

NATIONAL TECHNICAL UNIVERSITY OF ATHENS SCHOOL OF ELECTRICAL AND COMPUTER ENGINEERING SCHOOL OF MECHANICAL ENGINEERING

INTERDISCIPLINARY POSTGRADUATE PROGRAMME "Translational Engineering in Health and Medicine"

Digital Health Innovation in Greece, from academia to market

Postgraduate Diploma Thesis

Postgraduate student Athanasios Vidakis

Supervisor George Matsopoulos, Professor, National Technical University of Athens, School of Electrical and Computer Engineering

Athens, February 2025



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The postgraduate diploma thesis has been approved by the examination committee on 21^{st} February 2025

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The ideas and conclusions presented in this paper are the author's and do not necessarily reflect the official views of the National Technical University of Athens.

Abstract

Greece's healthcare system is at a turning point, needing to update outdated systems while building on its long research tradition and growing software industry. In this thesis, I explore the various challenges that hinder digital transformation in Greek hospitals, from fragmented IT infrastructures and poor interoperability to ad hoc procurement methods and tight budgets. By examining international best practices from countries like Denmark, Estonia, Israel, and Chile, as well as insights from institutions such as Stanford Health Care and Karolinska University Hospital, I identify critical factors that contribute to successful digital health adoption, including strong leadership, unified standards, and continuous training. Based on these findings, I propose a comprehensive framework to steer Greece's digital health strategy. The framework highlights the need for agile procurement processes, cloud-based infrastructures that adhere to HL7 FHIR and OMOP standards, pilot projects in dedicated "lighthouse" hospitals, and a national digital health authority to coordinate policy and funding. It also emphasizes engaging local SMEs, attracting venture capital, and creating opportunities that bring Greeks back to work in Greece by leveraging their expertise and resources. Ultimately, the thesis shows that by bridging technical, organizational, and regulatory gaps, Greece can modernize its hospitals cost-effectively and build a sustainable platform for digital health innovations on the global stage.

Keywords: digital health, digital transformation, innovation, SMEs, policy making, framework, agile, software development, SaMD

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1. Introduction

Translational engineering in health and medicine is a vital interdisciplinary field where innovative technologies merge with clinical practice to transform patient care and hospital operations. In today's digital era, healthcare institutions around the world are adopting advanced tools, from electronic health records and AI-driven diagnostics to telemedicine and remote monitoring, in order to enhance service delivery and operational efficiency. Despite these global advances, the Greek healthcare system still faces significant challenges, such as outdated digital infrastructures, fragmented data management, and complex regulatory hurdles that slow the adoption of modern technologies. This thesis aims to diagnose these challenges within Greek hospitals and propose a comprehensive framework that addresses current gaps and lays the groundwork for a sustainable, integrated digital health ecosystem.

1.1 National Context

In Greece, the digital transformation of healthcare encounters unique challenges. Although Greece has a strong background in research and a growing software industry, many hospitals continue to rely on outdated, paper-based systems and legacy software that hinder efficient data sharing and quality patient care. The public nature of Greece's healthcare market further limits innovation, as many initiatives are state-controlled. As a result, researchers and innovators often look abroad—especially to more advanced markets like the United States—instead of launching pilot projects locally. This trend not only restricts local experimentation but also delays the introduction of cutting-edge technologies into the Greek healthcare system. This context underscores the urgent need for a thorough assessment of these challenges and the development of a robust framework to enable a smooth transition toward an integrated and innovative digital health ecosystem in Greece.

1.2 Problem Statement

The Greek healthcare system faces a complex set of challenges across technical, regulatory, financial, and organizational dimensions. Technically, hospitals struggle with a severe lack of interoperability¹ and standardization, relying on custom-made, siloed solutions that are hosted locally rather than on scalable, cloud-based platforms. This fragmentation disrupts seamless data exchange and leads to isolated digital initiatives that do not integrate into a national framework. On the regulatory front, the absence of a clear national digital health policy, along with sparse EU guidelines, leaves hospitals without the strategic direction needed to implement and maintain modern digital solutions. Financially, the common reliance on ad hoc public tenders² to address isolated issues drives up costs and reduces efficiency, making it difficult for researchers and SMEs to deploy innovative solutions effectively. Organizationally, these challenges hinder the secure and federated secondary use of healthcare data—a critical

¹ <u>https://www.ekathimerini.com/news/1179739/greece-still-ranks-low-in-digital-health/</u>

² <u>https://www.iefimerida.gr/ellada/idika-erga-beltiosi-ypiresies-ygeias-gia-polites</u>

aspect for advancing research while upholding high standards of ethics, security, and GDPR compliance. Urgent action is needed to develop a clear national architecture and strategy that will streamline digital transformation across Greek hospitals and enable cost-effective innovation and integrated data use throughout the healthcare ecosystem. A comprehensive digital transformation across hospitals and universities could drive significant improvements in digital health innovation, improve patient care, streamline operations, and ultimately enhance health outcomes nationwide. Moreover, enabling the secondary use of healthcare data can drive research and development, empowering providers to make better decisions and tailor treatments to individual patients.

1.3 Objectives of the Thesis

The primary objective of this thesis is to propose a comprehensive framework that fosters and enables the digital transformation of Greek hospitals while empowering Greek SMEs to build innovative solutions with global scalability. The framework will begin by assessing Greece's current digital health landscape, identifying critical issues such as a lack of interoperability, insufficient standardization, and the absence of a unified national digital health strategy, factors that result in fragmented, on-premise systems that hinder efficient data sharing and integration. It will then diagnose the technical, regulatory, financial, and organizational challenges that slow both the digital transformation of healthcare and the ability of local innovators to develop scalable solutions. Finally, the framework will outline strategic guidelines for implementing integrated, cloud-based systems and fostering collaborative partnerships among hospitals, universities, SMEs, and regulatory bodies. This approach is designed not only to streamline healthcare delivery locally but also to provide Greek SMEs with the tools and ecosystem necessary to create robust digital health innovations that can be deployed and scaled in international markets.

1.4 Significance of the Study

This study is significant because it addresses a critical gap in the digital transformation of Greek healthcare—a sector essential to national well-being yet hindered by outdated systems and fragmented digital initiatives. By diagnosing the technical, regulatory, financial, and organizational challenges facing Greek hospitals, the research lays a robust foundation for developing a comprehensive framework that streamlines healthcare delivery and promotes local innovation. In proposing strategic guidelines for integrated, cloud-based digital health solutions, this work has the potential to reduce operational costs, enhance interoperability, and improve patient outcomes. Moreover, by empowering Greek SMEs to design and scale innovative solutions for both local and international markets, the study contributes to the broader economic development and global competitiveness of the Greek digital health sector. Ultimately, the findings and framework developed in this research are expected to influence policy, promote multi-

stakeholder collaboration, and serve as a blueprint for sustainable, scalable digital transformation in healthcare.

2. Literature Review

2.1 Digital Transformation in Healthcare: Global Context and Trends

Today's healthcare landscape is changing fast. Digital transformation is no longer an option, it's a necessity. From electronic health records and telemedicine to AI-driven diagnostics and remote monitoring, healthcare providers around the world are integrating advanced digital tools to improve patient care and operational efficiency. In many countries, these changes have led to better clinical outcomes, reduced operational costs, and more seamless communication between care providers. Another key trend is the rise of personalized medicine, where patients have greater access to their own health data. Major EHR systems like Epic and Cerner in the US, as well as platforms like Apple Health³, are already enabling individuals to monitor and manage their health data. Over the past year, the US has also leveraged the OMOP Common Data Model (CDM)⁴ and the OHDSI community to support research through federated learning, which allows multiple institutions to collaborate on data analysis without compromising patient privacy. In the EU, digital health is taking a big step forward with the recent vote on the European Health Data Space (EHDS)⁵. The EHDS will empower individuals to take control of their health data and facilitate data exchange for primary healthcare delivery across the EU. It will also foster a genuine single market for electronic health record systems and provide a consistent, trustworthy, and efficient framework for reusing health data for research, innovation, policy-making, and regulatory activities. Data network platforms like EDHEN⁶ and DARWIN⁷ facilitate standardized health data sharing & analysis using OMOP CDM. Key examples of a successful digital health innovation ecosystem can be found in institutions such as Stanford, with its biodesign team⁸, and Karolinska Institutet in Sweden. Both maintain a close loop between hospitals, academia, and SMEs/industry, demonstrating how collaborative approaches can drive continuous innovation and effective integration of digital health solutions.[1], [2], [3], [4], [5].

2.2 Rationale and Purpose of This Review

Given the rapid pace of digital transformation worldwide and its potential to reshape healthcare delivery, I believe it is essential to closely examine the factors driving these changes. This review is intended to explore the underlying reasons why digital health initiatives succeed or fail and to identify the main challenges and opportunities in adopting these technologies. My goal is to establish a clear understanding of both the

³ <u>https://www.healthcareitnews.com/news/epic-moves-forward-health-app-interoperability</u>

⁴ <u>https://ohdsi.github.io/CommonDataModel/</u>

⁵ https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

⁶ <u>https://www.ehden.eu/</u>

⁷ <u>https://www.darwin-eu.org/</u>

⁸ <u>https://biodesign.stanford.edu/</u>

theoretical and practical aspects of digital health, which will serve as the foundation for the framework I propose later in this thesis. By linking global experiences with the unique conditions of the Greek healthcare system, this review helps to justify the need for a tailored, comprehensive approach that addresses not only technical issues but also the regulatory, financial, and organizational challenges faced by hospitals and innovators alike.

2.3 International Best Practices

Around the globe, healthcare systems are exploring a variety of strategies to use digital technologies, ranging from national e-government initiatives and cloud-based hospital infrastructures to AI-driven telemonitoring and personalized medicine. In the sections that follow, I examine representative examples from Estonia, Denmark, Chile, India, Israel, Cleveland Clinic (USA), Stanford Health Care (USA), and Karolinska University Hospital (Sweden). Each case highlights unique approaches to integrating digital solutions, shedding light on both the opportunities and challenges of implementing transformative healthcare innovations at scale [6], [4]. You can see the key digital approach, unique features, impact/outcomes, and key lessons for each country/institution in the table (Table 1) below:

•	Key Digital Approach	Unique Features	Impact / Outcomes	Key Lessons
Estonia	Nationwide Interoperable EHRs	 Centralized patient registry Mandatory electronic data exchange Digital ID for citizens 	 Over 95% digitization of patient records Lower administrative costs Improved data- driven research 	•Strong legislative support is crucial • Unified national strategy drives scalable, interoperable solutions
Denmark	"Smart Hospitals" with Cloud & IoT	 Large-scale government investment New Odense University Hospital as a fully digital model AI and IoT integration 	 Enhanced service delivery Improved care management efficiency Modernized national healthcare systems 	 Substantial funding clear objectives accelerate transformation Emphasis on integrated IoT & AI
Chile	Telemonitoring & AI for Chronic Disease (AccuHealth)	 Remote sensors & tablets for patients Real-time data analytics for at-risk alerts 	• 20–40% reduction in hospital readmissions • 30% decrease in	 Private-sector innovation can address public health challenges Targeted AI helps

 Table 1 International Digital Health Initiatives: Key Approaches, Unique Features, Impact, and Lessons

			therapy costs • Fewer ER visits	manage chronic conditions
India	mHealth Solutions for Maternal/Newborn Care (ReMIND)	 Mobile app for community health workers (ASHAs) Culturally adapted health messaging 	 Significant reduction in pregnancy-related risks Higher follow- up & better neonatal outcomes 	 Low-cost mobile tech bridges resource gaps Training non- clinical workers is vital
Israel	AI-Driven Radiology at Sheba Medical Center	 Real-time alerts for stroke and other anomalies Machine learning to prioritize urgent cases 	 32% decrease in diagnostic delays Optimized staff workload Improved diagnostic accuracy 	 AI can handle high data volumes efficiently Automated prioritization improves care speed & quality
Cleveland Clinic (USA)	Integrated EMR & Decision-Support Tools (Family Care Path)	 Genomics & oncology decision support Telehealth & EMR integration 	 Earlier interventions Streamlined care pathways Enhanced patient engagement 	• Translating academic research into clinical practice at scale • User-friendly interfaces boost adoption
Stanford Health Care (USA)	Academic-Clinical Collaboration via EHR & MyHealth App	 AI research & precision medicine Patient access & digital engagement 	• Efficient telemedicine & remote monitoring • Real-time data for clinical decisions & R&D	 Strong university- hospital synergy fosters innovation Patient-centered apps improve continuity of care
Karolinska University Hospital	Data Analytics & EHR Integration for Research-Driven Care	 Close alignment with Karolinska Institutet Patient-reported outcomes for quality improvement 	 Personalized treatments Iterative refinements to clinical protocols Strong research pipelines 	 Consistent investment in infrastructure & training Linking outcomes to research accelerates innovation

Estonia is often highlighted as a global leader in e-government and nationwide digital health initiatives. Its approach to interoperable electronic health records (EHRs) rests on four foundational components: a centralized patient registry, robust digital services for citizens, a digital imaging program, and e-prescriptions. By mandating that healthcare providers record and exchange patient data electronically, Estonia has achieved more than 95% digitization of all patient records. The centralized architecture not only streamlines clinical workflows but also lowers costs and opens the door to data-driven research. Strong legislative support—including standards for privacy and

secure access—underpins this success, offering a template for how cohesive national strategies can propel healthcare digitization.

Denmark has embarked on one of the most ambitious healthcare reforms in Europe by investing heavily in "smart hospitals" and digital platforms. Backed by a multi-billiondollar budget, the country aims to modernize its public healthcare system through the integration of IoT-based medical devices, cloud-driven data exchange, and AI analytics. A prime example is the development of the New Odense University Hospital, which is designed to be fully digital—from centralized patient records to clinical workflow automation. Early results indicate an overall upgrading of service delivery and the capacity to manage care more efficiently. Denmark's success illustrates how large-scale government funding, paired with clear strategic goals, can catalyze transformative digital health projects.

In **Chile**, the company AccuHealth provides a window into how telemonitoring and artificial intelligence (AI) can improve the management of chronic diseases. By equipping patients with sensors and tablets for biometric data collection—covering blood pressure, glucose levels, body weight, and more—AccuHealth facilitates remote patient monitoring. Their AI platform analyzes real-time data to flag at-risk patients, enabling timely medical intervention. Studies report notable benefits: a 20–40% reduction in hospital readmissions, a 30% decrease in therapy costs, and a measurable drop in emergency visits. Chile's experience underscores the role of private-sector innovation and targeted AI solutions in addressing public health issues in emerging markets.

In India, the "Reducing Maternal and Newborn Deaths (ReMIND)" program exemplifies the power of mHealth solutions to enhance primary care at the community level. By deploying a mobile application to Accredited Social Health Activists (ASHA), the initiative supports pregnant women and new mothers through targeted counseling, risk assessment, and appointment reminders. Over a two-year period, the program demonstrated a significant decrease in pregnancy-related risks, with higher follow-up rates and better neonatal outcomes. India's case highlights how mobile health can bolster care in resource-constrained settings, particularly when local healthcare workers are trained to leverage simple, cost-effective digital tools [7].

At **Israel's** Sheba Medical Center, AI-driven image processing has markedly reduced diagnostic and treatment times in radiology. By prioritizing urgent cases via an AI algorithm, radiologists receive real-time alerts for abnormal scans (e.g., indicating a possible stroke), accelerating decision-making. Early evidence shows a 32% decrease in diagnostic delays and a notable improvement in diagnostic accuracy, all while optimizing staff workload. Israel's example demonstrates how machine learning can

address capacity constraints in high-volume hospital departments, providing a scalable model for data-rich clinical specialties like radiology [2].

Cleveland Clinic (USA) represents a prominent example of marrying academic innovation with real-world patient care. With a global footprint, it pioneered the "Family Care Path," a series of web-based clinical decision-support tools integrated directly with the patient's Electronic Medical Record (EMR). Sub-programs like MyLegacy and CancerNav accelerate genetic testing, oncology care coordination, and telehealth consultations, ensuring earlier interventions and streamlined care pathways. By combining cutting-edge genomic research with user-friendly digital interfaces, Cleveland Clinic showcases how major healthcare providers can translate research into patient-centric digital services at scale.

Stanford Health Care (USA), affiliated with Stanford University, is widely regarded as a pioneer in integrating academic research with clinical practice to advance digital health. The institution's Epic EHR platform is tightly woven into its clinical workflows, supporting everything from telemedicine appointments to AI-driven patient triage. Stanford also developed the MyHealth app, enabling patients to access real-time health data, schedule virtual visits, and engage in remote monitoring programs. This patientcentric digital ecosystem is bolstered by ongoing research collaborations in AI diagnostics, precision medicine, and wearable health technologies. In addition, Stanford's Biodesign Digital Health Group plays a crucial role in empowering the digital health community to rapidly prototype and build innovative solutions across various platforms. Their open-source contributions, such as the Stanford Biodesign Digital Health Group repository⁹ and the Spezi framework¹⁰, an open-source framework for the rapid development of modern, interoperable digital health applications based on HL7/FHIR standards, further underscore the value of open collaboration in accelerating digital transformation. Stanford's model shows how strong university-hospital alliances, dedicated R&D resources, and open-source initiatives can drive digital transformation, ultimately enhancing patient care and advancing global healthcare innovation.

Sweden's **Karolinska** University Hospital stands out for its deep integration with Karolinska Institutet, one of Europe's leading medical universities. This close academic collaboration fuels a robust pipeline of clinical research, innovation pilots, and evidence-based practice. Karolinska has steadily incorporated EHR systems, digital imaging solutions, and telehealth platforms to streamline both inpatient and outpatient care. Notably, the hospital leverages data analytics for personalized treatment and quality improvement, collecting patient-reported outcomes to refine clinical guidelines. Karolinska's iterative approach—combining scientific rigor with patient-centered

⁹ https://github.com/StanfordBDHG

¹⁰ https://github.com/StanfordSpezi

design—demonstrates how consistent investment in technical infrastructure, interdisciplinary training, and clinical research can drive sustainable digital health adoption.

2.4 Common Challenges

From my review of digital health initiatives in Estonia, Denmark, Chile, India, Israel, and leading institutions like Cleveland Clinic, Stanford Health Care, and Karolinska University Hospital, I noticed a recurring set of challenges. Even though these locations and organizations have different contexts and success stories, they still face issues like interoperability gaps, fragmented policies, and limited patient engagement—all of which can limit the impact and scalability of digital health projects. The table (Table 2) below summarizes these obstacles, illustrating how each one can slow progress and highlighting why a coordinated approach is so important.

Challenge	Description	Examples / References	Implication
Lack of Interoperability	Siloed systems and data formats that hinder seamless patient-data exchange	Estonia's push for EHR standardization; Denmark's "once- only" principles	Redundant testing, inefficiencies, difficulty scaling AI/analytics
Fragmented or Absent Policies	Absence of a unified strategy or clear regulation, leading to ad hoc solutions	Sparse EU guidelines, patchwork regulations in various emerging markets	Delays implementations, drives up costs, limits large-scale coordination
Financial Constraints	High upfront costs for infrastructure and ongoing funding for maintenance/upgrades	Denmark's large investments; resource limitations in India, Chile	Inability to sustain pilot projects, underfunded IT, reliance on external grants/VC
Technical Skill Gaps	Insufficient IT expertise or training among healthcare staff	Challenges in Israel (radiology AI training), global shortage of skilled personnel	Resistance to adopting new tools, underutilized technologies, increased implementation errors
Cultural / Organizational Resistance	Reluctance from clinicians, administrators, or patients to embrace digital workflows	Many institutions globally experience staff skepticism toward new tech	Slow adoption rates, minimal user engagement, risk of reverting to paper- based systems
Data Security & Privacy Concerns	Fear of breaches, GDPR compliance, or lack of robust cybersecurity measures	EU's GDPR requirements; high- stakes data in hospitals	Limits data sharing and big data analytics, raises legal and ethical issues
Scalability & Sustainability Issues	Difficulty moving from pilot projects to large-scale systems	India's pilot-based mHealth projects, ad hoc solutions in Greece	Fragmented solutions, duplicative efforts, inability to maintain or expand successful pilots

Table 2 Common Challenges in digital health

Limited Patient	Tools not sufficiently	Chile's remote	Low adoption of digital
Engagement	addressing patient needs or	monitoring overcame	tools, missed opportunities
	lacking user-friendly design	engagement barriers,	for self-management and
		but many fail	improved outcomes

2.5 Key Factors Driving Successful Digital Health Adoption

Several key factors consistently emerge from international digital health success stories, highlighting the core requirements for effective transformation. These include strong leadership and supportive policies, a clear strategic vision with measurable goals, and a robust technical infrastructure that emphasizes scalability, cloud integration, and data security. Equally important are interoperability and standardization, often guided by common protocols, to ensure seamless data exchange. A patient-centered approach keeps individuals actively engaged in their own care, while ongoing training and management change encourages staff acceptance and long-term adoption. Finally, academic industry collaborations drive cutting-edge research and innovation. The table below (Table 3) summarizes these factors and their key elements.

Factor	Key elements
Leadership & Policy Support	Funding, Regulation, Sustainability, High-level Buy-in
Strategic Vision & Clear Objectives	Measurable Goals, Alignment, ROI, Benchmarks
Robust Technical Infrastructure	Scalability, Cloud, AI, Data Security, Interoperable
Interoperability & Standardization	Common Protocols, Once-Only Principle, Data Sharing
Patient-Centered Approach	Access, Personalization, Engagement, Outcome-Focused
Ongoing Training & Change Management	Skills, Trust, Acceptance, Workflow Integration
Academic–Industry Collaboration	Research Synergy, R&D Pipeline, Advanced Training, Tech Transfer, Real-World Pilots

Table 3 Key Factors Driving Successful Digital Adoption

Strong Governmental and Institutional Leadership

High-level commitment and policy support are critical for both sustainability and scale. Estonia's national-level strategy for digitizing patient records, Denmark's substantial healthcare investment in building "smart hospitals," and India's government-backed mHealth initiative all illustrate how legislative frameworks and robust funding mechanisms create an environment where digital solutions can thrive [8], [9].

Strategic Vision and Clear Objectives

Successful programs typically outline measurable goals—whether it be reducing hospital readmissions (Chile), enhancing diagnostic speed (Israel), or improving maternal health outcomes (India). By defining a unifying vision, stakeholders can align

their efforts, justify significant initial investments, and measure progress against wellestablished benchmarks [4], [5], [10].

Robust Technical Expertise and Infrastructure

The shift from legacy on-premise systems to cloud-based platforms (as in Denmark's hospital developments) and the adoption of AI-driven analytics (as showcased by Israel and Chile) demonstrate the necessity of scalable, interoperable IT architectures. Such infrastructures must be capable of handling large volumes of clinical data in a secure and efficient manner, paving the way for advanced applications like machine learning and predictive analytics [5].

Focus on Interoperability and Standardization

Interoperability is a cornerstone of effective digital health. Estonia's "once-only" principle and Denmark's nationwide EHR integration show how standardized data structures and common communication protocols reduce redundancies and empower seamless collaboration among healthcare providers, patients, and ancillary services [11].

Patient-Centered Approach

Digital tools must directly address patient needs to ensure meaningful engagement and adoption. Initiatives like India's ReMIND mHealth program and Chile's AccuHealth telemonitoring solution highlight the potential for technology to improve access to care, personalize treatment, and reduce costs for chronic conditions. When services are tailored around patient outcomes, uptake tends to be both faster and more sustainable [12].

Ongoing Training and Change Management

Technology alone cannot drive transformation without proper training and change management. Effective programs invest in the human factors of adoption by ensuring that clinicians, administrators, and patients are equipped with the necessary skills to integrate new workflows and trust new platforms. From AI-assisted diagnostics to telemedicine consultations, end-user acceptance is often the determining factor in whether digital tools deliver their intended benefits [1], [13].

Collaboration Between Academia and Industry

Close cooperation between hospitals, universities, and industry partners can be a powerful catalyst for innovation. For example, Stanford Health Care's strong ties to Stanford University have accelerated breakthroughs in AI diagnostics, telemedicine, and precision medicine by translating cutting-edge research directly into clinical practice. Similarly, Karolinska University Hospital's integration with Karolinska Institutet fosters a steady pipeline of research-driven initiatives and advanced training opportunities, allowing new digital solutions to be piloted, refined, and quickly adopted

at scale. These academic-industry collaborations not only advance technological capabilities but also help in developing the specialized workforce needed to support and sustain digital transformation [14], [15].

By addressing these core elements: leadership, clear objectives, robust infrastructure, interoperability, patient focus, and ongoing training, healthcare systems can overcome common hurdles to digital transformation. As demonstrated by the global case studies, when these factors are successfully implemented, hospitals and healthcare networks experience enhanced operational efficiency, improved clinical outcomes, and sustained innovation.

2.6 The Greek Context: Specific Challenges and Opportunities

Greece's national health system (ESY) is mostly public and serves about 10.7 million people through around 131 public hospitals and a network of primary healthcare centers. Even though the system provides universal coverage, there are still big differences between urban and rural areas, and a traditional focus on hospital-based care places additional strain on resources. These challenges are made worse by uneven funding and the lasting impact of a long economic crisis. As part of its national strategy, the government has started prioritizing the digitization of health services. One of the main organizations involved is IDIKA S.A. (the Hellenic eGovernment Center for Social Security Services), which runs critical eHealth systems like the national ePrescription service and the myHealth mobile app and also supports cross-border eHealth efforts. Within this public framework, Greek hospitals vary in their level of digital readiness. Many still depend on older IT platforms, and only a few have fully integrated Electronic Health Records (EHRs) that meet modern interoperability standards. While national digital health programs-such as e-prescriptions-have shown progress, a truly unified approach to digital healthcare remains out of reach. Projects often operate in isolation, with limited coordination and fragmented budgets, which can derail larger goals for modernization. Still, the government has launched several improvement programs, many backed by EU recovery funds and the National Strategic Reference Framework (NSRF). These efforts aim to fix long-standing problems like outdated infrastructure, limited IT staffing, and the lack of standardized data-exchange protocols. However, without a clear, long-term roadmap, these initiatives could end up being quick fixes rather than long-lasting reforms.

Existing Digital Infrastructure and Interoperability in Hospitals

Greek hospitals vary widely in their level of digital maturity. Many still depend on older, stand-alone IT systems, and only a few have fully integrated EMRs that meet modern interoperability standards. This patchwork of isolated solutions, such as Enterprise Resource Planning (ERP) and Laboratory Information Systems (LIS), leads to inconsistent data formats and scattered patient records, disrupting care continuity and limiting the potential for research and analytics. According to various studies, the lack

of uniform digital tools remains a significant barrier to both efficiency and patient safety¹¹. Although certain digital services are in place, most notably e-prescriptions, there is no unified, nationwide access to electronic health records. Numerous databases, managed by organizations like IDIKA, still operate without a consistent interoperability framework. Policymakers have taken steps to address this by working on a National eHealth Interoperability Framework (NeHIF), but real-world implementation is still at an early stage. Efforts to protect data privacy under the General Data Protection Regulation (GDPR) are also in progress, but outdated systems and manual processes continue to weaken these safeguards [3].

Key Tenders and Ongoing Projects

In an effort to modernize, the Greek government has launched several large-scale digital health projects, supported by both national and EU funds. Digital transformation of the health sector is a key goal in Greece's national strategy, aided by the Recovery and Resilience Facility (RRF). Of the \notin 5.23 billion designated for health services, \notin 394.8 million is set aside for e-health infrastructure. Projects include unifying various registries, digitizing oncology care, completing the Individual EHR, and updating hospital systems to improve infrastructure and encourage interoperability. However, these projects depend heavily on consistent policy guidance and strong cooperation among hospitals, as noted in policy analyses. Below is a summary of some of the major projects in progress [16]:

Project	Budget
Unification of IDIKA Registers (healthcare & social security)	€12.2 million
Digital Transformation for Oncology Care	€29.4 million
Completion of the Individual EHR	€45.1 million
Hospital Systems Modernization	€139.5 million
Upgrade of IDIKA's Data Center	€12 million
RIS/PACS & Medical Transcription Systems	€15.8 million

Table 4 Major Healthcare Tenders¹²

These initiatives collectively address cancer pathways, integrated health records, administrative consolidation, and advanced imaging solutions. While each project has the potential to reduce fragmentation, their success depends on consistent policy direction and robust inter-hospital collaboration. Delays from administrative or legal hurdles could hamper the long-term viability of these improvements.

¹¹ https://www.ihe-europe.net/sites/default/files/PDF%20EXP%2022/1-

IHE ExP DAY PPT Kotsiopoulos v2.pdf

¹² https://www.iefimerida.gr/ellada/idika-erga-beltiosi-ypiresies-ygeias-gia-polites

Impact of current Healthcare System on Innovation

Because Greece's healthcare system is largely public, digital health efforts are often shaped by immediate needs and tight budgets rather than a broader plan for digital transformation. This has sometimes discouraged private-sector involvement and slowed the adoption of new technologies. The absence of an overarching roadmap can also leave vendors and researchers dealing with frequent regulatory shifts. On a more positive note, the current focus on national EHR deployment, along with additional EU funding, may create a better climate for large-scale, innovative solutions in the years ahead.

2.7 Success Cases in Greek Healthcare

Onassis Cardiac Surgery Center (Onassio)

The Onassis Cardiac Surgery Center stands out in Greece as a leader in cardiovascular care and digital health. Although it operates within the public ESY system, Onassio has invested heavily in modern diagnostics and imaging, such as 3D echocardiography and digital cath labs, that are fully integrated with its electronic medical records. This integration gives clinicians immediate access to high-quality imaging and patient data, enabling faster diagnoses and more precise treatments. Onassio's strong commitment to data-driven research, in close collaboration with academic institutions, further improves patient outcomes and strengthens its role as a specialized research hub. Leadership at Onassio prioritizes technology pilots and training programs that foster collaboration among IT staff, clinicians, and administrators. Strategic partnerships with private tech firms and international organizations also help the center implement digital tools more quickly than many other public institutions.

Papageorgiou Hospital ("Smart Hospital")

Papageorgiou Hospital in Thessaloniki shows how a large public facility can transform into a "smart" hospital by modernizing its operations through digital technology. The hospital has replaced old telephony systems with IP-based solutions and equipped staff with secure mobile devices, allowing clinical teams and administrators to access realtime data and communicate instantly. This shift has reduced patient wait times and improved overall workflow efficiency, freeing up medical staff to focus more on patient care. Innovations like RFID tags for asset tracking help monitor high-demand equipment, ensuring efficient resource allocation and lowering operational costs. With an emphasis on a patient-focused environment, Papageorgiou offers easy wireless access and intuitive digital platforms that support clear communication between patients and providers, creating a continuous loop of feedback to refine its digital systems.

Common Factors Driving Success

Although Onassis and Papageorgiou serve different specialties, both examples show how well-planned digital investments can overcome long-standing challenges in the ESY. Strong leadership that views technology as a tool for improving clinical care, rather than just an administrative aid, is a key factor. Both hospitals implement digital projects that align closely with their clinical missions, ensuring that solutions directly meet operational needs. Regular communication between IT teams and frontline staff, as well as collaborations with academic partners and technology vendors, has proven essential in drawing on external expertise and securing diverse funding sources. Additionally, building robust digital infrastructures has allowed these hospitals to introduce telehealth, advanced analytics, and other innovations gradually and smoothly, without the disruptions that often come with major system overhauls.

2.8 Role of Universities and SMEs in Driving Digital Health Innovation

Greek universities play a key role in advancing digital health by focusing on research, workforce training, and collaboration on tech projects. Institutions like the National Technical University of Athens (NTUA) and the University of Athens Medical School have set up labs dedicated to eHealth, data analytics, and health informatics¹³. Doctoral students and researchers often work with local hospitals to develop proof-of-concept software, pilot telemedicine applications, or fine-tune AI algorithms for clinical decision support. These joint projects help hospitals test new digital tools under controlled conditions and generate scientific publications that can lead to future funding. However, the broader impact on the Greek healthcare system depends on how well hospitals can integrate these successful pilot projects into their everyday operations. In practice, limited administrative resources and fragmented funding sometimes prevent promising technology from moving beyond the pilot stage [16]. Collaboration between academic institutions and healthcare providers is also strengthened by specialized consortiums and EU-sponsored networks. Programs such as Horizon Europe allow Greek universities to partner with hospitals, SMEs, and other European institutions to tackle complex digital health challenges. These partnerships speed up the exchange of knowledge and help local researchers adopt international best practices in areas like interoperability and cybersecurity. They also give Greek students hands-on experience in designing and testing digital systems, which in turn expands the pool of professionals ready to drive modernization. Small and medium-sized enterprises (SMEs) are another important force in Greek digital health innovation. SMEs tend to offer agile, specialized solutions that can quickly adapt to changing clinical needs. While large IT vendors may focus on broad-scale projects, SMEs excel in niche areas such as remote patient monitoring, AI-based diagnostics, and patient engagement apps, where rapid iteration and close user feedback are essential. However, working with the predominantly public ESY can be a double-edged sword for SMEs.

¹³ https://i-sense.iccs.gr/

On one hand, it provides a stable, large market; on the other, it involves cumbersome procurement processes, complex regulations, and unpredictable timelines [17]. Some Greek startups have managed to secure EU grants or join accelerators like the EIT Health Accelerator, which help them refine their products and approach hospitals with validated prototypes. Yet, SMEs still face challenges such as complying with medical device regulations (e.g., MDR for software-as-a-medical-device) and dealing with non-standardized data formats in hospitals. These issues raise the cost and complexity of launching new products. In addition, while an SME might find early success in one or two pilot sites, expanding to other regions with different IT systems and procurement rules can be difficult. Some companies navigate these challenges by focusing on simpler, consumer-facing applications, while others turn to more venture-friendly overseas markets. Ultimately, the potential for SMEs to transform Greek digital health depends not only on their technical skills but also on the adoption of policies that standardize interoperability and streamline procurement, allowing innovative products to scale across multiple public hospitals.

3. Diagnostic Analysis for Framework Preparation

3.1 Critical Technical, Regulatory, Financial, and Organizational Challenges Hindering the Digital Transformation of Greek Hospitals

Greek hospitals often work with fragmented IT systems, including stand-alone ERP and Laboratory Information Systems, and many lack fully integrated EMRs that follow modern standards. This creates data silos and disrupts the continuity of care. There are also regulatory gaps, such as incomplete adherence to EU eHealth guidelines, which lead to inconsistent data protocols and uneven progress among institutions. Financially, hospitals depend on short-term EU funding, while venture capital is scarce due to uncertain procurement and slow decision-making. Additionally, staffing shortages in IT and limited change management slow new technology adoption. All these factors result in patchy, ad hoc digital solutions instead of a large-scale transformation, increasing the risk of duplicative or incompatible systems across the national health system.

3.2 Impact of the Absence of a Unified National Digital Health Strategy and Sparse EU Guidelines

Without a unified national digital health strategy, Greek hospitals and agencies often update their systems through isolated tenders and one-off upgrades driven by urgent needs rather than a long-term plan. Although EU guidelines exist, they are often seen as too generic and fail to address Greece's specific structural and financial challenges. As a result, hospitals interpret and apply these guidelines inconsistently, leading to localized solutions and fragmented digital infrastructures. This fragmented approach makes it hard to scale successful pilot projects across the system. Moreover, EU funding conditions sometimes impose strict objectives and timelines, leaving little room for local innovation to grow naturally.

3.3 Essential Components of a Comprehensive National Framework for Digital Transformation

Based on international best practices and Greece's unique situation, a comprehensive national framework should include clear policy and governance structures—such as a central digital health authority to set policies, technical standards, and procurement guidelines. It should also support an interoperable, cloud-based infrastructure with integrated EMRs and standardized data formats for real-time data exchange. Sustainable funding mechanisms, like multi-year funding or public—private partnerships, are needed to move beyond short-term grants. In addition, robust cybersecurity measures and compliance with GDPR and EU directives are crucial, as is investing in change management and workforce training to prepare staff for new digital tools. Finally, a collaborative ecosystem with SMEs and academia will help simplify procurement, encourage joint R&D, and provide testing environments to refine

and scale solutions without heavy administrative barriers. The table below summarizes the above:

Key Component	Why	How
Clear Policy and Governance Structures	Ensure coordinated oversight and clear direction	Establish a central authority to set policies, standards, and procurement guidelines
Interoperable, Cloud- Based Infrastructure	Enable seamless data sharing and continuity of care	Develop integrated EMRs on secure cloud platforms with standardized protocols
Sustainable Funding Mechanisms	Provide long-term, reliable financial support	Create multi-year funding lines or public–private partnerships
Robust Cybersecurity and Compliance	Protect patient data and meet regulatory requirements	Align with GDPR/EU directives, invest in IT training, and implement multifactor authentication
Change Management and Workforce Training	Foster staff adoption and a culture of innovation	Invest in education programs and empower digital champions
Collaborative Ecosystem with SMEs and Academia	Accelerate innovation and scalable solutions	Simplify procurement, encourage joint R&D, and set up testing sandboxes

Table 5 Key Components for Digital Health Transformation: Why They Matter and
How to Implement Them

3.4 How Greek SMEs Can Effectively Integrate Digital Health Solutions into Hospital Workflows

Greek SMEs often excel in niche areas like telemonitoring, AI-based diagnostics, and patient engagement apps, but they face long procurement cycles and regulatory challenges. To integrate more effectively into hospital workflows, SMEs should engage in **pilot-based** collaborations with hospitals through EU or national programs that demonstrate clear clinical benefits and cost savings. Forming partnerships with **academic institutions and industry consortia** can add credibility and technical expertise, while working with established health-tech vendors can speed up product validation and adoption. It is also important for SMEs to design solutions that meet recognized **interoperability standards like HL7/FHIR**, reducing friction when connecting with various hospital systems and preparing for future national data-sharing requirements. Additionally, developing scalable business models that comply with

international standards, such as European MDR for software-as-a-medical-device, will improve their chances of expanding globally.

To overcome domestic challenges and position themselves for international growth, SMEs need to secure diverse funding sources by combining EU project grants, local seed investments, and accelerator programs like EIT Health. They should focus on optimizing regulatory compliance by meeting medical device regulations, maintaining clear clinical validation data, and obtaining the necessary certifications, which will boost credibility with both Greek hospitals and international clients. Building long-term partnerships with public hospitals, academic institutions, and private consultancies is also key, as these relationships foster mutual trust, enable iterative refinement of prototypes, and open doors for multinational collaborations.

4. Proposed Framework for Digital Transformation in Greek Healthcare

Building on insights from global eHealth leaders (e.g., Denmark, Estonia, Stanford Health Care, Karolinska University Hospital) and drawing upon Greece's own Digital Transformation Bible [18], this framework outlines a multi-layered approach to modernizing Greek hospitals. While technology stacks, cloud infrastructure, and interoperability standards form the technical bedrock, the framework also emphasizes agile procurement, iterative design-thinking, robust governance structures, and a skilled workforce. By uniting these policy, technological, and human elements, Greece can shift from fragmented digital pilots toward an integrated, continuously improving healthcare ecosystem that aligns with European standards and fosters local innovation. For a visual overview of these pillars, stakeholders, and desired outcomes, see Figure 1 bellow.

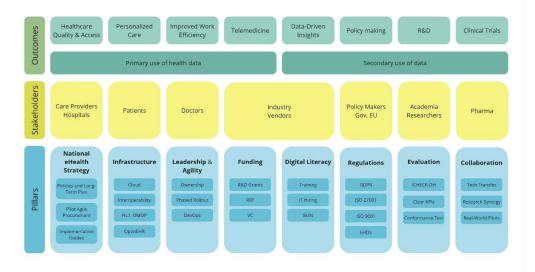


Figure 1 Proposed Framework Pillars, Stakeholders & Outcomes

4.1 Policies and Long-Term Plan

A cornerstone of effective digital health transformation is a clear, government-led digital strategy grounded in long-range objectives and iterative design-thinking methods. Greece's Digital Transformation Bible [18], initially formulated using a Value Proposition Design (VPD) [19], offers a foundation for building such a roadmap. However, to achieve consistent implementation, the national framework must incorporate best practices, particularly from countries like Denmark and Estonia, whose success in digital health derives from strong central governance and legally mandated interoperability.

Consolidate Policy and Governance

A single digital health authority should manage eHealth standards, oversee tender processes, and coordinate multi-year funding—ensuring alignment across ministries

and regions. Informed by global best practices—like Denmark's centrally driven "smart hospital" blueprint and Estonia's nationwide EHR policy [6]—this authority would develop standards, draft interoperability mandates, and serve as the primary liaison between public institutions, EU agencies, and private stakeholders ([2]). Denmark's long history of digital healthcare epitomizes how a national board can drive standards and guarantee interoperability; MedCom, for instance, has facilitated inter-sectoral communication of individual health services since 1994, and the National Board of eHealth actively oversees a national ICT infrastructure and enforces consistent technical standards across different regions. Meanwhile, Estonia's strict legal requirement for EHR use and interoperable data exchange provides another robust template for ensuring compliance and uniformity across healthcare providers.

Foster Agency Ownership and User Engagement

Drawing from Vasilakis et al. (2018) [20], high-level mandates can overcome institutional resistance, but the executing agency must have the autonomy and resources—dedicated staff, agile contracting models—to address real-time challenges. Collaborative sessions with hospitals, SMEs, and academic stakeholders help refine requirements and nurture a co-design culture where solutions are iteratively validated. Such participatory governance prevents top-down directives from becoming overly rigid, instead enabling hospital-level innovation within a supportive national framework.

Adopt a Participatory, Design-Thinking Mindset

Emulating the Public Sector Innovation approach that shaped Greece's Digital Transformation Bible [18], policymakers can integrate iterative feedback loops, user research, and prototype validations at each policy formation stage. Tools like iCHECK-DH [21] aid in documenting implementation goals, methods, and outcomes, thereby standardizing project reporting and improving stakeholder buy-in. By integrating design-thinking principles at both the policy and operational levels, Greece ensures that digital health projects remain aligned with real-world clinical needs and patient experiences throughout their lifecycle.

By uniting these policy elements under a long-term plan, Greece lays the groundwork for robust leadership and efficient deployment of digital solutions in hospitals. A centralized authority—empowered by legislation and guided by design-thinking—can replicate Denmark's structured eHealth oversight (e.g., MedCom's pivotal role) or Estonia's legally enforced EHR integration, thereby minimizing fragmentation and accelerating the adoption of interoperable systems across the national healthcare landscape [6].

4.2 Technology Architecture Aligned with Cloud, Interoperability, and Secondary Data

Interoperability and Open-Source Implementation Guides

Building a unified, cloud-based EHR backbone requires strict adherence to open standards, and HL7 FHIR (Fast Healthcare Interoperability Resources) is widely recognized as a preferred protocol. To accelerate adoption in Greece, it is important to publish Greek-specific FHIR profiles, similar to the US Core IG¹⁴, using tools like FHIR SUSHI¹⁵ to maintain consistent Implementation Guide versions and reduce confusion across hospitals. Open-source projects such as HAPI FHIR¹⁶ (Java), fire.ly¹⁷ (C#), and Medplum¹⁸ (Node.js) provide robust libraries and data solutions, supporting interoperability and enabling developers to build systems without starting from scratch. Moreover, the HL7 Hellas Workgroup plays a key role in this ecosystem by bringing together clinicians, IT experts, and public-sector representatives to create localized FHIR Implementation Guides. By following the example of other countries, this collaborative effort can ensure that Greece has clear, community-driven standards that support agile iteration and consensus, rather than relying solely on top-down mandates.

Secondary Data Use with OMOP CDM and OHDSI Tools

Enabling **secondary use of health** data for research, AI training, or public health analytics starts with a standardized model like the OMOP Common Data Model (CDM)¹⁹. Championed by OHDSI²⁰ (Observational Health Data Sciences and Informatics), the OMOP CDM provides a flexible structure to harmonize diverse clinical data. This standardization not only supports multi-institution observational studies and real-time epidemiological insights but also lays the groundwork for advanced approaches such as federated learning, where institutions exchange questions and answers rather than raw data, ensuring privacy while still benefiting from shared insights.

The OHDSI community, one of the largest in digital health research with thousands of researchers from over 40 countries, offers a rich ecosystem of tools and resources. For example, ATLAS, an open-source analytics platform, enables users to design studies, build cohorts, and run analyses on standardized data. Along with ATLAS, other tools from OHDSI support detailed analytics and visualization, driving more informed decisions in healthcare.

In addition, networks such as EDHEN and DARWIN facilitate federated learning environments that work seamlessly with the OMOP model and OHDSI tools, allowing

¹⁴ https://build.fhir.org/ig/HL7/US-Core/

¹⁵ <u>https://github.com/FHIR/sushi</u>

¹⁶ https://hapifhir.io/

¹⁷ https://fire.ly/

¹⁸ <u>https://www.medplum.com/</u>

¹⁹ https://ohdsi.github.io/CommonDataModel/

²⁰ https://ohdsi.org/

for secure, distributed analytics across different institutions and regions. These networks help create an ecosystem where Greek hospitals can safely share insights without compromising sensitive patient data, further supporting large-scale research and innovation.

If Greece fully supports OMOP, the country could significantly boost its chances of **joining international clinical trials through the established OMOP networks**. Standardizing datasets using OMOP not only makes data more accessible to pharmaceutical companies and research organizations but also ensures that patient privacy is rigorously maintained. This alignment would open new avenues for collaborative research and pave the way for Greek healthcare institutions to participate in cutting-edge clinical studies, ultimately driving innovation and improving patient outcomes.

Centralized vs. Decentralized

Greece must decide whether to store data in a **single, central repository** (hosted by a government entity) or allow decentralized data governance where hospitals retain control but upload to standardized OMOP repositories upon request. A **hybrid model** may be needed, balancing privacy with research utility.

This high-level diagram underscores **cloud-based EHR** interoperability, open-source FHIR tooling, and OMOP-based analytics, linking hospital systems (HIS) with specialized SME solutions. The national eHealth authority ensures consistent standards, while HL7 Hellas Workgroups coordinate FHIR adoption.

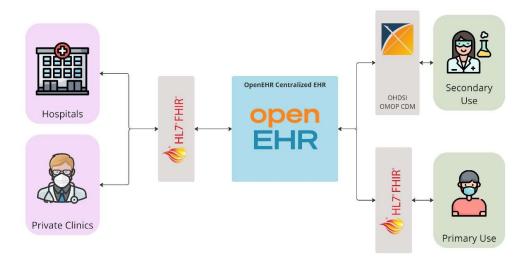


Figure 2 EMR - High Level Open Standard Centralized Architecture

4.3 Agile Implementation with Phased Rollout

Hospital-by-Hospital Pilots

A phased or "lighthouse" approach suits Greece's resource constraints, as upgrading all 131 public hospitals at once would be impractical. Instead, the national strategy should start with selected pilot institutions, such as high-volume teaching centers or specialized facilities like Onassis Cardiac Surgery Center, which already have leadership support and readiness for digital solutions. These early adopters act as incubators, validating specific EHR modules, telemedicine pilots, or AI-driven triage tools under real-world conditions. The process can begin by rolling out partial EHR modules or telemedicine pilots in a small subset of wards, keeping the project manageable and allowing meaningful feedback loops. Early wins, like shorter patient wait times or automated appointment scheduling, generate stakeholder enthusiasm. Once initial implementations show clear benefits, user input from clinicians, administrators, and patients drives incremental refinements, mirroring agile project management. Finally, distinct "sandbox" environments can be reserved for more experimental innovations, similar to Stanford's approach, allowing rigorous testing of advanced tools without disrupting regular hospital workflows [21].

Integrating Agile Procurement Methodologies

Greek healthcare modernization often relies on public tenders, yet these can be linear and time-consuming. According to OECD recommendations [10], agile procurement can speed up digital projects and cut administrative overhead. Practical guidance for contracting, coordinated by entities like the Hellenic Single Public Procurement Authority (HSPPA), could feature case studies of successful agile initiatives, showcasing iterative contracting, flexible deliverables, and performance-based milestones. Piloting agile procurement with Information Society S.A. would further refine these methods before applying them to larger-scale tenders. Over the medium term, a specialized unit under the Ministry of Digital Governance could serve as a competence center for agile procurement in healthcare, bringing together expertise in legal frameworks, technical standards, and vendor management to ensure that agile practices gradually become standard.

Overcoming Resistance Through Top-Down Pressures and Agency Ownership

Adopting principles outlined by Vasilakis [20] ensures that top-down mandates and local agency empowerment work hand in hand. Government-level requirements—such as making certain eHealth services mandatory for official documentation—create a strong incentive for hospital compliance. For instance, administrative acts might only be valid if hospitals use standardized EMR protocols. At the same time, pilot hospitals and similar agencies need the autonomy and resources to address issues quickly, whether that involves allocating dedicated IT staff or cutting red tape that delays software rollouts. This approach lets frontline entities adjust priorities in real time.

Ongoing engagement of stakeholders, from chief medical officers to nursing staff, builds collective ownership of newly deployed systems, and regular feedback sessions help identify bottlenecks and training needs, supporting iterative refinements that enhance adoption. When combined, these methods create a responsive, learningoriented environment where digital projects can scale effectively once proven in lighthouse sites. Over time, agile procurement, top-down leadership, and local autonomy form a robust engine to sustain Greece's digital health transformation.

4.4 Regulatory and Security Alignment

Cloud Architecture and DevOps Governance

A DevOps-oriented culture is central to streamlining healthcare software deployment, integrating regulatory compliance (GDPR, ISO 27001, 9001) and continuous security checks into CI/CD pipelines (Continuous Integration/Continuous Deployment). By merging development and operations teams, hospitals and software vendors can ensure that every software release undergoes automated testing and verification against both functional requirements (e.g., correct patient-data handling) and regulatory constraints (e.g., adherence to GDPR privacy rules). This approach not only shortens feedback loops, allowing faster bug fixes or feature updates—but also embeds iteration and risk assessment at every step of the software life cycle.

DevOps fosters cross-functional collaboration, with developers, QA staff, and clinicians working together to identify potential vulnerabilities or compliance gaps early in the development process. Tools like version-controlled "Infrastructure as Code" ensure that test environments reflect production conditions, reducing the chance of environment-specific failures when new functionality goes live. Real-time monitoring and log analysis quickly detect anomalies (e.g., spikes in system resource usage), echoing best practices from institutions where robust digital health infrastructures must stay online 24/7.

When mapped to medical device software, including telemedicine platforms or AIbased diagnostics, DevOps processes can incorporate IEC 62304 guidelines, which define life cycle requirements for software problem resolution and change control [17]. By embedding iterative analysis, risk assessment, and thorough documentation of modifications directly into development pipelines, healthcare organizations can demonstrate conformance to regulatory standards while maintaining the agility needed to update clinical software.

Security by Design

"Security by design" entails integrating cybersecurity measures—such as encryption, multifactor authentication, and continuous penetration testing—throughout DevOps workflows rather than tacking them on at the end. This approach fosters trust among clinicians and patients who rely on cloud-based telemedicine or AI for essential

diagnoses, ensuring that data and operations remain protected. Transparent governance, via version-controlled artifacts (e.g., Git repositories for infrastructure code and software configuration), helps quickly roll back or patch systems if vulnerabilities are identified.

Problem resolution and change control gain special relevance in a DevOps environment managing software medical devices. Frequent software changes demand iterative risk analyses, consistent with the IEC 62304 standard, so each update is evaluated for its potential impact on the device's overall safety and performance. A well-structured architecture—sometimes referred to as a *Software Maintenance Architecture (SWMA)*—enables cost-effective but rigorous traceability of reported issues, their resolution, and any effects on the broader system. This life cycle management approach can detect and address problems before they propagate to production, minimizing downtime or risk to patients.

In essence, the DevOps culture merges agile software engineering with continuous regulatory oversight, creating a dynamic feedback loop that simultaneously addresses compliance requirements (GDPR, ISO, IEC 62304) and the evolving clinical needs of hospital environments. By embracing these principles, Greek healthcare providers can deliver rapid, secure, and user-aligned digital solutions while preserving the integrity and safety of patient data and medical device software.

4.5 Alignment with EU/EHDS (European Health Data Space)

Fully integrating Greek healthcare into the European Health Data Space (EHDS) paves the way for seamless cross-border data exchanges, collaborative research, and interoperable digital health services. As the EHDS framework evolves, Greece must designate a National Contact Point (IDIKA) responsible for translating EHDS guidelines into local technical and policy requirements. This coordinated approach ensures both **primary** and **secondary** use of health data adheres to robust data governance and EU-wide interoperability standards.

Primary and Secondary Use of Data Under EHDS

The EHDS envisions two overarching data use categories:

- 1. **Primary Use**: Patient care activities, such as cross-border referrals, telemedicine services, and retrieval of health records for continuity of care. Enforcing consistent FHIR-based (for instance, to share patient summaries) streamlines these processes across EU member states.
- 2. Secondary Use: Large-scale analytics, research, public health planning, and AI development. By employing anonymized or pseudonymized data sets, Greece can participate in multi-country epidemiological or precision medicine studies, expanding beyond purely local hospital data.

Clear Implementation Guides

While HL7/FHIR are recognized standards for data exchange, final EHDS implementation guides remain somewhat fluid. Some partial or preliminary guides (e.g., <u>XT-EHR Common IG²¹</u> or <u>XPandH PS²²</u>) exist, but are not yet finalized. Similarly, various FHIR Implementation Guides on <u>FHIR.org's registry²³</u> appear in different maturity stages. Greece should proactively monitor these evolving guides, adapting them for local use instead of merely republishing static PDF versions that may quickly become outdated. A dynamic, web-based repository of national adaptions ensures rapid iteration and alignment with new EHDS releases.

Collaboration with Vendors and National Agencies

Ongoing cooperation between Greek NCP, local healthcare providers, IT vendors, and EU-level authorities will ensure solutions remain interoperable with pan-European initiatives. Specific actions include:

- 1. **Joint Workgroups**: Form or strengthen national committees that bring together HL7 Hellas, the Ministry of Health, vendor representatives, and academics to maintain live FHIR IG documents aligned with EHDS updates.
- 2. Vendor Readiness: Encourage software providers to design flexible data export/import modules, ensuring compliance with EHDS guidelines, particularly around data privacy (GDPR compliance, pseudonymization) and structured exchange protocols.
- 3. **Testing & Certification**: Implement pilot cross-border exchange scenarios, such as forwarding patient summaries for a Greek patient needing urgent care in another EU state—to validate technical conformance and refine workflows.

By **adhering to EHDS** protocols for both primary and secondary data use, Greece can expand its telemedicine services, facilitate cross-border referrals, and harness large-scale analytics or AI research that spans multiple countries. Embracing **live**, **web-based** FHIR implementation guides and collaborating closely with EU partners fosters a future-proof strategy, enabling Greek digital health solutions to evolve in sync with the broader European digital health ecosystem.

4.6 Enabling Innovation Through Close Academia–Industry Collaboration

Fostering Alliances Among Leading Hospitals, Academia, and SMEs

Close collaboration among hospitals, universities, and industry players is essential for sustainable innovation. Karolinska University Hospital's strong relationship with Karolinska Institutet, or Stanford Health Care's partnership with its university research labs, demonstrates how joint labs can quickly pilot novel digital solutions while training

²¹ <u>https://build.fhir.org/ig/Xt-EHR/xt-ehr-common/</u>

²² <u>https://build.fhir.org/ig/hl7-eu/xpandh-ps/</u>

²³ https://fhir.org/guides/registry/

future digital health professionals. In Greece, high-potential teaching hospitals particularly those designated as "lighthouse" sites—can act as innovation incubators, partnering with academic institutions and SMEs to test standardized FHIR or OMOP data flows. This arrangement ensures real-world validation by allowing advanced imaging analytics, patient apps, or AI-driven triage to be tested in clinically demanding environments, refining solutions before a nationwide rollout.

Several measures can strengthen these alliances. Joint R&D grants, funded by public agencies such as the Ministry of Digital Governance or EU structural programs, can drive telehealth, AI-assisted diagnostics, and clinical analytics initiatives, requiring participation from both universities and SMEs so that research outcomes address immediate clinical needs. Teaching hospitals can create dedicated innovation hubs—similar to Stanford's "sandbox" clinics—where SMEs co-develop and refine products in live settings, speeding up feedback loops and reinforcing user-centered design. In addition, Greek universities can establish student and faculty exchange programs that place graduate students and faculty in hospital IT departments or SME research groups, equipping emerging professionals with practical skills in health informatics, DevOps, and regulatory compliance, and bridging the gap between academic theory and real-world implementation.

Catalyzing Innovation Through Lighthouse Hospitals

When leading ("lighthouse") hospitals commit to **co**-design with academic labs and specialized SMEs, the entire national system gains a blueprint for integrated digital health solutions. Successes at these sites—such as improved AI-based diagnoses or streamlined telemonitoring—can then be scaled to other institutions, greatly accelerating the country's adoption curve. The iCHECK-DH checklist [21] aids in systematically documenting the pilot's objectives, methods, and outcomes, thereby enabling knowledge transfer and reproducibility across regions. Over time, this interplay of R&D innovation and clinical validation transforms the Greek digital health landscape into an adaptive ecosystem where modular solutions can be swapped, upgraded, or expanded without the disruptions characteristic of monolithic or proprietary platforms.

By knitting together leading hospitals, research-intensive universities, and agile SMEs under a cohesive, standards-based framework, Greece creates fertile ground for dynamic digital health innovations that serve both immediate clinical demands and broader, long-term national goals.

Building Modular, Standards-Based Digital Health Ecosystems

Modern healthcare solutions must address data heterogeneity, ensure reusability, and account for security/privacy from the earliest stages of design (The Path to a Modular and Standards-based Digital Health Ecosystem [14]). Greece can adopt an open-source "Spezi-like" approach, where modular components—covering everything from AI diagnostics to data ingestion and telemonitoring—are assembled to create flexible,

standards-aligned platforms. By publishing these components under permissive licenses, local and international developers gain access to reliable building blocks that can be reused, modified, and integrated with emerging hospital IT systems. This modular ethos not only democratizes advanced digital health tools but also encourages SMEs to focus on innovative add-on services (e.g., specialized AI modules) rather than reinventing the entire infrastructure stack.

4.7 Building a Central Digital Health Team at the National Level

A National Digital Health Team, established within the Ministry of Health or as an autonomous eHealth authority, can significantly accelerate Greece's digital health transformation. Echoing OECD [10] suggestions on "agency ownership," this specialized group would hold the legal authority and capacity to shape procurement, funding, and innovation frameworks. Its responsibilities span the entire life cycle of digital health initiatives, from crafting tender requirements aligned with interoperability rules to expediting regulatory approvals and orchestrating pilot rollouts across multiple hospitals.

By bridging policy and technical domains, the digital health team ensures agile pilots those initiated in "lighthouse" hospitals—are executed coherently and scaled effectively. This centralized unit would also offer advisory services to local hospitals, SMEs, and academic partners on good procurement practices, data security, and compliance with GDPR, ISO, and medical device regulations. Finally, the group would monitor and evaluate national eHealth progress, facilitating knowledge exchange among established pilot sites and newly onboarded facilities so that lessons learned in one region can quickly inform implementations elsewhere.

To function effectively, the digital health team requires a cross-functional blend of experts in informatics, policy, procurement, law, cybersecurity, and clinical workflows. Having both clinical and technical specialists under one roof streamlines decision-making and avoids contradictory or redundant procurement cycles across different regions. By serving as a unified command center and competence hub, this national authority embodies the agency ownership approach recommended by the OECD, ensuring policies can be flexibly adapted to real-world challenges without succumbing to rigid bureaucratic constraints. Ultimately, a well-empowered digital health team fosters transparency, agility, and coherence across Greece's evolving eHealth ecosystem.

4.8 Strengthening Human Capital: People, Teams, and Training

No matter how advanced the technology, digital transformation ultimately relies on capable, motivated individuals throughout the healthcare ecosystem. Clinicians must trust and effectively use AI-driven decision supports, telemedicine workflows, and cloud-based EHR modules. DevOps engineers, data analysts, and FHIR integrators are needed to maintain secure cloud infrastructures, manage data exchanges, and ensure

interoperability. Administrators and policy-makers require a solid grasp of agile procurement, project management, and data governance to steer modernization with minimal friction.

Each healthcare organization should prioritize hiring staff with robust IT competencies, ensuring that local teams can configure, optimize, and troubleshoot essential software. Many Greek hospitals currently operate with understaffed or underqualified IT departments, which can impede even the best-designed digital solutions from functioning at scale. By recruiting and retaining skilled professionals—from cloud architects to cybersecurity experts—organizations enable themselves to respond swiftly to evolving technological demands, patch vulnerabilities, and exploit emerging AI or big-data possibilities.

In addition, implementing ongoing training programs is indispensable. Structured courses in AI literacy, workflow digitization, and data security can be offered in collaboration with academic institutions or leading SMEs. Leadership development is equally critical: designating "digital champions" at each hospital fosters local ownership, rapid troubleshooting, and consistent feedback loops. Building a continuous learning culture entails incorporating performance metrics, user satisfaction surveys, and iterative improvements into daily operations—ensuring that digital health rollouts stay aligned with both clinical needs and organizational capacity.

4.9 Leadership and Evaluation in Each Step

Creating a digital ecosystem depends on strong stakeholder ownership from hospital managers, frontline clinicians, SME developers, and academic partners. Greece can improve accountability and adaptability by defining clear KPIs-such as reduced readmission rates, shorter waiting times, and increased telemedicine usage-to measure the impact of new technologies objectively. In addition, conducting periodic reviews on a regular basis (e.g., quarterly or semi-annually) allows pilot hospitals to share progress, best practices, and challenges, enabling timely adjustments when tools fall short of benchmarks. Embedding tools like iCHECK-DH [21] to document each digital intervention's goals, methods, and outcomes ensures clear communication and smooth knowledge transfer across institutions. Finally, legislating ongoing stakeholder involvement-for example, through regional digital councils or collaborative committees—helps maintain user engagement beyond the initial pilot phase and fosters a shared sense of ownership. Drawing inspiration from Stanford's cyclical approach to technology pilots and Karolinska University Hospital's data-driven refinements, Greek hospitals should integrate evaluation at every stage. A continuous "Plan-Do-Study-Act" cycle, with defined milestones and regular reviews, enables agile adjustments and systematic learning, ultimately leading to a stable, human-centered digital health ecosystem.

5. Fostering Efficiency, Innovation, and SME Collaboration

A primary objective of this framework is to streamline operational workflows, invigorate Greece's innovation ecosystem, and create a fertile environment where Small and Medium-Sized Enterprises (SMEs) can thrive. By adopting interoperable standards (e.g., HL7 FHIR) and encouraging modular, cloud-based architectures, Greece can catalyze digital solutions—such as AI-driven diagnostics, digital therapeutics (DTx), and advanced patient engagement tools—to be developed, tested, and deployed with minimal overhead.

Simplified Access for Researchers and SMEs

Traditional use of monolithic public tenders has historically pushed aside smaller, more agile vendors. The agile procurement measures outlined in Section 4.3 reverse this trend by enabling **shorter contract cycles** and **targeted pilots in "lighthouse**" hospitals. Instead of wrestling with heavy bureaucratic processes, SMEs and research consortia can propose focused solutions, gather data more quickly, and scale successful pilots without waiting for multi-year tender processes.

Joint R&D "sandboxes" at high-volume teaching hospitals or specialized centers, supported by the National Digital Health Team, serve as test beds for novel solutions. These low-barrier environments allow SMEs and academic teams to run real-world pilots, with feedback from these settings refining prototypes and paving the way for broader adoption once technical and clinical validation is complete. Additionally, by standardizing on FHIR-based REST APIs and open-source approaches, innovators can integrate with hospital data swiftly and focus on adding value—such as developing AI modules for disease prediction—instead of spending time on repetitive custom data mappings [11], [23].

Lower Operational Costs and Improved Resource Allocation

Agile implementation and modular architectures help lower operational costs by reducing the need for repetitive development that often drives up hospital IT budgets. When telemedicine and analytics solutions adhere to common data standards, procurement teams spend less time building interfaces repeatedly, and hospital IT staff benefit from lower maintenance requirements. Once a pilot solution proves successful, it can be quickly duplicated at other facilities, minimizing redundant contracting and retraining of staff. This efficiency not only streamlines integration but also reallocates resources, freeing up hospital budgets for research, enhanced patient care, and other strategic investments.

5.1 Greece-Developed Solutions, Scalable Abroad

Greece's digital health innovation is uniquely positioned to scale both within the EU and globally, thanks to widespread international standards such as FHIR and OMOP. This "develop locally, scale globally" model enables solutions refined in Greek healthcare settings to be easily adapted and implemented in other markets. For example,

cloud deployments through H-Cloud allow SMEs to meet security and GDPR requirements using a national or EU-certified cloud platform. Once a deployment blueprint is validated in Greece, it can facilitate cross-border health data exchange and commercial expansion without reinventing the wheel. Similarly, innovations in AI-driven triage and digital therapeutics (DTx) built on Greek best practices meet the common compliance and interoperability demands of health systems worldwide.

Agile implementation and modular architectures further contribute to cost savings by reducing repetitive development work that often inflates hospital IT budgets. When telemedicine or analytics solutions are designed to adhere to common data standards, procurement teams avoid the expense of building multiple interfaces, and IT teams experience fewer maintenance challenges. Successful pilot projects can be rapidly scaled to additional facilities, minimizing redundant contracting and retraining efforts. This streamlined approach reallocates resources effectively, freeing up hospital budgets for research, enhanced patient care, and other strategic investments.

Digital therapeutics and remote care platforms stand to benefit greatly from this framework. With seamless data flows enabled by FHIR and unified DevOps pipelines, DTx modules can be onboarded quickly with minimal friction. These modules are capable of collecting real-world evidence and feeding outcomes data back to providers in near real time, which supports continuous improvement. Telehealth applications, meanwhile, can leverage standardized vitals and observational data to generate continuous or event-based alerts that align with chronic condition management. This synergy not only reduces the frequency of acute hospital visits but also provides a foundation for SMEs to develop advanced analytics and patient-support modules, driving further innovation.

A sustainable digital health ecosystem in Greece also depends on building a dynamic "flywheel" of research and commercial activity. In this model, hospitals identify gaps in care—such as medication adherence issues—while agile SMEs propose targeted solutions that are then validated in real clinical settings. Academic partners contribute by refining algorithms, defining outcome metrics, and enhancing user experience through hands-on research and feedback. As these projects prove their value, they can be scaled regionally or nationally with minimal reintegration efforts. This iterative cycle creates an environment where innovation leads to quick results, attracts additional investment, and continuously fuels the growth of the domestic digital health industry.

Together, these elements form a robust ecosystem where Greek digital health solutions can evolve from localized pilots into scalable, internationally competitive products. The combined benefits of streamlined integration, cost-effective operations, and collaborative innovation not only enhance patient care but also position Greece as a leader in the global digital health arena.

6. Conclusion

This thesis aimed to identify the challenges slowing digital transformation in Greek hospitals and propose a clear framework to guide them toward a modern, patientcentered, and innovation-friendly environment. The literature shows that healthcare systems worldwide are rapidly digitizing, driven by advances in AI, cloud computing, and telehealth. Success stories from Estonia's unified EHR and Denmark's smart hospitals prove that strong leadership, government commitment, and clear data standards can greatly improve clinical efficiency, patient care, and cost management.

In Greece, outdated systems, fragmented governance, and one-off procurement practices have led to isolated solutions that limit scale and sustainability. Recent government efforts—such as developing an Individual Electronic Health Record and modernizing hospital IT—are important steps forward, but the absence of a unified strategy and standardized data sharing continues to slow progress. Greek SMEs, despite their strong technical skills, struggle to bring innovations to market because of complex tendering processes, unclear data standards, and limited support for pilot testing.

The proposed framework offers a multi-layered approach to address these issues. It calls for the creation of a central digital health authority that sets data standards, coordinates efforts across ministries, and manages agile procurement. The framework also advocates for using HL7 FHIR, OMOP, and open-source tools to support data sharing, advanced analytics, and compliance with EU regulations and the European Health Data Space (EHDS). Starting with pilot projects in "lighthouse" hospitals using shorter contract cycles and iterative improvements can validate solutions before broader adoption, thereby reducing financial and operational risks. In addition, strengthening collaboration among academic institutions, hospitals, and SMEs through innovation hubs, shared R&D grants, and specialized consortia will combine academic research with industry agility to create effective telehealth and AI solutions. Empowering hospital staff through targeted training and leadership development is essential for creating a culture of digital innovation, while regular evaluation using tools like iCHECK-DH and the PDSA cycle will ensure that each project meets clear performance indicators and continuously improves.

By aligning strategies, sharing common standards, and engaging all stakeholders, this framework not only aims to reduce current inefficiencies in Greek hospitals but also to create an ecosystem where Greek SMEs can develop interoperable, cloud-ready digital health tools with global impact. Over time, moving from fragmented, ad hoc systems to a robust, EU-aligned digital health infrastructure will lead to more efficient care, better data-driven decisions, improved patient experiences, and new commercial opportunities for Greek technology providers.

6.1 Future Directions

Further research could look into the cost benefits of fully cloud-based EHRs in a mainly public system, test the feasibility and security of locally hosted versus centrally

managed data solutions, and explore next-generation cases like AI-powered triage or personalized genomic medicine. Also, examining real-world outcomes from pilot projects—especially in rural or underserved areas—would provide valuable insights into the social, economic, and cultural aspects of digital health adoption. As EU guidelines and the European Health Data Space continue to change, ongoing alignment in policy and technology will be crucial. Collaboration among government bodies, academic institutions, healthcare organizations, and SMEs will be essential to turn promising pilots into nationwide innovations. Ultimately, sustainable transformation depends on continuous investment in people, governance reform, and technology upgrades, ensuring that Greece's healthcare system becomes more efficient, patientfocused, and competitive in the global digital health landscape.

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