, 2019

In conclusion, while Vietnam demonstrates enthusiasm for digital transformation in healthcare, the structural ecosystem remains underdeveloped. Addressing the systemic gaps outlined above will require a comprehensive, multi-actor strategy rooted in legal reform, infrastructural investment, financial innovation, and institutional coordination.

5. POLICY FRAMEWORK / DISCUSSION

To unlock the full potential of digital health startups in Vietnam, a coherent, multi-dimensional policy approach is required. This approach must address structural bottlenecks in regulation, data infrastructure, and financial systems while fostering ecosystem-wide collaboration. Drawing from successful international case studies, three strategic policy pillars are proposed to guide the development of an inclusive, scalable, and sustainable digital health innovation environment in Vietnam.

5.1. Establishing a Regulatory Sandbox for HealthTech Innovation

A major structural barrier in Vietnam's digital health landscape is the absence of a regulatory framework that accommodates experimentation with emerging technologies such as artificial intelligence (AI), blockchain-based medical records, and algorithmic decision support systems. Traditional top-down regulations often lag behind technological advancement, leading to uncertainty among innovators and cautious investment behavior.

A regulatory sandbox an environment in which new health technologies can be tested under real-world conditions with temporary regulatory exemptions provides a practical solution to this problem. In Singapore, the Infocomm Media Development Authority (IMDA) has successfully implemented a HealthTech sandbox that allows time-limited, scope-specific trials of digital health innovations. Participating firms operate under regulatory supervision and are required to submit evaluation data that helps regulators understand risks, refine legal frameworks, and build evidence for long-term governance models [6].

Adapting this model to Vietnam would require strong leadership from the Ministry of Health, in collaboration with the Ministry of Information and Communications and independent ethics and data security experts. The sandbox should prioritize technologies aligned with public health goals and designed with privacy-by-design principles. Eligibility criteria must include proof of concept, clinical relevance, adherence to international data standards, and a plan for post-sandbox regulatory compliance. Legal exemptions must be narrowly tailored, time-bound, and revocable based on ongoing risk assessments and safety reports.

In addition, sandbox projects should include mandatory reporting obligations, such as interim evaluations, user experience feedback, and incident response protocols. These mechanisms are essential to safeguard public interest and ensure that lessons from pilot deployments feed directly into

regulatory reform processes. A formal pathway from sandbox to market authorization must be outlined at the outset, with support for product certification, clinical validation, and scale-up funding.

As emphasized by the OECD [5] and WHO [1], adaptive governance is essential in rapidly evolving digital sectors. A well-structured HealthTech regulatory sandbox in Vietnam would serve as a bridge between innovation and policy, enabling agile rule-making while maintaining patient safety and legal integrity. It would also signal to investors and global partners that Vietnam is committed to creating a supportive, forward-looking environment for health innovation.

5.2 Developing a Secure and Interoperable National Health Information Infrastructure

Fragmentation in data systems remains a critical impediment to innovation in Vietnam's healthcare sector. Hospitals use incompatible electronic medical record (EMR) platforms, there is no national Health Information Exchange (HIE), and data sharing remains ad hoc and insecure. To overcome these barriers, the government must invest in building a secure, interoperable health data infrastructure modeled on the European Union's European Health Data Space (EHDS) initiative [8].

The first step is to mandate the adoption of international interoperability standards such as HL7 FHIR in all new EMR and health IT systems, with government-certified compliance audits and technical assistance provided to public hospitals. A centralized data authority within the Ministry of Health should be established to manage HIE architecture, enforce cybersecurity regulations based on the EU's NIS2 Directive, and oversee tiered data access licensing for private innovators [17].

Pilot HIE projects should be launched in major urban centers like Ho Chi Minh City and Hanoi, with gradual national scale-up informed by performance metrics on access, usage, and clinical impact. Healthtech startups should be granted secure, anonymized access to government-approved datasets for algorithm training and product validation under clearly defined data ethics protocols [18].

Developing this infrastructure will not only facilitate care coordination and reduce duplication of services but also unlock the innovation potential of Vietnam's healthtech sector by making real-world data accessible and reliable.

5.3 Creating a National HealthTech Innovation Fund and Regional Innovation Hubs

Access to funding and institutional collaboration is one of the weakest links in Vietnam's digital health ecosystem. Most startups rely on self-funding or general-purpose tech investors, while public R&D support is generic and risk-averse. To fill this gap, the government should establish a National HealthTech Innovation Fund, modeled on Israel's public-private blended finance approach [7].

The fund should support digital health enterprises that demonstrate scalable solutions aligned with national health goals. Funding mechanisms should include milestone-based grants for clinical trials, support for compliance with data and medical regulations, and co-investment in expanding service access to rural and underserved areas [19]. Proposals must demonstrate partnerships with healthcare institutions and measurable health outcomes to qualify for support.

In parallel, regional innovation hubs should be launched in medical universities and tertiary hospitals across Vietnam. These hubs would house facilities for prototyping, ethical

review consultations, simulation labs, and regulatory advisory services. Inspired by the EU’s EIT Health model and WHO innovation centers, these hubs should also convene public-private-academic consortia around priority health themes such as chronic disease, mental health, maternal care, and infectious disease surveillance [1][20].

Such hubs would not only foster translational research and an entrepreneurial culture within academia, but also accelerate startup-hospital partnerships through challenge grants, open innovation calls, and data-sharing agreements.

Table 5. Summary of Policy Pillars

Policy Pillar	Key Instruments	Global Benchmark	Implementing Body
Regulatory Sandbox	Controlled testbeds, policy exemptions, pilot protocols	Singapore HealthTech Sandbox [6]	Ministry of Health + Ministry of Information and Communications
Health Information Infrastructure	HL7 FHIR adoption, data access governance, HIE pilots	European Health Data Space [8]	Ministry of Health (Data Authority)
Innovation Fund and Hubs	Blended finance, academic-industry partnerships, accelerators	Israel Innovation Authority [7]; WHO [1]	Ministry of Health + Universities + Innovation Agencies

6. CONCLUSION

The rapid evolution of digital health technologies offers transformative potential for healthcare systems worldwide, particularly in emerging economies like Vietnam. As outlined in this paper, the Vietnamese digital health startup ecosystem is at a formative stage, characterized by rising consumer demand, expanding digital infrastructure, growing entrepreneurial interest, and strong governmental ambition. However, the ecosystem remains constrained by fragmented and overlapping policies, the absence of a regulatory sandbox for emerging technologies, limited interoperability in health data systems, and inadequate institutional and financial support for innovation-driven enterprises.

By applying a systems-based analytical framework and benchmarking international practices from countries such as Singapore, Israel, and the European Union, this study has identified structural bottlenecks and proposed a comprehensive three-pillar policy strategy. These pillars include the establishment of a national regulatory sandbox for health technologies to enable safe experimentation and adaptive policymaking; the development of a secure and interoperable national health information exchange grounded in international standards such as HL7 FHIR; and the creation of a dedicated digital health innovation fund complemented by regional innovation hubs to support co-development, clinical validation, and cross-sector collaboration.

The effectiveness of these recommendations depends on several enabling conditions. First, policy coherence must be strengthened through inter-ministerial coordination mechanisms that clearly assign responsibilities for digital health governance. Second, the Ministry of Health should lead

the formulation of a national digital health master plan that integrates regulatory, infrastructural, and funding strategies under a unified vision. Third, regulatory capacity must be enhanced through targeted training for public officials, the establishment of expert advisory panels on AI and data ethics, and regular stakeholder consultations with startups and hospitals. Fourth, evaluation mechanisms should be embedded into all major programs, using performance metrics such as service uptake, patient satisfaction, clinical outcomes, and investment mobilization.

In addition to domestic reforms, Vietnam should also explore opportunities for regional cooperation in digital health, including cross-border telemedicine regulation, shared cybersecurity standards, and ASEAN-level interoperability initiatives. Participating in global digital health platforms will help ensure policy alignment with evolving international norms and enhance Vietnam's credibility as a regional leader in health innovation.

Ultimately, the transition toward a sustainable and inclusive digital health ecosystem requires a systemic approach that balances innovation with patient protection, experimentation with accountability, and national strategy with global learning. If implemented effectively, the recommendations presented in this paper can support Vietnam in achieving universal health coverage, strengthening health system resilience, and ensuring equitable access to quality healthcare services for all citizens.

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