

Faculty of Engineering of the University of Porto



**Study of effective frameworks to support medical
technology innovation in the hospital setting**

Mariana Alves Fernandes

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Supervisor: Daniel Marques de Vasconcelos

Co-Supervisor: José Coelho Rodrigues

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Resumo

O setor MedTech é um mercado global altamente lucrativo, avaliado em 550 mil milhões de euros em 2021, impulsionado pela procura de soluções que melhorem a performance e a eficiência em saúde. Apesar do forte investimento em investigação e desenvolvimento, persiste a dificuldade na disseminação de conceitos associados a inovação, refletindo-se na elevada taxa de insucesso das startups – sugerindo ausência de estratégia e a complexidade dos desafios na transferência de tecnologia médica inovadora.

Este estudo procura responder à questão: “Como é que Portugal pode desenvolver modelos eficazes para apoiar a inovação tecnológica médica em contexto hospitalar?”. Para tal, combina um método qualitativo exploratório baseado em entrevistas não estruturadas e semi-estruturadas e uma revisão da literatura focada nos quatro principais agentes do modelo de quádrupla hélice em inovação (Hospitais, Academia, Indústria e Governo). A principal contribuição desta dissertação é a identificação das melhores práticas, através de uma análise comparativa abrangente dos principais desafios e do estado atual da inovação em tecnologia médica entre Portugal e seis países de referência (Dinamarca, França, Alemanha, Espanha, Suíça e Estados Unidos). Os resultados mais notáveis deste estudo indicam que os hackathons no domínio da saúde promovem a interdisciplinaridade e a identificação de necessidades clínicas reais, e que a avaliação de tecnologias (HTA) pode ser uma estratégia para mitigar os riscos associados ao valor e à eficácia da inovação médica. Além disso, evidenciam-se a importância da definição clara e imparcial das necessidades clínicas reais, da educação e formação em competências empreendedoras e do alinhamento da visão e dos objetivos entre os agentes dos ecossistemas, para superar os fatores culturais, organizacionais e tecnológicos que dificultam a transferência de tecnologia médica.

Em suma, as propostas de apoio à inovação em tecnologia médica em contexto hospitalar devem priorizar o envolvimento dos vários agentes nos ecossistemas de saúde desde as fases iniciais de desenvolvimento, promover colaborações, capacitar os hospitais para servirem como bancos de dados e ensaios, estabelecer papéis e responsabilidades na gestão hospitalar, clarificar o objetivo da inovação e fomentar uma cultura orientada para a mesma. Esta dissertação pretende aconselhar os vários agentes envolvidos na inovação tecnológica médica em Portugal e noutros países. No entanto, reconhece como limitações a sua natureza exploratória qualitativa, a pequena população estudada e o período de investigação. Futuras melhorias no estudo incluem o desenvolvimento de uma proposta multinível para apoiar a inovação em MedTech, a gestão e estratégia hospitalar descentralizada e autónoma, e as iniciativas para promover a co-criação de ecossistemas, com ênfase no alinhamento da missão, visão e objetivos dos diferentes agentes.

Abstract

The MedTech sector is considered highly profitable with a global market value of 550 billion euros in 2021 driven by the demand for solutions to improve health outcomes and efficiency. The sector invests heavily in research and development, yet struggles to disseminate innovation-related concepts, as shown by the high failure rate of MedTech startups – suggesting a lack of a health innovation strategy and reflecting the complexity and challenges of developing and transferring new medical technological solutions from research to practice.

To answer the research question “What effective frameworks can Portugal develop to support medical technology innovation in the hospital setting?” this study combines an exploratory method, considering unstructured and semi-structured interviews, with a literature review focused on the main four agents of the Quadruple Helix Model in MedTech innovation (Hospitals, Academia, Industry, and Government). The main contribution of this dissertation is an identification of best practices and comprehensive benchmarking of the current state and challenges of medical technology innovation in seven global reference countries (Denmark, France, Germany, Portugal, Spain, Switzerland, and the United States).

The most outstanding research findings suggest that healthcare hackathons promote cross-linkage of knowledge and real need identification, and that Health Technology Assessments can be a de-risk strategy to assess the value and effectiveness of medical technology innovation. Moreover, the challenge of providing an unbiased and clear statement of the need for medical technologies, the need for education and training to promote entrepreneurial skills among researchers, the alignment of vision and goals among stakeholders, and the inexperience of agents in navigating cultural, organizational, and technological factors associated with medical technology development and transfer, were the most significant findings of this study.

In conclusion, effective frameworks to support medical technology innovation in hospital settings should prioritize the early involvement and interaction of the various agents within healthcare ecosystems, promote collaborations, empower hospitals to serve as data owners and test beds, establish roles and responsibilities for hospital management, clarifying the purpose of hospital innovation and prioritize a culture towards it. This dissertation aims to provide valuable insights and knowledge for researchers, clinicians, policymakers, industry, and other agents involved in medical technology innovation in Portugal and beyond. However, the study recognizes its qualitative exploratory nature, small population studied, and research the short period as limitations. Future research improvements include the development of a multi-level framework to support MedTech innovation, decentralized and autonomous hospital management and strategy, and initiatives to foster the co-creation of ecosystems, with emphasis on the alignment of mission, vision, and objectives of different agents.

Keywords: MedTech Innovation, Healthcare Ecosystem, Medical Technology Transfer, Healthcare Hackathon, Health Technology Assessment, Clinical Engineering.

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"Engineering is not just about math and science. It is about figuring out solutions to problems and using your creativity to make the world a better place." — Marissa Mayer

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Abbreviations

2CA-Braga	Centro Académico Clínico de Braga
CAC	Centro Académico Clínico
CAGR	Compound Annual Growth Rate
CVC	Corporate Venture Capital
EPO	European Patent Office
GDP	Gross Domestic Product
GDPR	General Data Protection
HCP	Health Cluster Portugal
HTA	Health Technology Assessment
IP	Intellectual Property
KOL	Key Opinion Leader
LSD	Laboratório de Saúde Digital
M&A	Mergers and Acquisitions
MedTech	Medical Technology
MIT	Massachusetts Institute of Technology
NIH	National Institute of Health
PACTT	Powering Academia-industry Collaborations and Technology Transfer
PHSSR	Partnership for Health Systems Sustainability and Resilience
R&D	Research and Development
SME	Small and Medium-sized Enterprise
SNS	Sistema Nacional de Saúde
SPMS	Serviços Partilhados do Ministério da Saúde
US	United States
WIPO	World Intellectual Property Organization

Introduction

Medical technologies are key in promoting improvements in service quality and, therefore, quality of life in the healthcare sector [1][2]. These innovations are a part of the progression in medicine, which requires new technologies, or organization models as innovative alternatives to delivering care [3]–[5]. The success of such progress is mainly dependent on four premises: solid and strong academic education and research, robust health and hospital systems, a culture of entrepreneurship, and adequate infrastructure [6]. However, they pose ongoing challenges for their adoption by healthcare providers and systems, while innovators face difficulties in ideating and developing solutions to address identified clinical needs.

The development of any impactful healthcare innovation begins with the patient [7]. According to the World Economic Forum [8], the healthcare system of the future will undergo major transformations, emphasizing the shift towards a patient-centric approach, where the stakeholders of healthcare systems – Hospitals, Academia and Technological Infrastructures, MedTech industry, and Government and Regulators – will focus on prevention and access through technology and digital tools to improve efficiency and performance. A hospital-centered innovation model supports patient-centered care and contributes to an efficient and value-based healthcare system, aimed to enhance the quality of healthcare provision, through access to innovative medical technologies. The synergy between stakeholders can result in the emergence of innovative medical devices and diagnostic tools [9], thus enhancing the precision, efficacy and resource management of healthcare. The cooperation between clinicians and researchers to develop solutions [7], promoted by policymakers and supported by the industry, has the potential to ensure that innovations within the MedTech sector are introduced, adopted and implemented, maximizing the benefits for healthcare delivery and systems [10].

The adoption of medical technologies requires a strategy to identify and define clinical problems, while providing a clear unbiased statement of need. Among recommendations for the success of innovative medical technology transfer, solutions converge on the earlier involvement of clinicians in the process since the beginning, to educate and train researchers on how to properly transfer technologies to the hospital setting, aligning the vision of all stakeholders involved in transferring valuable ideas with social impact. Moreover, challenges and failure causes that hinder the adoption, diffusion, commercialization, and transfer of medical technologies, such as the absence of screened needs for the development of solutions and technologies, the difficulties in raising capital, and other system and industry barriers are addressed in this dissertation.

The successful adoption of medical technologies relies on a well-defined strategy to identify and address clinical problems while providing a clear unbiased statement of need, and involving clinicians from the inception phase of the process to ensure the smooth transfer of technologies [11][12]. However, it is generally recognized the lack of a

systematic screening process to determine the clinical needs, as well as legal and financial challenges, and obstacles within the healthcare (eco)systems and MedTech industry [13].

This study is focused on these general points and further specific limitations and factors, aimed at overcoming challenges to ensure a positively impactful adoption and integration of medical innovations, based on a patient-centric and value-based healthcare model. With the goal of promoting a successful adoption and transfer of innovative medical technologies, by addressing limitations and unknown factors, it provides valuable insights, organized in Building Blocks for Hospital MedTech Innovation, presented in the Key Lessons Learned and Recommendations section. This dissertation aims to contribute to develop and propose effective frameworks to support medical technology innovation in hospital settings. Driven by the research question “*What effective frameworks can Portugal develop to support medical technology innovation in the hospital setting?*”, the objective is to study and analyze the transfer of innovative medical technologies, focusing on Portugal, and establish a connection among stakeholders, disclose critical points and optimize current practices.

In addition, my experience in clinical environment and technology transfer management inspired me to study medical technology innovation in hospitals. During my academic years, I participated and witnessed to discussions about the management and commercialization of academic technologies. At the same time, I noticed the absence of screened needs for the development of solutions and technologies, the difficulties in raising capital, and other barriers for adoption, diffusion, commercialization, and transfer.

Some projects fail to achieve effective technology transfer due to a lack of transparency, while others were confined to academic settings or did not produce viable outcomes [14]. As an enthusiast in this field, I advocate for the potential and significance of medical technology innovations for common good. Moreover, I argue that their success hinges not only on the innovation teams and the project quality, but also on the stakeholders, partners, system, organization and infrastructure involved. In this dissertation, I will identify some challenges and gaps in the healthcare system and ecosystems, benchmark international references, and analyse data from various sources, including previous research, literature, reports, articles, news, and interviews.

This study is expected to break silos, foster collaboration, interaction and bridge the gap between stakeholders of healthcare innovation in hospital settings and (eco)systems – namely academia, hospitals, industry and policymakers. The study will draw on the perspectives, lessons learned and recommendations of diverse experts from international regional references. Finally, conceptual frameworks to support medical technology innovation in hospital setting will be proposed – the Building Blocks for Hospital MedTech Innovation – that identify and relate the drivers of innovation (oriented to the Portuguese panorama), articulate agents and variables that drive innovation in the Portuguese hospitals’ case.

The aim of this dissertation is to explore the effective frameworks for supporting medical technology innovation in hospital settings, with a focus on the Portuguese context. The Theoretical Background and Key Concepts chapter provides a literature review of the theoretical background and key concepts related to MedTech innovation, innovation models, healthcare ecosystems and agents, and regions as international references, from which the interviewees were selected. The Methods chapter describes the research methodology, which followed a qualitative exploratory sequential approach, based on unstructured and semi-structured interviews. The interviews were analyzed using thematic coding, which generated the themes for the next chapter. The Results and

Discussion chapter presents and discusses the results of the interviews comparing them with the literature review findings. The chapter identifies the main challenges, opportunities, and best practices for MedTech innovation in hospital settings. The Key Lessons Learned and Recommendations chapter draws on the previous analysis to propose Building Blocks for Hospital MedTech Innovation, which are effective frameworks that cover various aspects of MedTech innovation in hospital settings, such as: Innovation Process in Hospital Setting, Innovation Process Flowchart, Holistic Patient Care, Addressing Unmet Needs and Valuable Ideas, Collaborations and New Perspectives, Inclusion of Society in Innovation Models – the fifth helix, Innovation Networks, Commercialization Programs and Platforms, Education and Training on Hospital MedTech Innovation, Specialized Centers, Professionals and Dedicated Structures. The Conclusions and Future Improvements chapter concludes this dissertation by summarizing the main contributions and implications of the study, acknowledging its limitations, and suggesting directions for future research.

Theoretical Background and Key Concepts

2.1 Innovation

Innovation can be defined as the implementation of new and adaptive solutions with commercial and societal impact, exploiting technologies or inventions that create value, drive economic growth and promote international competition [15][16]. Organizations may opt between closed or open innovation, depending on their objectives – closed innovation focuses on internal idea development and dissemination; open innovation involves external ideas and resource acquisition, particularly related to globalization and new solutions through inbound or outbound strategies of knowledge exploration or exploitation [17]. Innovation ecosystems are structures that consist of agents (or stakeholders, including organizations and members) and interactions, alongside non-economic elements as technology, institutions, sociological dynamics, and culture [16]. Within these structures, agents interact and collaborate to generate value in a specific field by fostering perspectives, shaping visions and ideas, and leveraging resources within entrepreneurial communities [18]. Innovation ecosystems have a positive impact on healthcare and the development of innovative products and services, particularly in terms of enhancing access, diagnosis, treatment, outcomes, quality, cost-effectiveness, efficiency, and end-user experience of technologies transferred [19] to improve healthcare systems [4][5]. In the context of this dissertation, it is important to define the concepts such as adoption, diffusion, and transfer, since these terms relate to both the technologies and the agents of the process in study. Adoption refers to the desired acceptance and use of an innovation by an organization [20]. Transfer consists of the act of sharing knowledge and technology between organizations involved in the development of innovative technologies with an emphasis on the fit and suitability [21]. Diffusion means that innovation is communicated and disseminated among stakeholders [20].

2.1.2 Medical Technology Innovation

The MedTech sector encompasses products, services and solutions aimed to prevent, diagnose, and treat clinical conditions. In 2021, the MedTech industry reached a global market value of approximately 550 billion euros [22], with North America and Europe accounting for 36% and 28.9% of the global revenue, respectively [23]. The industry also boasts high profitability, with an average margin of 22%, and is expected to increase its profit pool to \$72 billion by 2024, a 38% rise from 2019, driven by innovation in premium

products and industry consolidation [24]. Medical technologies have enabled the cure of previously intractable conditions, the enhancement of quality of care and the optimization of healthcare delivery [1][2][11] – fact which might justify the increased demand for medical technology in the European Union, where the sector contributes to the economy with more than 32,000 medical technology firms, employing more than 730,000 people [25]. Moreover, according to Evaluate MedTech [26], the sector heavily invests in research and development, with an average estimated rate of around 8%.

Medical technologies aim to improve patient safety, minimize medical errors, and support shared decision-making in diagnosis and treatment [5][7]. Hospitals are ideal sites for the innovation cycle of medical technologies, from ideation and development to adoption and implementation, as they can integrate them into clinical practices, automate manual processes, simplify workflows, and alleviate the workload on healthcare professionals and systems.

Medical technologies face several obstacles in their development, transfer, adoption, and implementation. These include varying and complex regulations across countries regarding safety, efficacy, and quality assurance [27]; high costs and time demands of research and development, clinical trials, and regulatory compliance (especially challenging for smaller companies and startups) [13][24]; risk and cost-effectiveness evaluation of new technologies [28]; lack of compatibility with existing systems [2][30], limited access to and sharing of large data sets for training and validating medical technologies [30]–[32]; accountability of healthcare professionals and innovators, as end-users expect evidence of value [33]; resistance of hospital community to adopt and implement new technologies that disrupt established medical practices and clinical workflows [27][28]; and ethical implications of risk and benefits for stakeholders, particularly patients and healthcare providers [18].

2.1.3 Technology Transfer in Medical Technology

Notwithstanding, the MedTech industry strives to collaborate with hospitals by developing innovative solutions, while hospitals seek to improve their performance and practices by adopting new technologies [11]. Innovative medical technology demands a long-term strategy until it reveals to be profitable, which requires patience, dedication, and a willingness to learn throughout the process [10]. However, historically, mostly due to the high-risk associated, the healthcare sector has been slower to adopt and integrate medical innovations in comparison to other sectors as retail, media, transportation, and hospitality [36]. Hockaday [37] defines medical technology transfer as a complex and challenging process of transitioning from innovative ideas to exploitable scientific results: with Hospitals participating across the whole process and in all the phases from ideation to commercialization, and Government and Regulators responsible also for promoting, supporting, and fostering the articulation between stakeholders [38]–[40]. Figure 1 describes the medical technology innovation transfer process, agents involved, their interactions and contributions in each phase – which are further discussed in this chapter, when analysing and introducing the Triple and Quadruple Helix Models.

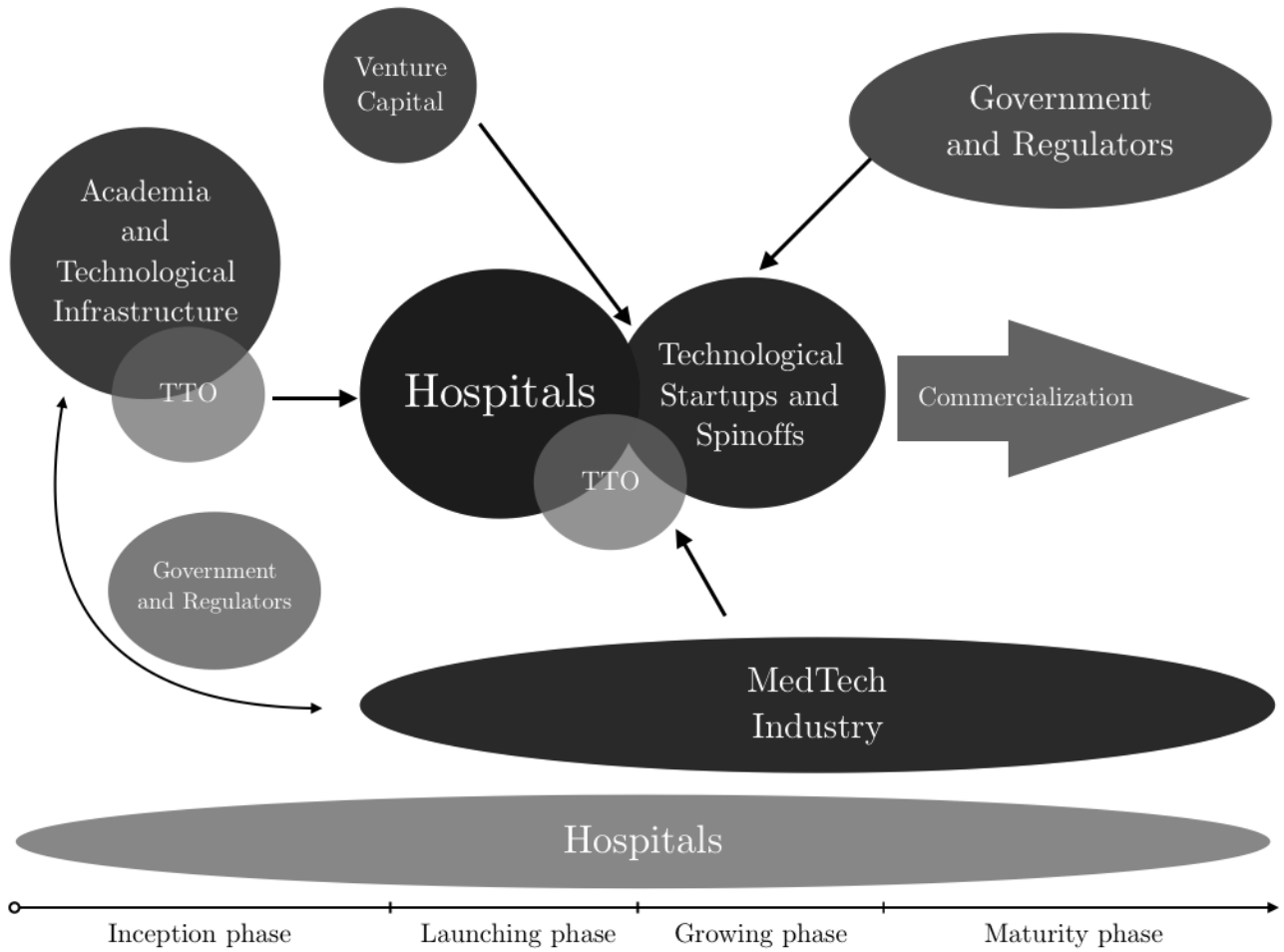


Figure 1. Overview of the medical technology innovation transfer process, agents involved, their interactions, and contributions in each phase. Adapted from [38]–[40]. Hospitals are represented not only at the center but also along and contributing to the full process (as represented in lower opacity), and so Government and Regulators are key in fostering and promoting the approximation of different agents in an earlier phase (as represented in lower opacity).

Universities, academic and research institutions are vital for the medical technology sector. They can impact societies as they possess a wealth of expertise and resources that leverage technology transfer mechanisms to facilitate the translation of innovative scientific results to be commercialized with clinical applications [5]. Complementary, MedTech start-ups and spin-offs are active players in the industry focused on offering innovative solutions, access to new markets, and opportunities for value creation. Start-ups are founded by entrepreneurs who have innovative technology to address clinical needs. Spin-offs are created by researchers or employees who developed a technology within an academic or technological institution, or a larger company and later form an independent entity to commercialize it. However, according to 2019 data, 90% of MedTech startups eventually fail [41].

Technology transfer is the process of transferring scientific knowledge and results, from academia, into products and/or services to be commercialized with or for other agents. Part of technology transfer activities aims to link academic, industry, and business

environments, requiring multiple competencies such as legal expertise, marketing and negotiation skills, and multidisciplinary and knowledge management [37].

Especially in public hospitals, the medical technology innovation transfer process is particularly hindered, where health systems are complex and care models are fragmented, denoting incongruent regulations, and a lack of interoperable structures, incentives, and resources. Hockaday [37] delves into the contribution of hospitals as key partners in the process, as expertise, funding, and other resources providers, emphasizing their role as an essential partner for the MedTech industry to design, test in clinical setting [37] and enter the market. The next sections will focus on the instrumental role of hospitals in the medical technology transfer process, highlighting its articulation with the industry, as well as with academia, government, regulators, and the most relevant causes of failure.

2.1.4 The Role of Hospitals in the Medical Technology Transfer Process

The literature on the management of medical technology in the hospital setting is fragmented, but it shows the need for organization and integration to implement [3]. From ideation to commercialization, MedTech innovation requires the involvement of experts with different backgrounds and resources – such as data, feedback from the hospital community (patients and healthcare providers), physical space and equipment –, and access points at every stage of the process [7][10]. Medical technologies improve the efficiency, practicality, and accuracy of care for the community, allowing healthcare providers to focus on essential medical tasks without distractions from daily and administrative tasks [42]. They also enable more comfortable and convenient treatment for incurable diseases that were previously unavailable. Additionally, they reduce financial costs and expenses and shorten treatment time for hospitals, administrators, policymakers, insurance companies, and other entities [43].

According to Polónia and Gradim [17], hospitals should adopt open innovation strategies that involve multiple agents, emphasizing strong social interactions, when implementing organizational changes. To achieve this, the barriers that create misperceptions about the objectives of innovation concepts and processes must be overcome. These barriers include clinicians' resistance to external knowledge and new technologies, scarcity and misalignment of incentives, product development time and costs, intellectual property protection, and regulatory affairs.

Hospitals facilitate innovation by collaborating with innovators, policymakers, researchers, and industry [5], aimed to address real clinical needs of patients and healthcare providers. This way and through innovation processes, they can benefit themselves and other stakeholders by testing and validating new technologies, adapting and re-designing innovative solutions for later adoption and implementation, ensure their cost-effectiveness and market entry. In 2023, the MedTech sector is expected to face financial challenges and increased research and development demand [42], so it needs to be flexible, adaptable, innovative, and invest in cross-sector partnerships and academic collaborations. Collaborations and partnerships are valuable once the hospital setting is ideal for clinical immersion, prototyping, testing, and de-risking [9][36]. Hospitals can be understood as a platform for collaboration between academia and technology infrastructures, patients, clinicians, and industry – serving as the contact point between stakeholders for knowledge sharing, networking [19], and accelerating the transfer of innovative medical technology [45].

2.1.5 Causes of Failure in Medical Technology Innovation

The success of medical innovation depends on different aspects, namely the level of investment, evolving regulations and policy, clinical (and market) demand, scientific evidence, and technology adoption and implementation in clinical workflows.

The healthcare sector resists integrating new technologies, facing several barriers such as technology-averse physicians, professional autonomy, privacy concerns, lack of incentives and technical support [36]. According to Deloitte, medical technology innovations' success depends on how well the stakeholders adapt to clinical needs and digital technologies, and navigate policy and legal constraints [46]. In addition, EY concluded that to succeed, MedTech industry players must balance short-term and long-term goals, leverage core capabilities, and invest in partnerships and collaborations [47].

At the organizational level, hospitals and healthcare professionals lack incentives to implement medical technologies and digital health systems or share data, impeding the digital transformation of healthcare [36]. This not only restricts the potential of exploiting patient data across systems but also negatively affects the progress of the healthcare ecosystems toward innovation. Further challenges involve the high costs, loss of productivity during the transition to new clinical workflows, concerns about the future obsolescence of technologies, and, even in the case when organizations adopt medical innovations, clinicians choose to avoid using them [36].

2.1.6 Healthcare Ecosystems

The development of an ecosystem is gradual and long-term, involving different agents who identify a specific issue of concern and devise an effective solution, followed by the creation of connections and partnerships [7]. In the near future, healthcare ecosystems will transition from a model of competition to a model of collaboration, where the whole ecosystem provides an optimized cycle of care and improved outcomes at a larger scale [7][34].

By contrast with a system – closed, static, linear, and hierarchical –, an ecosystem is characterized by its open, dynamic nature, non-linear component interactions, and high level of collaboration and cooperation [19]. The successful translation and adoption of medical technology innovation with social impact require mission-driven ideation and development, demand-driven policies that focus on the healthcare system and overcome inefficient models, and the establishment and promotion of ecosystems where all the agents/stakeholders collaborate [48]. Figure 2 illustrates the roles, actions and contributions of agents involved in medical technology innovation and healthcare ecosystems, explored in this section, analysing a model which considers innovative hospitals.

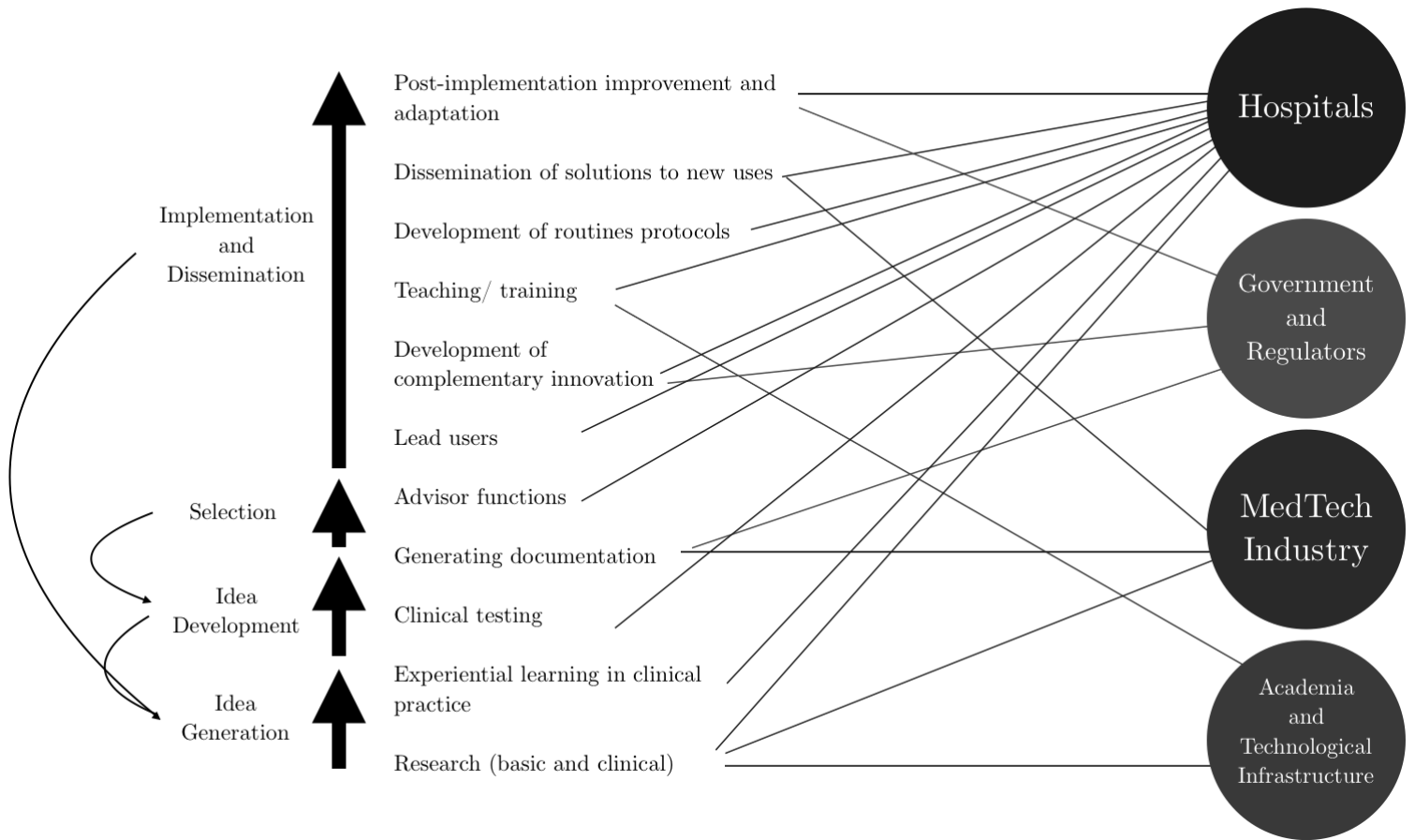


Figure 2. Roles and contributions of Quadruple Helix Model agents in healthcare ecosystems and medical technology innovation process. Adapted from [38].

The Triple Helix Model, proposed by Leydesdorff and Etzkowitz [39], suggests that innovation ecosystems are shaped by dynamic interactions between the industry, government, and academia. In this model, agents' traditional boundaries and roles are transcended, resulting in a system of interdependent relations: the industry is the centre of production, the government facilitates reliable and stable interactions and exchanges through contractual mechanisms and incentives, and academia acts as the source of knowledge and expertise. The three agents are the main drivers of the collaborative network that shapes ecosystems, fostering and sustaining the interconnections between the institutional pillars, facilitating the transfer of knowledge, and coordinating the co-creation of new values and innovations with a shared vision [19].

The contributions, roles (Figure 2), and importance of the agents in fostering innovation vary along the evolution of the innovation process. Therefore, a correspondence between Figure 1, Figure 2, and the contrast with the previous analysis [39] on innovation processes and ecosystems resulted in the following analysis on MedTech innovation transfer.

Inception phase — in close partnership with hospitals, the need is validated, idea is generated, and the innovation team, resources, and first prototype are established. Universities and research institutions are the main sources of knowledge, technology, and human capital, but they also participate in entrepreneurial initiatives (namely in incubators, accelerators, venture funds and spin-offs). Industry (including accelerators and business angels) provides funding,

mentoring, and networking opportunities, while corporations engage in early-stage innovation – collaborating with academia, investing in startups, or acquiring them. The government fosters the collaboration between the agents and supports entrepreneurship (through tax incentives, regulation facilitation, collaboration promotion, and the provision of platforms for testing and showcasing new technologies).

Launching phase — refers to the phase where the technology attracts interest and capital, and agents (hospitals, primarily) provide feedback, engage in designing and testing, and initiate the diffusion and dissemination of the technological innovation among interested entities. It is crucial to prove the effectiveness and viability of technologies in this phase. Academia continues to provide knowledge, human capital, as well as education and training programs. Industry stakeholders, especially venture capitalists, become prominent funding sources, providing guidance, connections, and credibility; and corporations increase their involvement by establishing corporate venture funds, innovation labs, or open innovation platforms. The government maintains entrepreneurship support by offering tax incentives, facilitating regulations, fostering collaboration, and providing platforms for testing and showcasing new technologies, promoting initiatives to nurture regional innovation networks and clusters.

Growing phase — the technology undergoes rigorous testing and validation of prototypes, accompanied by a de-risking strategy to assess its viability and safety for adoption in the hospital setting. This phase brings the technology closer to market competition, requiring increased involvement in regulatory compliance and pathway adherence. Not so proactive as in previous phases, academic institutions keep providing knowledge, expertise, and human resources, but now with a focus on education, training on innovation concepts and activities, establishing strategic partnerships with industry and government agencies to facilitate innovation, technology transfer, and knowledge dissemination. Industry stakeholders reinforce their commitment to innovation through the acquisition of startups, the creation of joint ventures, and technology licensing. The government fortifies its supportive role in fostering entrepreneurship and increasingly becomes influential in policymaking and regulatory compliance, accelerating market entry.

Maturity phase — the final phase when technologies reach stability and profitability within the market, face higher competition, and seek new opportunities for innovation and expansion. Academia intervenes with less expression as companies and corporate research laboratories expression grow. The industry assumes the most important role as venture capitalists seek to exit their investments in startups through, for example, M&As; corporations solidify their market position by acquiring startups, creating joint ventures, licensing technologies, and facing disruption from new entrants or technologies. The government plays its role in policymaking, balancing the interests of stakeholders (as consumers, workers, investors, and competitors), and regulating the social and environmental impacts of innovation.

The Triple Helix Model is characterized as an innovation ecosystem and has evolved over time [16][40][51]. Recent literature extends and incorporates a social dimension, proposing the Quadruple Helix Model [49][16]: the most common model to characterize

healthcare ecosystems [49], and the economic growth driven by sustained innovation across the four interrelated helices [16].

Healthcare ecosystems are shifting from a centralized and linear to a decentralized and open model, involving the co-creation of value by civil society [49]. This requires the collaboration of various actors in innovation processes, such as patients, healthcare providers and administrators, healthcare institutions and organizations, governmental and non-governmental agencies and regulators, and the industry, and external actors – such as universities, research institutions, non-profit and public institutions – in innovation processes [23]. In this dissertation, the Quadruple Helix model was adopted and, following the perspective of the study of Moreira et al. [2], hospitals will be considered the fourth helix – once the hospital community comprises both end-users and social actors of innovative medical technologies. Therefore, the considered four helices Academia and Technological Infrastructure, MedTech industry, Government, and Hospitals, thus confirm a synergistic effect between agents.

Academia and Technological Infrastructure – with universities and research institutions recognized as sources of expertise, knowledge, and innovation, which provide intellectual capital and ideas.

MedTech industry – including companies, venture capitalists, firms, and other businesses at the forefront of the development and commercialization of innovative medical technology products and services, driven by real-practical needs to solve through valuable ideas.

Governments and Regulators – comprising policymakers and actors able to shape the policy and regulations for the deployment and commercialization of innovative medical technologies and entrepreneurship, providing funding, supporting research, promoting the articulation of the other agents, and ensuring equitable distribution of the benefits to society.

Hospitals – covering clinicians and patients, who are the primary users of medical technologies, collaborating in the identification of clinical needs, designing, testing, and providing feedback along the innovation process, de-risking, and evaluating the cost-effectiveness of innovative medical solutions.

The MedTech sector has distinct market patterns that are shaped by regulatory, normative, and cultural factors [50]. These differ across national, regional, and local requirements, depending on the role and nature of the end-user, with business-to-institutional sales being slower and more limited in terms of internationalization when compared to business-to-business approaches [51]. The academic environment is a catalyst for innovation, technology development, and company creation, providing a “neutral environment” for medical technology firms and clinicians to support programs that focus on “learning by doing” [31]. These interactions are vital for healthcare at different levels, with also educational and economic benefits as outcomes [50][51].

The integration of hospitals establishes a participatory framework [2], enabling the involvement of society to shape the future with a focus on the interconnections among the four agents. This fosters the sharing of knowledge and information among all the stakeholders and enables each pillar to bring its strengths and perspectives to the discussion, thereby contributing to the generation of innovative and valuable solutions.

2.1.7 Medical Technology Innovation in Different Regions

The biggest global medical technology players [54] are the United States (43%) and the European Union (27%), representing 70% of the world market – the United States is the leader in medical technology innovation [25]. The combined two largest market sizes on medical technology, North American and European [54] were estimated to be worth USD 270.4 billion in 2020 and are projected to increase at a CAGR of 11.5% between 2021 and 2028 [55]. Healthcare systems in Europe and North America have aimed to support the development of new medical innovation technologies that can be effectively implemented in clinical practice as medical technologies or clinical procedures. They have also strived to structure the medical technology innovation process in a way that produces meaningful and applicable results with a direct positive impact on human health and accelerates the translation of innovation into practice [56].

Deloitte reported that 2023 will be a period of more patient-centric, co-created experiences, including patients as partners in decision-making throughout the cycle of care, enhancing the personalized and improved delivery of healthcare [57]. Local institutions lack effective coordination across Europe for knowledge, contact sharing, or synergy identification [56]. Also, compared to the US, the European Life Sciences industry has experienced slower growth due to insufficient funding – taking the example of the Swiss startup Bioegen, which is planning to relocate its headquarters to the United States, to access better financing and conditions for its development [58].

2.1.7.1 Region – United States

The literature presents the United States of America as the global leader in medical technology innovation [25][54] – a fact evidenced by its world-leading position in terms of innovative healthcare solutions that receive regulatory approval [56]. According to Euronews' global ranking in 2023, the US has the best hospitals overall, with 10 out of the top 25 and 46 out of the 250 hospitals listed [59].

Intellectual property is instrumental for effective technology transfer, especially in such high-risk market as healthcare is. Patents can facilitate technology transfer, by providing incentives for firms to use academic research through the exclusive rights granted to the patent holder, thereby encouraging investment in research and development and generating revenue through licensing or sale to third parties, which can provide universities with a financial motivation for research and development investment and support further activities [60]. The United States has done in the past major reforms to foster innovation, empowering the Academia. The Bayh-Dole Act of 1980 allowed universities, non-profit research institutions, and small businesses to own, patent, and commercialize innovations that result from federally funded research [58][60]. According to Patval's survey [60], university-owned patents represent a much lower fraction in Europe than in the US and universities in Europe are more likely to patent results from collaborative work with the private sector than from independent research.

Patent ownership by universities can promote and support collaboration by facilitating technology transfer from research entities to market participants – namely startups, spin-offs and established companies –, act as a marker of innovation and a repository of technical knowledge – helping to draw potential collaborators or sponsors from academia or industry –, and enhance the reputation and visibility of the academia and its researchers, encouraging further innovation efforts [68][69]. Considering the example of Stanford University, renowned for its excellence in medical technology innovation, stands as a paradigmatic example that effectively applies the recommended best practices

for the transfer of medical technologies to hospitals, placing hospitals at the center of the innovation process. As a result, its model, culture and programs served as an inspirational blueprint for numerous countries worldwide [45].

Stanford Medicine

Stanford Medicine is an institution comprising Stanford Children's Health, Stanford School of Medicine, and Stanford Healthcare [64] – part of the Stanford University, established in 1908 in Stanford, California – which offers a variety of educational programs, dedicated to improving health through patient care, research [53] and translation of knowledge [65]. The school has a strong emphasis on interdisciplinary research collaboration [53], having received funding from the NIH and other organizations for research projects [53]. In the mid-1950s, Stanford Medicine moved to Palo Alto, within the university campus, which was a decisive factor for Stanford's phenotype as a research-intensive medical school [53]. In 1959, Stanford recruited of extraordinary basic scientists to Palo Alto, remaining clinical in San Francisco and establishment of the Stanford Hospital on the same campus as the new school of medicine. This transformed Stanford Medicine into an Academic Health Center, an educational institution that integrates multiple components of the health care system, including medical education, research, and patient care. In its early years, the focus of students and academia was research and education oriented but, over time, clinical services increased and, today, faculty care for over 80% of patients admitted to Stanford Hospital [53].

Stanford Medicine has promoted and supported medical technology innovation in its environment, as Stanford Center for Innovation in Global Health, which supports scientific and clinical research, implementation science, and development of innovative solutions in health care implementation or delivery [66], Stanford Biodesign Fellowship that provides postgraduate health technology innovation training [53], and Healthcare Innovation Lab at Stanford Medicine that accelerates precision health technology research and development and clinical adoption [67]. Moreover, the school hosts healthcare hackathons, such as Health++, an annual two-days initiative co-hosted by Stanford's Medical and Engineering Schools that brings together over 300 engineers, designers, healthcare professionals, and business experts to validate their ideas and solutions for healthcare and technology challenges [68]. The success of Stanford Medicine is a result of contributing factors, including its entrepreneurial culture, proximity to other schools and school size [53] – from the distinctive “Stanford Culture” that promotes horizontal collaboration among faculty members with limited growth, resulting in a cohesive and collegial atmosphere that stimulates creativity and problem-solving; to the physical proximity of the medical to other schools, enabling multidisciplinary interactions and partnerships and fostering a diversity of perspectives and approaches that enriches medical research and innovation; also considering the entrepreneurial spirit, which benefits from its location in Palo Alto, the birthplace of Silicon Valley and a global hub for technological advancements [69] (facilitating the engagement and collaboration of the medical school with the MedTech industry, allowing for the translation of research findings into practical applications); and the relatively small size of the medical school compared to its peers, which enhances the cross-fertilization of knowledge, the communication between innovators and clinicians, the personalization of training and research opportunities, and the alignment of interests and expertise among faculty and students.

2.7.1.2 Region – Europe

According to the literature, medical technology was the second most active field for European patent applications in 2021, with more than 15,300 filings, representing 8.1% of the total number of applications [70]. However, Europe faces challenges that hinder the translation of innovative healthcare advances into commercialized medical technologies. This phenomenon, known as the “European paradox,” highlights the disparity between the leading role of European research institutions in high-level scientific output and their relative inability to transfer innovation into successful commercial products, also in MedTech [60]. This inability and less agile dynamic can be attributed to various challenges, such as sharing and using personal (health) data, clinicians’ reluctance to adopt innovative medical technologies and the fragmented European funding [56].

In Europe, influenced by the Bayh-Dole Act, most universities may claim to own the intellectual property generated from their research achievements [60] – a practice which aims to regulate the commercialization of intellectual property, ensure the proper allocation of financial resources, and encourage scientific innovation.

Several medical technology innovation training programs have been emerging worldwide, including in Europe [45]. These programs offer training, mentorship and networking opportunities with industry experts for clinicians or other professionals who have an innovative idea. Europe has also adopted the need-driven innovation approach that aligns with real clinical needs. This approach involves engaging clinicians more extensively and earlier in the MedTech development process and educating them on how to identify and pursue valuable innovation. A qualitative survey [13] on Biodesign-based teaching programs in Europe examined Resources, Activities, Academic Performance, and Transfer Performance topics and found that there is an increasing demand for medical technology innovation and innovative training programs that address unmet needs, as well as an increased cooperation among stakeholders within healthcare ecosystems, as a productive unit with the common goal of developing need/market-driven technologies. A review [45] on MedTech acceleration programs in Denmark, France, Spain and Switzerland – respectively, Medico-Innovation, I-SIP, Moebio, FNTC and D-HEST – showed that, despite their specificities, they all aim to bring innovation in medical technology closer to the academic environment. Euronews [59] reported that the European countries with the most high-ranking hospitals in the top 10 were Germany, Switzerland, France and Denmark. The following paragraphs will present some of the regional context and best practices.

Denmark

Denmark is one of Europe’s leading medical technology countries, with over 900 companies operating in the MedTech field and being the third most prominent exporter of medical technologies per capita [71]. It has a representative mass of world-leading companies such as Coloplast, ReSound GN, Invacare, Oticon, Philips Healthcare, Widex, Cook Group and Agilent [72]. The healthcare industry is constantly evolving, and Danish hospitals are known for their open collaboration among society, research institutions, and businesses, fostering academic rigor, impactful solutions, and the long-term sustainability of partnerships [73]. They put patients at the centre of a healthcare ecosystem and services that meet all end-users needs [74].

In Denmark, 89% of clinicians report their organization is reasonably well or very well prepared for the adoption of medical technologies [75]. By prioritizing co-creation,

a user-centred design and fostering collaboration among public, private, and citizen stakeholders, Danish hospitals incite innovation based on user needs [80][83]. They also support innovation and technology by investing in modernized hospital infrastructure, for which the Danish government has earmarked 0.9 billion euros namely in medical technology [76] – investments expected to enhance the quality of research and development of innovative solutions. Moreover, they promote collaboration between healthcare professionals and innovators, allowing MedTech industry players to gain a deeper understanding of the clinical and practical needs to meet [73].

Healthcare Denmark is a non-profit partnership based in Odense that operates as a public-private collaboration to promote global recognition of Denmark's healthcare and care-related proficiency and to function as a hub for international innovation and technological advances within the Danish healthcare sector [77]. An example of such innovation is CoLab Denmark in Odense, where a hospital collaborates with a startup to develop innovative solutions for patients [73]. The Danish Industry Foundation also launched the MedTech Bridge program to assist medical device and digital health Danish companies in expanding their operations in the United States by providing guidance on market entry and coaching to materialize their potential [78].

Germany

The healthcare industry is a huge fraction of the German economy, employing one out of every six workers, with an expected CAGR of 5.1% in euro terms between 2020 and 2025 for the German medical equipment market. The healthcare technology industry accounts for 8.3% of the total exports, resulting in sales of 131.2 billion euros [79]. According to the 2021 World Index of Healthcare Innovation, Germany ranks third in the world [80], first for healthcare innovation quality [81], and dominates the European MedTech market [82] with the largest market share and 7.6% of the healthcare expenditure spent on medical technology in 2021 [83].

The German healthcare system prioritizes preventative care and is regulated by different government bodies, such as the Federal Ministry of Health and the Federal Joint Committee. It also strives to improve efficiency and cost-effectiveness [84], while maintaining a robust healthcare infrastructure, plentiful hospital beds, and well-trained staff [62]. However, the system is decentralized and self-governing, which makes it challenging to adapt to innovation. The German government aims to modernize the system with new laws.

Charité is associated with Universitätsmedizin Berlin and ranked seventh place overall best hospitals in Europe [59]. It is associated with the Berlin Institute of Health (BIH), a non-profit biomedical research institution established in 2013 as a joint initiative and formally recognized as a public corporation in 2015. Berlin Institute of Health is dedicated to translational research and precision medicine, focusing on translating biomedical research findings into personalized approaches for prediction, prevention, diagnosis, and therapy by addressing unmet medical requirements, leading to a better quality of life for patients [85]. The institute is mainly funded by the Federal Ministry of Education and Research, with some additional funding from the State of Berlin by 2026 [86]. It integrates staff across four Berlin campuses with an annual estimated budget of more than 100 million euros [85].

Switzerland

Recognized by its innovation and high-quality manufacturing, Switzerland is a leader in the global MedTech industry, with over 1,200 companies, ranging from small startups to large multinational corporations [87], employing approximately 67,500 people, creating 4,500 new jobs in the past two years [88].

The Swiss MedTech industry remained resilient despite the pandemic challenges and generated revenues of 20.8 billion Swiss francs in 2021, thanks to the efforts and flexibility of the companies [88], however companies should continue to invest in innovation and digitalization to remain competitive [87]. The Greater Zurich Area is a hub for the Swiss MedTech industry, with over 200 companies – including large multinationals such as Roche, Siemens, and Johnson & Johnson – and research institutions. It has a strong focus on research and development, with a high number of patents filed in the field [89]. The Swiss government supports the MedTech industry through funding for R&D and initiatives to attract and retain talent [87], being Switzerland is home to some of the world's leading universities and research institutes [88][90]. The Swiss MedTech industry invests around 12% of its revenues in research and development, fostering innovation in the sector [72].

The joint technology transfer office of the University of Lausanne and the University Hospital of Lausanne, PACTT, is a public support organization that bridges the gap between academia and industry, aimed to help researchers bring innovations to market while creating value for society [90].

Spain

In 2021, Spain spent 115.48 billion euros on healthcare, equivalent to 9.3% of its GDP, and ranked sixth in Europe for medical product expenditure, with a value of around 8 billion euros [92][93].

The Spanish healthcare system is mainly public, and the government is the main purchaser of medical technologies. To foster the development and adoption of innovative medical technologies, the government increased the budget for RedETS, a network that assesses the clinical and economic value of new technologies, from 6 to 10 million euros in 2021, and implemented tax incentives and subsidies for the MedTech sector [92][94]. Spain has a strong collaboration network among academia, research centres, hospitals, companies, policymakers, and public authorities. The Spanish MedTech sector is competitive and diverse, with a strong presence of both local and multinational companies. Some examples are Roche Diagnostics Spain, Philips Healthcare, Hospital Clínic in Barcelona, Medtronic in Madrid, and IVI RMA GLOBAL in Valencia [94]. Moreover, the Catalan life sciences and healthcare sector ranks among the top European ecosystems for its scientific production, economic impact, workforce, revenue, and foreign funding [95]. The MedTech sector has great potential for growth and innovation, mainly due to the Spanish advanced healthcare system and strong R&D capabilities [91]. However, the gap between research and innovation remains a challenge in Spain, influenced by cultural, financial, educational, regulatory, and interoperability factors [93][95]. Nevertheless, Spain offers attractive opportunities for foreign manufacturers to enter the market through various strategies such as partnerships with local companies, acquisitions of local companies, or direct investment [88].

Portugal

In Portugal, health represents an annual turnover of around 34.000 million euros and a gross value added of around 12.000 million, involving close to 105 thousand companies and employing almost 400.000 people [97]. Portuguese hospitals are innovating [98], mostly in new procedures/treatments, at different levels between public and private hospitals [2]. With the growing trend towards consumer orientation, there has been a recent influx of new players looking to enter the healthcare sector, where new entrants (previously engaged in unrelated fields to healthcare and activities) have identified business opportunities, supported by a sociocultural environment [14]. To enhance global competitiveness, it is essential to strengthen healthcare funding and promote autonomy in delivery services [106][107]. However, there is a scarcity of human, material and financial resources [100], as well as a lack of clinical trials and fast approval times [98] by the authorities – considering that Portugal takes six months to authorize clinical trials, while Belgium takes one month [101].

The Portuguese National Health System plays a preponderant role in supervising and managing medical technology in hospital settings within the jurisdiction. The SNS has established a comprehensive framework for accessing and implementing new technologies, and a public portal – to meticulously evaluate the scientific evidence, cost-effectiveness, and safety of the technology, and to emphasize the importance of innovation in the Portuguese healthcare ecosystem, respectively. However, a health innovation strategy is absent, resulting in a scarcity of (trained) clinicians and patients' involvement in the evaluation of innovative solutions [50] – recognizing that the innovation process is typically centered within academia, with narrow connections to hospital setting – and hindering small and medium-sized enterprises and start-ups from focusing on the development of scalable products within the ecosystem [17]. The Portuguese healthcare system primarily consists of state-owned hospitals with limited to no competition between facilities (in comparison with other European countries [102]), which typically overlook the importance of implementing and adopting innovative medical technology. As previously explained, the low adoption of medical technological innovation in hospital settings is often attributed to the lack of partnerships between hospitals and the other agents, supported by the absence of incentives, communication and proactivity among healthcare professionals and innovators to cooperate with [11][82][104]. Partnerships can benefit hospitals by enabling access to new capabilities and solutions that improve outcomes and efficiency, fostering collaboration and knowledge exchange among stakeholders, and facilitating the use of existing technologies that address clinical needs and reduce costs [14][106].

Getting medical technologies approved for use in the European Union, and in Portugal, is a complex and time-consuming process, being regulatory barriers hinder the speed of process approval for marketing medical technologies [103]. Considering the constraints imposed by the restrictive EU data policy, Portugal can effectively handle the existing data generated by patients, hospitals, and other stakeholders through technological services, highlighting the importance of introducing new information systems to standardize data while preserving the privacy of individuals.

Interoperability is a challenge for a patient-centered, digitally enabled, healthcare ecosystem in Portugal [5], which prevents agents in the ecosystem from leveraging data and technology to optimize the patient journey and outcomes. Portuguese hospitals should foster, promote, collaborate, and actively participate in studies and research projects to contribute to the development of the Portuguese healthcare ecosystem. In Portugal, 47.3% of health professionals have never received any training from their organization on the

use of new technologies or digital resources, compared with the European average of 25.5% [75]. Players in the MedTech industry pointed out “Bureaucracy”, “Finding the right technologies” and “Training staff to use technology” as the main challenges for implementing technological innovations in Portugal [75]. Portugal needs almost 700 days to make innovative therapies available, while, for example, in Germany this period does not reach 200 days [99]. A group of decision-makers, clinicians and other KOLs concluded that reducing this time should be a priority [99]. To ensure universal and equitable access to medical innovation, efficient and transparent regulation with auditable mechanisms for evaluation is required [100]. The government must find alternative funding mechanisms for innovative medical technologies, partnering with the industry. According to decision-makers from PHSSR – composed by London School of Economics, World Economic Forum and AstraZeneca –, the development of clinical research requires promoting Portugal as a center of excellence for medical and biomedical innovation by increasing clinical trials and translational research and development [99]. Clinical research has a massive impact on Portuguese NHS finances [98], as investing one euro in clinical trials generates a return of nearly 200% [100]. Some hospitals have started to integrate innovation departments for testing and validating technologies [104].

Portuguese success cases

Aware of the need to change and shift towards the goal, Portuguese hospitals have been progressing, with institutions, initiatives, partnerships, and collaborations noted.

São João Hospital

The São João University Hospital Centre – Centro Hospitalar Universitário de São João – has a proven track record of efficient management and quality care, supported by the implemented business management tools, such as Autonomous Management Units, and hospital management, to streamline areas and improve the standardization of information [105]. The hospital invested in hiring qualified business professionals, allowing for the institution to be competitive with other sectors, and the development of a consistent and strong external communication plan, key to increase the confidence and positive perception of the hospital community [105]. The hospital’s culture of active listening and feedback of its users promoted the dissemination of plans, decisions, and results to the entire hospital community, thus supporting a strong communication plan inside and outside the institution [105]. Even with infrastructure and investment limitations, the hospital improved its care response and quality by consolidating and expanding its Reference Centres and Integrated Responsibility Centres [105], being awarded a prize for the adoption of a system to monitor the daily flow of patients in the obesity service by integrating computerized data into the hospital setting, successfully increasing the adherence to treatment programs for this condition from 30% to 70% [106].

Partnerships Academia-Hospital

To facilitate the development of innovative solutions and provide resources to collaborative projects, 2CA-Braga association and the University of Minho Medical School started a funding program to support clinical trial partnerships: open for applicants with different backgrounds, this initiative helped 2CA-Braga to recruit more than 85% patients of the University of Minho Medical School to collaborate more with other healthcare providers, academic institutions, and companies for consultancy and clinical

research services [107]. Moreover, aiming to develop valuable ideas to be implemented in Portuguese hospitals, the Digital Health Laboratory is a unit of experts with different backgrounds who work with Centro Hospitalar Universitário de Santo António [108]. Primarily focused on the interoperability of different systems, the LSD is a technology incubator that coordinates digital health solutions based on academic research and clinical practice, aimed to facilitate communication between different departments and services, while providing training and partnering with other national and international health units to identify strategic projects and innovative technologies that have potential clinical applications [108].

Portuguese acceleration programs in health

RESOLVE [109] is a technology-based acceleration program that supports the growth of early-stage projects and start-up companies in the healthcare sector, facilitating the transfer of innovative ideas concepts into profitable business ventures. It provides resources such as Proofs of Concept and the validation of prototypes. Coordinated by Research Innovation unit at Instituto de Investigação e Inovação em Saúde (i3s), Resolve-i3s is a Living Lab format in collaboration with CUF. It scouts and selects high-potential technology-based entrepreneurial projects, and operates through Living Labs, platforms for teams to interact with end-users and industry experts. It provides seed funding, mentorship and training by business leaders, network opportunities with investors and other stakeholders, access to state-of-the-art facilities and market access-related regulatory issues and support on certification of medical devices and in vitro diagnostics.

CAC Católica Luz was created with the purpose of strengthening the partnerships between Universidade Católica Portuguesa, Luz Saúde, Hospital da Luz, GLSMED Learning Health and União das Misericórdias Portuguesas [133][134]. Clinical Academic Centers aim to improve healthcare services by integrating care, teaching, clinical and translational research activities of healthcare units, higher education institutions, and public or private research institutions. Previously collaborating, the entities involved in developed this strategy to enhance synergies, to create and align a common institutional culture focused on scientific and clinical quality in an international context. The mission of the hospital group is to achieve the best patient outcomes, through a quick and effective diagnosis and treatment, respecting their individuality, protecting data, while boosting an organizational environment to attract, develop and retain multidisciplinary teams [110].

Also, Portugal is also part of international networks and projects, such as DIGIT-PRE and TEF-Health. DIGIT-PRE [113][114] is a European innovation program that aims to develop and test digital technologies and tools for prevention, prediction and remote care in health. It offers services and access to living labs and test beds for innovative solutions, involving ten partners from seven different ecosystems in Europe. The objective is to create a sustainable network that generates value through inter-linked activities and supports the competitiveness of SMEs, especially in the healthcare sector [114], focused on mhealth apps and devices [113].

TEF-Health [116][117] is an European initiative led by Charité Universitätsmedizin Berlin aimed to develop and test artificial intelligence and robotics solutions for healthcare. It involves a consortium of fifty-one partners (Instituto Pedro Nunes, Centro Hospitalar Universitário de Coimbra, Centro Hospitalar Universitário de São João, Serviços Partilhados do Ministério da Saúde, EIT Health Innostars and Health Cluster Portugal from Portugal) from nine countries (Sweden, Germany, France, Italy, Belgium, Portugal and Slovakia) [117]. The project has a budget of 60 million euros and focuses on personalized medicine and citizen-centered care. In Portugal, the SNS co-

finances the Test and Experimentation Facilities within the Test Beds National Network under the Recovery and Resilience Plan [119][120].

Portuguese Healthcare Hackathons

Hackathons are becoming more frequent in the health sector in Portugal, following international trends. Some examples of these initiatives are: Hacking Health [121] (organized by Glinntt, an IT service provider for health, that challenges students and workers to develop innovative solutions at the interface of health and technology, using a platform that ensures the transparency of the process, and rewarding the best projects with 3,000 euros); X-eHealth Hackathon for Rare Diseases and Rare Cancers [122] (coordinated by SPMS, a public entity, supported innovations in the fields, based on the specifications developed by the X-eHealth project); or Hack for Good [123] (sponsored by Calouste Gulbenkian Foundation, a philanthropic institution, supported social innovation projects that address societal challenges, namely health, rewarding the best ones with 500 euros).

To conclude, this revision aimed to define the key concept and the agents involved in the transfer process, as well as the obstacles and the requirements for successful translation and adoption of medical technologies with social impact, and to use it as a starting point for the data analysis in this study. The key concept is medical technology innovation, which involves the adoption, diffusion, and transfer of innovations among organizations. The agents are academia and technological infrastructure, MedTech industry, governments and regulators, and hospitals, which provide expertise, knowledge, innovation, products, services, policies, regulations, collaboration, and feedback throughout the innovation process. The obstacles are complex and evolving regulations, high development costs and time, risk and cost-effectiveness assessment, lack of interoperability and data access, accountability and evidence of value, and ethical considerations of risk and benefits. The requirements are mission-driven ideation and development, demand-driven policies that focus on the healthcare system, and the establishment and promotion of ecosystems where all the agents/stakeholders collaborate. Additionally, it was defined the different phases of the innovation process (inception, launching, growing and maturity phases), where the interactions, roles and contribution of the agents vary along the evolution of the innovation.

Methods

3.1 Research Question, Objectives and Methodology

The exploitation, commercialization, adoption and implementation of medical technologies requires a strategy to identify clinical problems and provide a clear unbiased statement of need. The failure of transferring innovative medical technology can be prevented by involving clinicians from the start, educating and training researchers on how to transfer technologies effectively to the hospital setting, and aligning the vision of all stakeholders to transfer technology innovation with social impact.

A preliminary literature review from September 2022 to February 2023 was conducted to identify and understand the key concepts, initiatives, and context of the topic, using keywords (Biodesign, Biomedical Entrepreneurship, Healthcare Ecosystem, Healthcare Hackathon, Healthcare Innovation, Healthcare Technology Assessment, Hospital Management, Hospital Setting, Innovation in Hospitals, Innovation Management, Innovative Medical solutions, Medical Technology Innovation Policies, Medical Technology Innovation Support, Medical Technology Innovation, Medical Technology Transfer and Diffusion, MedTech Adoption and Implementation, MedTech Innovation Ecosystem, MedTech Acceleration Program, Technology Transfer in Healthcare, Translational Medical Technology) from journal articles and conversations with relevant stakeholders, and searching on platforms such as Google Scholar, Science Direct and PubMed.

This research followed qualitative methods to explore the best practices of medical technology innovation in hospital settings, based on the Quadruple Helix Model. Qualitative methods aim to understand a phenomenon through the meanings, experiences, and perspectives of individuals and communities, especially when conventional sources of information are insufficient or partial to support a comprehensive understanding of the context or geography [124]. The aim of this dissertation was to study an effective framework to support medical technology innovation in the hospital setting, reason why the research question this study aims to answer is:

What effective frameworks can Portugal develop to support medical technology innovation in the hospital setting?

The methodology used aimed to investigate topics, particularly concerning the role of hospitals in medical technology transfer process, healthcare ecosystems and the best practices that facilitate innovation. The interviews document practical experiences and perceptions of involved agents, identifying challenges, success factors, agent interactions and roles, best practices, and opportunities. Based on the interviews' findings, the study

proposed the Building Blocks for Hospital MedTech Innovation frameworks, which provide key lessons learned and recommendations for effective MedTech innovation in hospital settings. This study contributes to the literature on MedTech innovation in healthcare ecosystems, with a specific focus on how hospitals can support the development, commercialization, adoption, and implementation of MedTech innovation. The flowchart presented in Figure 3 depicts the steps and methods followed to achieve the final objective.

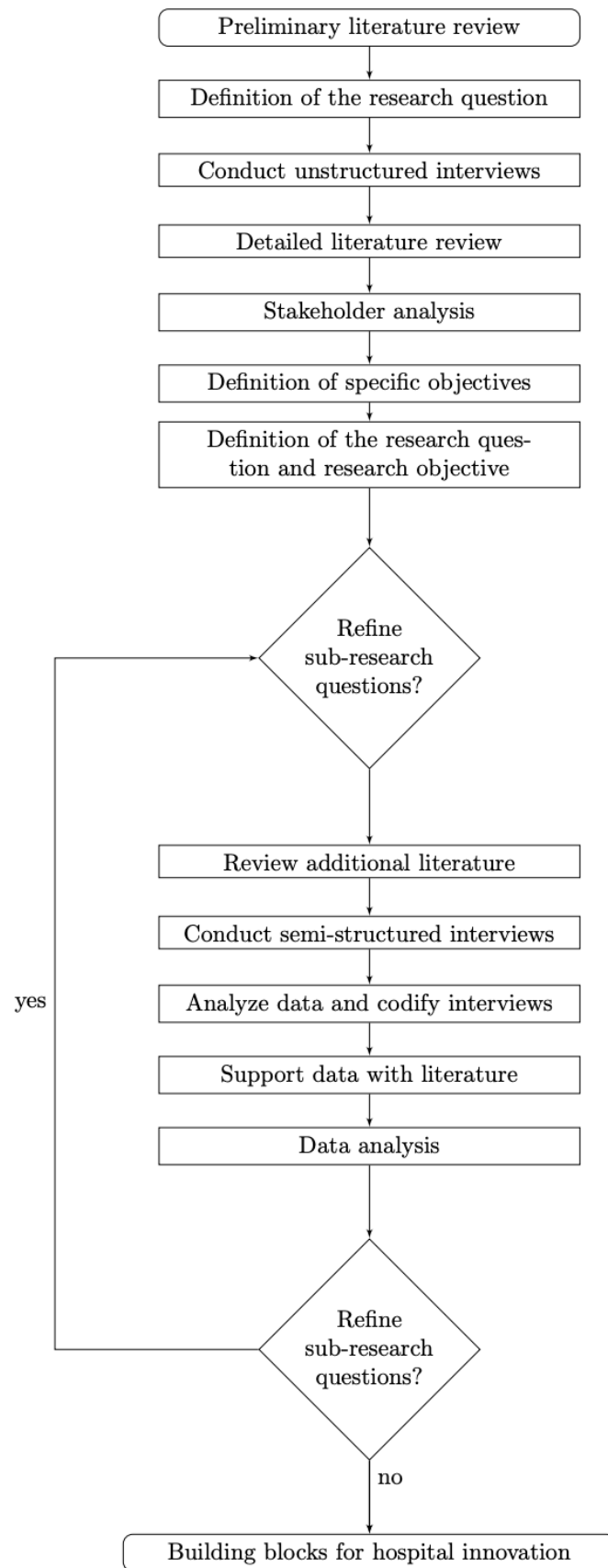


Figure 3. Flowchart of the qualitative exploratory sequential research design.

3.2 Research Design

This study used an exploratory sequential design [124][125] (as schematized in Figure 3) grounded on a review of the literature, as well as on unstructured and semi-structured interviews to benchmark international references and identify best practices to support medical technology innovation in hospital settings.

This research design involved two rounds of interviews with different professionals involved in medical technology innovation within hospitals, following a preliminary literature review. Consistent with the mixed method suggested by Yin [125], to ensure reliability of the research conducted, the first round of interviews served as a preparation for the subsequent, semi-structured data collection. From the outset, it was intended that the sample of interviewees should guarantee the inclusion of professionals from the benchmarked regions with distinct realities, some international references and others as similar references to Portugal, which is the focus of the study (in section 3.3 the selection criteria is detailed).

The first phase of the study consisted of unstructured interviews with four TTO managers from different regions (France, Spain, Switzerland and United States). Unstructured interviews were open-ended and lack a preconceived idea, conducted with minimal planning or organization [125] to acquire preliminary insights into the topic [124]. These interviews aimed to validate and refine the research objectives, questions, and scope, as well as to identify the key challenges, needs, measures, and stakeholders related to medical technology innovation.

The second phase of the study involved a review of additional literature and a second round of interviews consisting of semi-structured interviews – following a flexible set of questions to explore, validate and gather additional information [124].

3.3 Data Collection

This research used a four-step process to investigate the best practices of medical technology innovation in hospital settings, based on the Quadruple Helix Model.

The first step consisted of a preliminary literature review to identify the key concepts and theoretical background of the topic, drawing from various sources such as previous research, literature, reports, articles, news, and interviews. In the second step, unstructured interviews were conducted to validate and refine the first preliminary review of the literature, with four TTO managers – justified by the fact that those agents should be ones who should have a pivotal role in the Quadruple Helix Model – in different regions (France, Spain, Switzerland and United States), to validate the challenges (what to study), the need to address them (why to study), the measures implemented to overcome those (how to study) and the stakeholders theoretically identified (who to study). The third step, complemented with a more comprehensive review of the literature to refine research objectives and questions, semi-structured interviews conducted to compile recommendations, best practices, lessons learned, and findings. Semi-structured interviews were conducted with professionals from Denmark, France, Germany, Spain, Switzerland and the United States – that, according to Newsweek and Statista [126], have some of the best hospitals in the world. These countries are also leaders in medical technology innovation in the hospital setting, as explained in section 2.1.7. In addition, according to the European Innovation Scoreboard 2022, Denmark is an Innovation Leader, France and Germany are Strong Innovators, and Spain is a Moderate Innovator [127]. Furthermore, according to WIPO's 2022 Global Innovation Index [128], Switzerland and the United States are the most innovative economies. Similarly,

interviews have been conducted with professionals working in Portugal to characterize the current state of play in the country.

The fourth step consisted of further literature review to supplement the data from the interviews, ensuring validity and promoting a well-founded discussion of results. In this step, the selection of articles, news and other sources of complementary information was more rigorous, with preference given to current articles and reports (ideally no later than 2019) and recent news and press releases related to the topics. The timeliness of the webpages consulted was duly verified. This contributed to an informed and careful analysis, supporting a well-founded subsequent discussion of results.

The interviews were conducted in a confidential and professional way, with consent from all participants and respect for their privacy. The interviews were preferred to be face-to-face meetings, but written testimonials were also accepted when interviewees preferred (namely due to language' barriers). The interviews lasted approximately 60 minutes and involved 33 agents from two different regions – American and European – from different countries. Table 1 shows the number of interviews conducted per country and per agent of the Quadruple Helix Model.

The triangulation of these sources provided reliability and strengthened the results, as well as contributed to ensure a reliable discussion [124][125]. A summary on the key lessons learned, recommendations and best practices of each interview were recapitulated in Annex I.

Table 1 – Number and representation of Quadruple Helix Model' agents interviewed per country.

Country	Number of interviews conducted	Number of Quadruple Helix Model' agents represented
Denmark	3	1 Hospital, 1 MedTech industry, 1 MedTech industry (venture capital)
France	4	1 Academia and Technological infrastructure, 2 Government and Regulators, 1 Hospital, 2 MedTech industry
Germany	2	1 Hospital, 1 MedTech industry
Portugal	10	1 Academia and Technological infrastructure, 1 Government and Regulators, 2 Hospital, 3 MedTech industry, 2 MedTech industry (venture capital)
Spain	5	1 Government and Regulators, 2 Hospital, 1 MedTech industry, 1 MedTech industry (venture capital)
Switzerland	3	1 Government and Regulators, 1 Hospital, 1 MedTech industry
United States	6	2 Academia and Technological infrastructure, 2 Hospital, 2 MedTech industry

3.4 Data Analysis

Based on the preliminar literature review and unstructured interviews, a rigorous stakeholder analysis was performed to identify the professionals involved in medical technology innovation within hospital setting. This analysis helped to refine the specific objectives and questions and identify the professionals to be interviewed for a second round of semi-structured interviews. A stakeholder analysis was conducted between the two rounds to identify relevant regions, roles and actors in medical technology innovation within hospitals. The data collected from the interviews were organized and summarized to update and refine the research objectives and questions, as well as to corroborate and support the data analysis with the literature review. To decrease the ambiguity, subjectiveness, and breadth of the research question, which covers the past, present, and future, more research questions were considered to divide the main topic into subtopics to be analysed and effectively tackle the fragilities of the system and optimize the process:

What are the main challenges and causes of failure when transferring MedTech for hospital setting? What are the key factors that contribute to successful MedTech innovation for hospital settings?

How do different stakeholders (e.g., hospitals, patients, industry partners) contribute to the healthcare ecosystem and how can their roles be optimized to support medical technology innovation in hospital settings?

How can hospitals engage and collaborate with all the stakeholders to promote holistic patient care, and measures the success and impact of innovative solutions and MedTech innovation initiatives?

What are the risks associated with MedTech innovations in hospital settings, and how can these be mitigated?

A thematic coding approach was employed to analyse the interviews. To ensure the reliability and validity of the analysis of qualitative data obtained from semi-structured interviews, the MaxQDA2022 software was used – software that allowed to organize and manage data, code themes and concepts, and generate visualizations to support the analysis. The data analysis was guided by the research questions, codes and themes derived from them, as shown in Figure 4. The themes, representing the patterns and trends in the data, were used as the titles of sections 4.1. to 4.4 in the Results and Discussion section to structure the analysis, and the codes are shown in italic to facilitate reading. For example, section 4.1 addresses the Challenges and Causes of Failure in MedTech Transfer to Hospitals to answer the research question “*What are the main challenges and causes of failure when transferring MedTech for hospital setting? What are the key factors that contribute to successful MedTech innovation for hospital settings?*” assigning five codes to analyse data based on content or meaning – *financial, legal, organizational, strategic and technological challenges*.

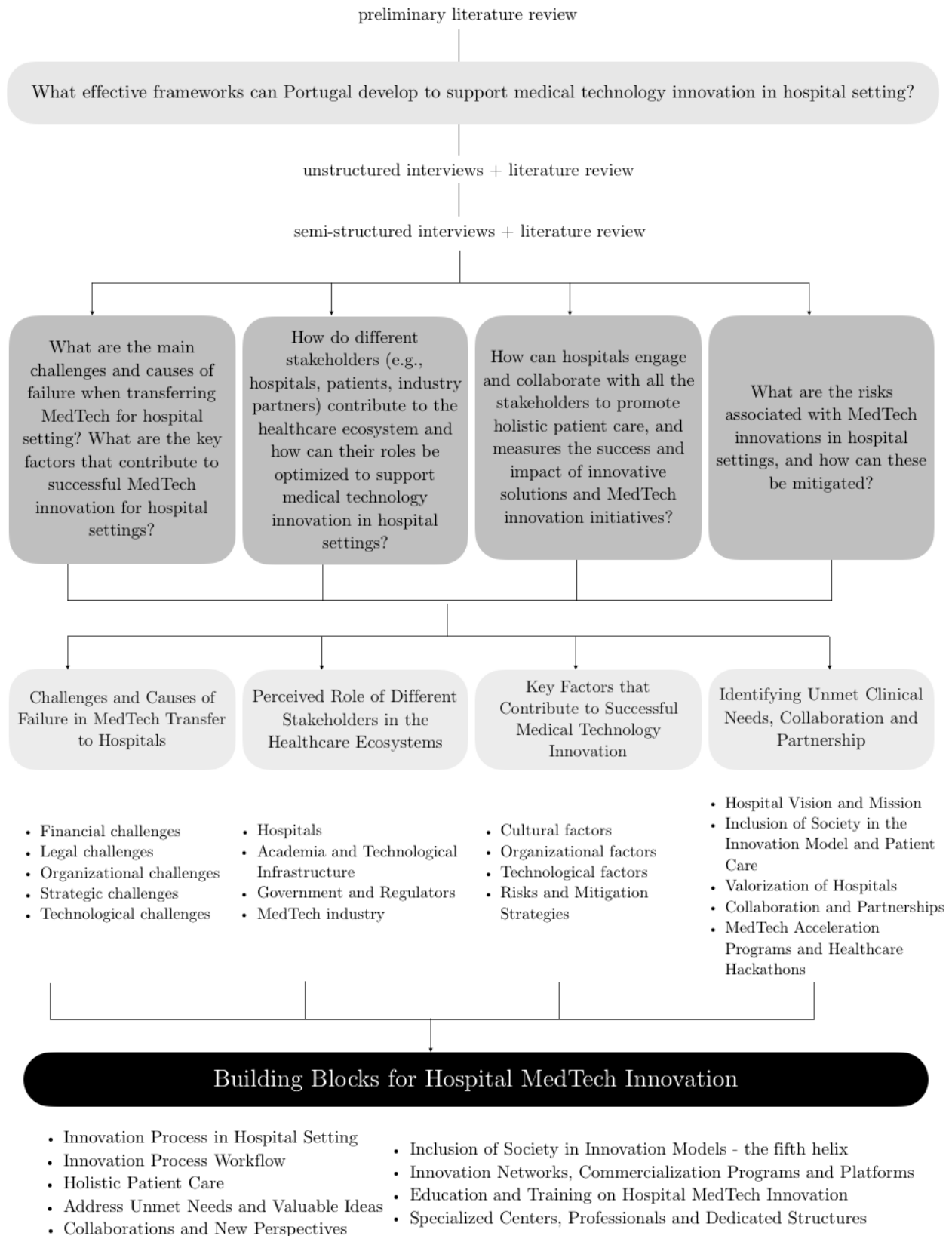


Figure 4. Schematic representation of the methodology to analyse the results and discuss the findings. Themes derived from the thematic coding, answering the research questions to accomplish the objective. The Key Lessons Learned and Recommendations led to the identification of the Building Blocks for Hospital MedTech Innovation as proposed frameworks for supporting medical technology innovations in hospital setting.

Results and Discussion

This dissertation aimed to study effective frameworks to support medical technology innovation in hospital settings. To achieve this, semi-structured interviews were conducted with 33 professionals – comprising hospital administrators, clinicians, engineers, business, attorneys, industry experts and more from seven different geographical regions, namely Denmark, France, Germany, Portugal, Spain, Switzerland and the United States. These professionals represented the four agents of the Quadruple Helix Model considered to describe the Hospital innovation model, from different regions, including both public and private hospital systems.

This chapter presents the results obtained from the interviews conducted and literature review to address the overarching research question of “*What effective frameworks can Portugal develop to support medical technology innovation in the hospital setting?*”. The findings confirm previous recommendations and expositions while challenging others, offering a fresh perspective on the subject. Due to the complexity and diversity of the research question and the stakeholders involved, the research question was broken down into research objectives, which guided the thematic coding described in the Methods section. The Results and Discussion section is structured accordingly, highlighting opinions and statements from the interviews and reporting the results of the data analysis based on the thematic coding. The subsequent findings guided, aligned and/or supplemented the literature review, which will be discussed in the next chapter, as the Building Blocks for Hospital MedTech Innovation – aimed to explore frameworks to support medical technology in hospital setting.

4.1 Challenges and Causes of Failure in MedTech Transfer to Hospitals

From the thematic coding of the interviews, challenges and causes of failure were identified in transferring medical technology to hospital setting, falling into five categories – financial, legal, organizational, strategic, and technological challenges and causes of failure are presented in Table 2.

Table 2 – Main specific challenges and causes of failure in MedTech transfer to hospitals reported by the interviewees.

Challenges and causes of failure	Main specific constrains reported by the interviewees
<i>Financial</i>	Obtain funding for the entire cycle of MedTech innovation, from creation to diffusion (due to the high costs, long timelines, and uncertain returns involved). Compete for public financial support or grants from governmental or non-governmental organizations. Securing seed or early-stage funding (from investors, venture capitalists, or other sources of capital) and overcoming the funding gap between early and later-stage funding or revenue generation (while facing regulatory and reimbursement barriers that delay the market entry). Balancing between allocating capital to meet one need or less money to reach more people, and budgetary and decision-making power (more pronounced in centralized systems) of healthcare organizations.
<i>Legal</i>	Complying with the complex regulatory landscape and ethical requirements to ensure cost-effectiveness and sustainability of technologies, across different countries and healthcare systems applied to different aspects (as product development, testing, approval, marketing, clinical application and use). Comply with different regulations dependent on the type and risk level of different medical technologies, its intended use, market, and data implications (in terms of management, security and value). Guarantee resources (such as financial, human and time) to support certification processes during long periods.
<i>Organizational</i>	Manage innovators' lack of expertise in commercialization and inadequate intellectual property strategy. Resistance of healthcare professionals to innovative technologies and solutions. Bureaucracy and slow adoption of innovative medical technologies and deficient management of internal processes, resources, communication and (entrepreneurial) culture within innovation teams, units and hospitals and between different agents. Centralized decisions, funding limitations for hospitals, organizational complexity, diversity, and dynamism of MedTech sector and healthcare systems.
<i>Technological</i>	Develop MedTech solutions that address clinical problems and expectations, overcoming clinicians' inertia and incorporating their feedback and involvement. Ensuring that innovations' compatibility and communication, with existing systems and clinical workflows, and exchange data with platforms (respectively). Managing the technical challenges, uncertainties, and variations that arise from MedTech innovation, such as new features, functionalities, or applications. Complying with the legal and ethical requirements and guidelines that govern MedTech design, production, distribution, and use.
<i>Strategic</i>	Develop and validate cost-effective, safe and profitable innovative medical technologies to the market, based on customer needs, use cases and value propositions. Equip and train innovators with the knowledge and skills to conduct market research, business planning, product development, regulatory affairs, and marketing for innovative MedTech, and manage external expectations from stakeholders and markets.

Both Hospitals and MedTech industry professionals mentioned obstacles in transferring medical technologies, especially smaller businesses such as start-ups and spin-offs. Some of the challenges encountered were related to raising funding, finding development and production partners, and scaling. Other industry-specific challenges included the resistance of healthcare professionals to new technologies, the lack of an intellectual property strategy, regulatory issues, and the non-readiness to run pilots. Regulatory compliance was agreed to be essential for patient safety and market commercialization, but also posing a barrier for businesses with limited resources to complete the lengthy certification process and, similarly, the readiness to run pilots and the hospitals willingness to test and validate new technologies in their clinical settings.

“Intellectual property (rights) serves as an economic tool to prevent monopolies: critical for hospitals, which are often subject to a lack of competition due to the high degree of specialization in their domains. Recurring to intellectual property, hospitals can help to foster a more competitive environment and prevent the concentration of power in the hands of a few dominant players” [Anonymous, Annex I]. The main causes of failure identified in the Academic and Technological Infrastructures sphere were related to the alignment of technologies with clinical real needs, the development of viable business models – common problem among innovators –, the access to funding, partners and scaling opportunities, the resistance of hospital’s community acceptance of new technologies to new technologies – associated with the fear of failure, trust in technology effectiveness, lack of incentives to be trained to adopt technologies, inability to implement those in clinical workflows or concerns about patient acceptance –, the (deficient) intellectual property strategy, and the slow pace of the innovation process.

According to the literature, capital is crucial to promote the adoption of medical technologies as it is key to invest in infrastructure and resources to ideate, select, implement and disseminate innovation to market [129]. The MedTech industry needs not only talent but also capital to survive [58], and access to funding is the top challenge for deep-tech companies, according to the industry itself and their investors [56], however governments and private investors are increasingly recognizing the potential of these innovations and providing funding and support to the industry [130].

Medical technologies present a number of challenges, such as the need for increased investment in research and development (R&D), which can be particularly burdensome for smaller organizations [16]. A growing trend is the investment in seed and early-stage startups born in hospital or academic setting, through joint investment funds between or involving hospitals, universities and venture capital [48]. Venture funds operate with shorter investments compared to hospitals, which can accelerate the scaling and commercialization of early-stage startups [28][105].

The emergence of accelerator programs has increased the availability, interaction and accessibility of big companies and angel investors as sources of investment for seed and early-stage startups. The most common engagement methods are Corporate Venture Capital funds (CVC), Corporate Accelerators, and acquisitions [39]. A collaborative effort between hospitals and venture capital funds can provide the resources and expertise required to support the growth of early-stage startups [131], resulting in the promotion of innovation and growth healthcare ecosystems. The life sciences and medical technology industries have economic significance, strength in Europe, and a long-established CVC tradition that merit their consideration [132]. CVC units are information acquisition and potential target assessment for acquisition by learning from entrepreneurial start-up firms. However, the development timescales for new products, R&D project costs, and patenting practices vary across industries, resulting in varying corporate venturing practices.

Therefore, CVC practices need to reflect industry characteristics to add value to the parent firm [132]. Despite the long-standing existence of CVCs, some investors and entrepreneurs remain sceptical about their maturity, however the current funding availability is exceptional, and CVCs are expected to become mature agents of the ecosystem in future [39].

Models for MedTech innovation translation from academia to industry [9][13] support the establishment of relationships with venture capital firms to help fund internal projects with potential to become successful startups, foster the collaboration between research institutions and investors to de-risk technologies and increase the initial valuation of technologies [44], provide access to teams of experts, strong intellectual property and technical data [16].

4.2 Perceived Role of Different Stakeholders in the Healthcare Ecosystems

With the objective to understand each agents' contribution and how their roles can be optimized in the process. The interaction between Hospitals, Academia and Technological Infrastructure, Government and Regulators, and the MedTech industry is critical in the development, adoption, and implementation of medical technology innovations. The literature and the interviews (see Table 3) highlighted the importance of collaboration and communication among different stakeholders for medical technology innovation, “necessary to ensure that medical technology innovations meet the needs of patients, the healthcare system, and civil society” [Giovanni di Napoli, Annex I].

Table 3 – Main specific agents, roles and interactions reported by the interviewees.

Agents	Main specific roles and interactions reported by the interviewees
<i>Hospitals</i>	The primary interested agents and drivers of innovative medical technologies. Identify real-needs and provide feedback on use cases and prototypes, participate in clinical trials, influence the commercialization and adoption of innovations by serving as early adopters, negotiate pricing and reimbursement rates, and influence regulatory policies. Expected to implement innovations in clinical workflows and promote trust by ensure safety and cost-effectiveness of new solutions in patient care, following a value-based patient-centric approach.
<i>Academia and Technological Infrastructure</i>	Support and foster entrepreneurship for startups, spin-offs and future innovators, through funding, resources and a national network of medical technology incubators. Conduct scientific and applied research, developing and prototyping innovative medical technologies, in collaboration and communication with other agents. Train, mentor, and educate the hospital community and staff on new solutions, innovation concepts, entrepreneurial mindsets, and evidence-based practices, through educational programs and initiatives (such as acceleration programs, coursework and hackathons). Providing laboratories and R&D facilities for development, testing and innovation in healthcare technology education.
<i>Government and Regulators</i>	Able to shape the environment and systems for medical technology innovation, through policies, norms, and regulations that govern the development, testing, approval, and reimbursement of technologies. Support and ensure safety and effectiveness standards, appropriate labeling, marketing, and equitable access of technologies.

	Incentivizing and encouraging innovation by approximating agents and promoting the cross-linkage of knowledge. Acting as funding agents and providing other forms of support, such as hackathons, accelerators, public-private partnerships, grants, incubators, and contract.
<i>MedTech industry</i>	Developing, manufacturing and scaling technologies that improve health care through earlier disease detection, less-invasive procedures, and more effective treatments. Contributing with capital, technological and other resources to incentivize and support spin-offs and start-ups creation. Collaborating with healthcare professionals and innovators to create holistic solutions that combine products, software, and services. Partnering with regulators to ensure that innovations are safe and effective and cooperating in policymaking responsibilities to accelerate the market entry of solutions. Commercializing and inciting the adoption of innovations by investing in dissemination and negotiating pricing and reimbursement rates.

The four agents identified by the interviewees matched the Quadruple Helix Model from the literature review. However, these views also reflected the regional contexts and factors that affected how each agent contributed to medical technology innovation, as this study explored. Table 3 shows the main roles and interactions that the interviewees reported as desirable for each agent.t.

4.3 Key Factors that Contribute to Successful Medical Technology Innovation

The interviews revealed four main criteria for successful innovative technologies. First, they should address the unmet needs of healthcare providers and patients, such as improving diagnosis, treatment, or prevention of diseases. Second, they should provide evidence of clinical and economic value, such as enhancing patient outcomes, reducing costs, or increasing efficiency. Third, they should improve the cycle of care, such as by automating clinical tasks, reducing manual processes, or facilitating communication. Fourth, they should use patient data and data from routine care to enhance it, such as by providing feedback, insights, or recommendations. The interviewees also emphasized the importance of having a facilitator (a person, a group, a team, an unit or an external partner) who can assist hospitals in participating and collaborating in the development and improvement of strategies from ideation to commercialization, promoting sustainable practices, and addressing the challenges of integrating technologies in clinical workflows, interoperability, clinician engagement, innovation and entrepreneurship awareness, and skills development. They further suggested that hospitals should standardize monitoring and evaluation processes to assess the success and impact of medical technologies on outcomes and hospital operations and healthcare initiatives to foster innovation, focus on validating and co-designing technologies with end-users, and enhance collaborations between hospital communities and external agents.

From the thematic coding, it is suggested that successful MedTech innovation in hospital settings depends on a combination of cultural, organizational, and technological factors and those are detailed in Table 4.

Table 4 – Main specific success factors in MedTech innovation in hospital settings reported by the interviewees.

Factors	Main specific success factors in MedTech innovation in hospital settings reported by the interviewees
<i>Cultural</i>	These factors relate to the alignment of the mission, vision and values of the agents, within or outside the hospitals, with the goals of innovation and progress in patient-centred value-based healthcare. They include the creation of a culture of collaboration that encourages innovation and embraces new technologies, entrepreneurial mindset, as well as building a strong healthcare ecosystem that connects different actors and sectors.
<i>Organizational</i>	These factors concern the clinical structures, processes, and resources that facilitate the adoption and implementation of new technologies. They involve identifying the critical unmet needs of the end-users, a clear strategy for medical technology innovation that addresses implementation and integration, autonomous decisions, interoperability, hospital community' engagement, and skill development. Innovation hubs were suggested as key platforms that foster partnerships, networking and knowledge sharing among various stakeholders, such as health systems, research institutions, industry partners, investors, and policymakers.
<i>Technological</i>	These factors pertain to the technical aspects of the technologies, such as design, functionality, use cases, and usability. They depend on the evidence of the value of the new solution, such as better patient outcomes, patient safety, lower cost, improved experience for providers and patients, and data harnessing to improve care. The compatibility of innovative medical technologies with existing systems and clinical workflows was also described as a factor of extreme importance.

It was a consensus recommendation for hospitals to standardize monitoring and evaluation processes to measure the success and impact of medical technologies on outcomes and hospital operations, focus on validating and co-design technologies, foster collaborations between hospital communities and external agents, and bring a business perspective to impact patient care in sustainable economic means.

According to the literature review, interoperability is the ability of different technologies, systems and devices to communicate and exchange data, which can facilitate data sharing among stakeholders, enhance the quality of care patient outcomes, and improve cost-effectiveness [18][32]. However, interoperability remains a challenge in healthcare [12], as it faces a lack of standardized definitions and frameworks, political and economic barriers to innovation diffusion, and the alignment of policy and practice. Interoperability requires not only technical and semantic compatibility, but also political and organizational cooperation to ensure alignment and coherence between innovation attributes and system requirements [14][32]. Moreover, interoperability faces challenges regarding open data, data protection and confidentiality, as the healthcare sector creates large amounts of data that need considerable investment for their reuse.

The literature introduces innovation hubs are the focal point of organizational models that enable cross-disciplinary collaborations among professionals with diverse backgrounds and resources to accelerate the development of innovative technologies and boost the generation of intellectual property [9][128]. They play a key role in providing financial support and mentorship to startups within healthcare and life sciences

ecosystems, along with venture capital firms [134]. Hospitals, especially those affiliated with academia, are integral components of health innovation systems as they are sources of healthcare services and end-users of new technologies. They act as hubs within larger networks, driving medical innovation process by identifying needs and proposing solutions, and linking the dispersed system of stakeholders [38].

Healthcare hubs support clinicians, researchers, entrepreneurs, and industry leaders to connect, collaborate, and innovate by addressing unmet healthcare needs. They can be realized through a physical location or a virtual platform. The concept emerged several decades ago but is now entering a phase of maturation, with systematic engagement with startups and the provision of resources – such as mentorship and operating structures – to support their development [134]. The success of hubs in European countries suggests that similar initiatives can be successful in Portugal, if policymakers and stakeholders prioritize the development, support and stimulation of hubs to foster regional development and innovation, promoting economic growth and job creation, a key component of the healthcare innovation ecosystem [48][133]. The success of these initiatives is often attributed to supportive policy frameworks, funding, and collaboration between stakeholders: for example, in Spain, a network of over 200 digital innovation hubs has developed 2,000 projects since 2016, supported by national and regional policies that provide funding and support for entrepreneurs and SMEs in the digital field. In Denmark, Digital Hub Denmark provides access to funding, expertise, and networking opportunities, and has helped to create more than 1,300 jobs since 2015.

Risks and Mitigation Strategies

After performing the thematic coding of the interviews conducted, to answer the research question “*What are the risks associated with MedTech innovations in hospital settings, and how can these be mitigated?*” it was possible to identify risks and strategies to mitigate them, with emphasis on Health Technology Assessments (HTA) – “a process that evaluates the clinical effectiveness, safety, and cost-effectiveness of medical technologies, providing evidence-based information for healthcare professionals, policymakers, and patients” [João Diniz, Annex I] with “special importance in bigger projects” [Michel Nemery, Annex I].

Interviewees reported safety, cost-effectiveness and financial limitations as risks in the MedTech. Also, regulatory risks were mentioned, associated with meeting the local, national and international regulatory requirements for new medical technologies, their type and use cases. In addition, clinician’s reluctance to MedTech acceptance, performance and how it could impact their reputation were stated. Moreover, technical risks related to ensure technical viability, compatibility with systems and interoperability, were emphasized. To mitigate these risks, the integration of an actor with a scientific background in engineering (for example a clinical engineer) able to bridge the gap between science and health, training and education for all the agents on bioeconomy and entrepreneurial principles, the development of a strong IP strategy, and the establishment of platforms for MedTech commercialization, data sharing and networking were recommended.

Risk Assessment

Investing in emerging technologies requires specialized knowledge, skills, and expertise to assess their potential and limitations with the guidance of internal or external KOLs [56]. Hospitals can make informed decisions about implementing new medical

technologies and ensure patient safety by conducting a risk assessment process, identifying and evaluating potential risks and their tolerability, considering risk scores, organizational and regulatory requirements, and the potential benefits of accepting the risk. [44]. For example, the Wyss Institute, renowned for its supportive framework for medical technology innovation and translation across the academic-industrial interface [9], has a rigorous risk assessment process for all technologies that pass through the innovation funnel. It includes reviews by an intellectual property attorney, insights from business developers and Advanced Technology Team members with technology-relevant industrial expertise. The Institute also runs internal projects to de-risk technologies further, providing additional financial support, access to facilities and know-how, and partners with entrepreneurs-in-residence experts, with relevant application and industry-specific experience, to help nurture Institute's projects.

European agents tend to be more risk averse than Americans, who are more concerned about the potential for impact and growth when investing in new technologies [56]. However, current methods for risk assessment in hospital settings are inconsistent by the lack of consultation and representation of stakeholders, the inconsistency and opacity of the process, and the insufficient guidance for conducting thorough assessments [44]. Healthcare organizations often focus on regulatory compliance, rather than quality improvement of existing processes [12]. Performance should be assessed through a qualitative study that considers the value and judgments of the end users of the health technology [2], and defined by explicit goals and objectives. A study in Cambridge [44] that used mixed methods and document analysis to design a risk assessment framework identified several essential elements, as regulations, protocols and procedures; risk sources; predictable and unanticipated events and factors; impact domains; risk categorization, scoring, prioritization and acceptability; control measures and assessment methods; recording and documentation of risks; plain language; quick risk assessment; ease of use; adaptability to different circumstances and contexts; accessibility when needed; and compatibility with other tools and methods.

Health Technology Assessment

Health Technology Assessment (HTA) is a process that evaluates the medical, social, ethical, and economic consequences of medical technologies [44]. It aims to evaluate the clinical and economic value of new clinical solutions by reducing the risks, assessing the benefits, and guiding the adoption and implementation of innovative medical technologies. It also ensures safety, cost, and clinical effectiveness, and aligns them with the broader goals of the healthcare systems, existing and implemented technologies, and the system structure, organization, and procedures [136].

Interviewees reported that patient involvement in health technology assessment can enrich the evaluation processes with patients' preferences and needs, enhance transparency, and align assessment activities with the overarching objectives of ecosystems. However, patient involvement varies across European countries, with different levels of proactivity and influence of patient groups and associations [137]. A study [138] analysed the current state and future challenges of HTA in Portugal and other European countries suggested that the Portuguese HTA framework needs to be adapted to the upcoming challenges and to improve access to innovation in hospital settings. The study also proposed some improvement opportunities and solutions to the HTA framework, such as expanding and creating national level registries, assuring patient participation, using managed entry agreements, applying multi-indication pricing, and

improving registry/system interoperability. Interviewees mentioned the importance of patients' involvement in HTA performed by hospital community.

HTA should only generate comprehensive and high-quality assessments, which decision-makers can use according to their needs and resources. Therefore, community-level decisions may differ depending on the available resources and the local requirements, and the timing of HTA may depend on the type, stage, and purpose of the technology being assessed. Thus, a value-based patient-centric model, grounded on economic and regional contexts, should support the evaluation process, enabling it to use locally relevant data.

Kaya et al. [44] developed and evaluated a risk assessment framework to address the challenges of risk assessment in hospitals, such as lack of consultation, consistency and transparency. The framework consists of a model (Figure 5), explanation cards, and a form that guide users through the risk assessment process, based on national and international standards and user needs. The pilot testing and user evaluation indicated positive results and suggested that the framework could improve risk assessment practice and patient safety.

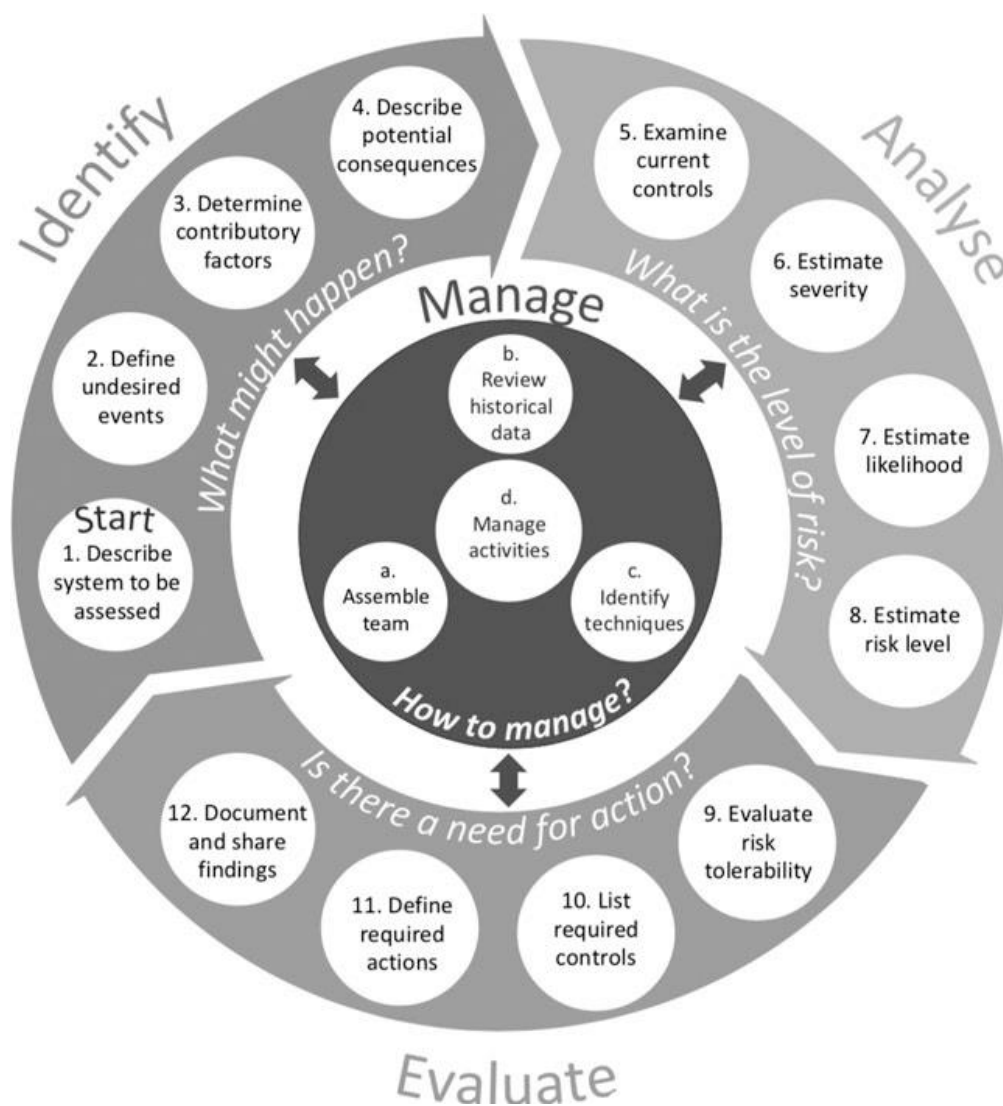


Figure 5. Risk assessment model [44].

4.4 Identifying Unmet Clinical Needs, Collaboration and Partnership

This study also aimed to answer the question “*How can hospitals engage and collaborate with all the stakeholders to promote holistic patient, and measure the success and impact of innovative solutions and MedTech innovation initiatives?*”. To answer this question, data on the *Hospitals Vision and Mission, Inclusion of Society in the Innovation Model and Patient Care, Valorization of Hospitals, Collaborations and Partnerships, and MedTech Acceleration Programs and Healthcare Hackathons* was analysed, complemented, and supported by the literature.

Hospitals Vision and Mission

The interviewees emphasized the importance of hospitals and other stakeholders having aligned and transparent mission and vision statements, crucial in promoting a culture of innovation that bring into line their goals and objectives, “imperative for the creation and sustainable long-term success of an ecosystem” [Xavier Monné, Annex I]. “Hospitals must prioritize a patient-centred approach when developing and adopting medical technologies” [João Diniz, Annex I], involving engaging patients and healthcare professionals in the development process to ensure that innovations meet the real clinical needs of end-users, as “ideas with value” [Clint Matthews, Annex I]. Furthermore, hospitals must access and consider the rate of acceptance at the decision-making stage when adopting medical technologies, while mitigating risks. To stay relevant and provide high-quality care that serves the best interests of end-users and has a clear mission and a culture of innovation that fosters creativity, experimentation, and collaboration, leading to the development of innovative technologies.

Inclusion of Society in the Innovation Model and Patient Care

“Healthcare is becoming increasingly complex and interconnected, it is more important than ever to involve patients and other stakeholders in the innovation process.” [Giovanni di Napoli, Annex I]. By soliciting input from those who stand to benefit most from new technologies and solutions, hospitals can ensure that their efforts are grounded in a deep understanding of real-world needs and challenges. “Innovative hospitals are based on patient-centred design principles to develop solutions that meet the needs of patients” [Michel Nemery, Annex I] and this may involve the creation and partnering with patient associations or other advocacy groups to gather feedback and insights, or leveraging patient data platforms to earn a more comprehensive and fundamental understanding of patient needs and feedback, aiming to create a more holistic and patient-centred approach to care that considers the full range of factors that impact health outcomes.

Valorization of Hospitals

According to the interviewees, hospitals can be valorized throughout the medical technology innovation process, “from the identification of the need or problem to the implementation of the valuable solution” [Aleksandar Marinkovic, Annex I]. Grounded on the data gathered from the interviews, the contribution of hospital in each phases considered in this study was compared with the literature, in line with the phases considered in previous studies [39]. Hospitals play a crucial role in the innovation process,

from the inception to the maturity phase. At the phase of inception, they are involved in identifying and refining the real unmet clinical needs of patients and healthcare professionals, by communicating and cross-linking the skills and expertise of multidisciplinary teams. They also provide feedback to refine the ideas and concepts of potential solutions. Hospitals support the launching phase by conducting clinical trials that are essential for obtaining regulatory approval, building trust within the hospital community, and demonstrating the value of the scientific results. They also may organize, promote and participate in initiatives that foster innovation with other agents, such as hackathons and acceleration programs, where they can share their insights and challenges. Particularly in growing phase, hospitals partner with the MedTech industry to disseminate the technology among the end-users, enhancing its visibility, trust, and acceptance. Hospitals provide resources and conditions for designing and testing technologies in the growing phase. They serve as testbeds where technologies can be refined under the supervision of clinicians and experimented by patients. They also encourage clinical trials that allow for assessing the effectiveness, performance, and improvement of the technologies. In the realm of the stability of the maturity phase, hospitals adopt and implement innovations into their clinical workflows, practices, and operations. They provide training and education to the hospital community on how to use new technologies and seek feedback for continuous improvement and update of existing technologies. Hospitals also foster collaborations and partnerships with other healthcare organizations, aiming to enhance their reputation and competitiveness in terms of innovation.

Hackathons and acceleration programs seem to be two interesting approaches that enable hospitals to contribute to the MedTech innovation process. In addition to the conventional perceived role of supporting clinical trials, hospitals can help to identify unmet clinical needs, collaborate with other stakeholders to ideate and develop new solutions (product concept definition), creating clinical innovation units to facilitate communication between innovators, business, regulators and healthcare professionals, and by designing and participating in the education and training of the next generation of professionals. The motivation underlying a prominent role of hospitals is likely related to enhance their reputation, attract funding, and promote economic development in their communities' foster partnerships with the MedTech industry.

Collaborations and Partnerships

The interviewees reported that hospitals need to collaborate and partner with all the agents – academic institutions and research organizations, MedTech companies and other industry partners, government agencies, policymakers, and regulatory bodies – to stay at the forefront of MedTech innovation. By leveraging the expertise and resources of these external organizations, hospitals can co-create and develop new solutions and technologies that improve patient outcomes and drive growth external and internally. Concretizing these synergies, some examples of the latter are:

Hospitals – Academia and Technological Infrastructures: collaborating to co-create innovative solutions. This involves joint research projects, shared facilities and equipment, cross-linkage of knowledge and expertise, and keeping hospitals updated with the latest scientific and technological advancements.

Hospitals – Government and Regulators: partnering to navigate regulatory landscapes, accelerating market entry and shaping policies and regulations that support innovation and value-based patient-centred care. This involves developing

new de-risk strategies, technology assessment models, setting quality standards (and help on identifying funding opportunities).

Hospitals – MedTech Industry: to develop new medical technologies to improve patient care and promoting initiative to reunite multidisciplinary teams to ideate valuable medical technology assessing real clinical needs. This involves collaborative research and development projects, co-design and testing agreements, shared expertise and knowledge, and enhancing organizations' reputation and competitiveness by providing access and development of innovative technologies and up-to-date medical advancements.

MedTech Acceleration Programs and Healthcare Hackathons

As a consequence of the shift towards more collaborative and flexible work environments, and the importance of diversity and inclusion in entrepreneurship, accelerators and hackathons are programs that help startups and entrepreneurs develop new products and services [93].

“Depending on the (frequency) consistency of the initiative and the volume of demand for new startups addressed acceleration programs and hackathons’ impact is variable” [António Murta, Annex I]. When asked about the relevance of MedTech acceleration programs and healthcare hackathons, healthcare hackathons were pointed out as the future “with huge impact” [Francis Tricot, Annex I]. Accelerators provide mentorship, funding, and resources to help startups to grow and scale their businesses in a longer time span, while hackathons are events where participants collaborate to develop solutions to specific challenges over a short period of time [139].

MedTech Acceleration Programs

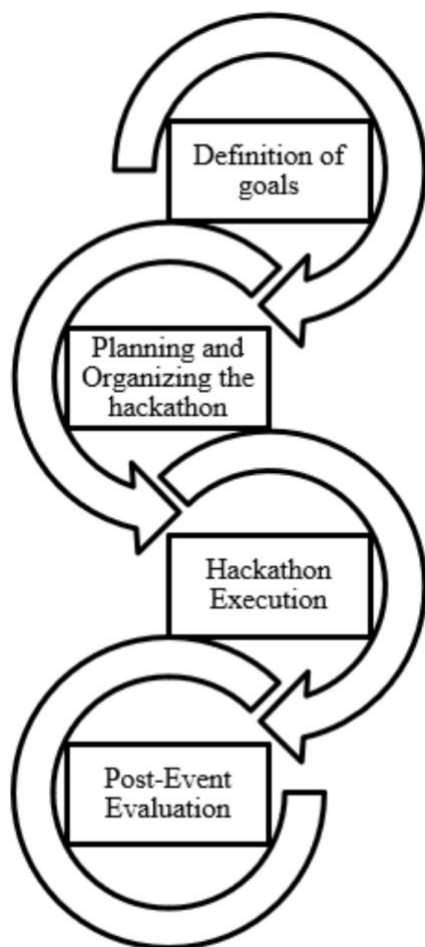
Reviewing the literature, it is perceptible that one big challenge is not the scarcity of innovative technologies, but the dissemination of innovation-related concepts [3]. The proactive role of Academia in knowledge-based society economy is a trending topic discussed when accessing the entrepreneurial university paradigm [48]. The development of clinical-centred medical technologies is hindered by the later involvement and residual collaboration between healthcare professionals and innovators. To overcome challenges of this nature, initiatives as meetings at clinical setting, coaching and training sessions or seminars at hospitals were established to promote interaction and fostering shared knowledge, as a response to minimize organizational boundaries [140]. Accelerators have been an emerging practice of the technology economy and innovation ecosystems, serving as incubators to support start-ups through funding, mentorship, network access and coaching [35]. In this context, MedTech acceleration programs can provide a reference framework fostering and accelerating the development and commercialization of medical technologies, articulating intervening variables, stakeholders and expertise for researchers and businesses thus promoting a synergistic effect between agents [28][98]. Either running their own in-house or outsourcing its administration to a partner, accelerator programs are also common strategies exploited by companies and corporations to collaborate with start-ups [39]. In a more broad view, accelerators are ecosystems builders helping at building up an institutional framework with clear regulative, normative and cultural-cognitive elements [51].

These programs are valuable opportunities for hospitals, universities, and companies to bring innovative medical technologies to the market, aiming to provide structure, support, and key resources, with the focus on how the patient is seen, heard, and needs

are met. In particular for hospitals, participating in acceleration programs exposes them to a wide range of new medical technologies and ideas, which can enhance their reputation, while orienting the direction of future technological development in the MedTech industry [13]. Conversely, hospitals have the potential to serve as a vital component of the education system by providing training to new practitioners [58], providing funding, network access, interaction with the industry, resulting in a high rate of startup formation and an increase in seed deals, the emergence of accelerator programs became notable in the last decade [28][37][98].

Healthcare Hackathons

The literature review revealed that acceleration programs and hackathons are two different approaches to support startups and innovation: acceleration programs provide long-term support (as physical space, legal guidance, and mentorship), to help innovators grow and develop their solutions; hackathons are short-term events, usually lasting a few days, where interdisciplinary teams collaborate on a specific challenge and develop prototypes that are pitched to a panel of judges [141]. Firstly introduced by technology companies as internal events, hackathons were created for engineers and scientists to work together and build innovative solutions, addressing industrial problems in a short period [142]. Hackathons are considered a cost-effective and time-efficient approach to bring innovation namely to healthcare, helping to build an ecosystem and opening the opportunity for people to network [141]. Hackathons also combine technical and non-technical aspects of design and business modelling [142]. Healthcare hackathons, which started with MIT's Hacking Medicine in 2011 [100][101], aim to identify clinical needs and develop products, systems, services, datasets, and tools to improve healthcare delivery [141], while providing training, mentoring and collaboration opportunities for participants from diverse backgrounds and disciplines [142], aimed to encourage diversity in people, projects, and to tackle complex healthcare challenges with multidisciplinary teams [141]. Healthcare hackathons involve stakeholders in the early design phase [141], and enable interdisciplinary teams of healthcare professionals, data scientists, engineers, designers, business professionals, students, and others to collaborate and create innovative medical solutions, developing (initial) prototypes, pitch them to a panel of experienced judges, iterate and quickly alter them according to feedback [141]. A study that measured the impact of healthcare hackathons on the digital health community in Berlin and the subsequent events after the first hackathon found that the digital health community grew significantly and that larger hackathons followed: it was concluded that hackathons are more efficient and economical than traditional methods of innovating in healthcare – validating problems, ideas and prototype – when compared to academic research, clinical trials, or industry partnerships. Hackathons can introduce new ideas, methods, or technologies that can improve the quality, accessibility, or affordability of healthcare services or products for patients, providers, or systems [143]. An example of prominent healthcare hackathons are Stanford University's Health++ hackathon in 2016 – funded by Stanford departments, organizations, and industry sponsors – that aimed to foster collaboration between professionals from different fields for 36 hours [142]. Figure 6 presents a guide to organize healthcare hackathons.



Definition of goals

Define the clinical problem or challenge the hackathon aims to address – as improving patient outcomes, reducing costs, or enhancing accessibility.

Identify the target user group, needs and preferences.

Clarify the expected deliverables and evaluation criteria for the hackathon participants.

Planning and Organizing the hackathon

Decide whether the hackathon will be thematic or open-ended, depending on the scope of the problem.

Choose a suitable venue and time frame for the event, considering the availability of resources and facilities.

Recruit and select participants with diverse backgrounds and skills – as healthcare professionals, patients, engineers, designers, students and entrepreneurs.

Provide incentives for participation – namely prizes, mentorship, and networking opportunities.

Hackathon Execution

Orchestrate the matching process between hospital community and innovators, through methods as speed dating, pitch sessions, or online platforms.

Encourage iterative and frequent interactions between the teams, end-users, external stakeholders – as mentors, sponsors, or experts.

Encourage feedback and prototyping cycles to help teams refine, re-design and test innovations.

Post-Event Evaluation

Create a sense of ownership and recognition for the teams by showcasing solutions to a wider audience and inviting judges – as KOLs, business and industry experts, clinicians – to evaluate them.

Provide constructive feedback and suggestions for improvement.

Build relationships and secure support for teams to continue working on their solutions – as supporting developers to create startups – after the hackathon.

Raise awareness and educate teams namely on IP and regulatory compliance.

Figure 6. Guide to organize MedTech Hackathons with phases and activities. Adapted from [140][143][144].

Key Lessons Learned and Recommendations

This study brought findings, corroborating existing evidence and recommendations, while revealing other aspects, offering a fresh perspective and perception on supporting medical technology innovation, emphasizing the role of hospitals as enablers and participants in the process. The results contributed to the literature, synthesizing lessons learned and providing a compilation of the opinions how medical technology innovation – from ideation to commercialization – process organization, failure causes and challenges in transferring, success factors, best practices, and risk’ mitigation strategies, hospital innovation, and operational performance are related. There are specific limitations and unknown factors that aimed to highlight and address the importance of this dissertation:

1. It is unclear how to provide an unbiased and clear statement of need for medical technologies, a critical step in addressing the identified clinical problems effectively;
2. The education and training of the entrepreneurial spirit of researchers, on the proper methods of transferring technologies to the hospital setting: knowledge gap hinders the successful integration of innovative ideas into healthcare practices and workflows;
3. The alignment of the vision and goals of all stakeholders involved in the transfer process, to ensure that valuable ideas with social impact are effectively transferred into a healthcare ecosystem, which requires a coordinated effort and shared understanding among all parties;
4. The inexperience and difficulty of quadruple helix agents navigating the cultural, organizational and technological factors associated with the development and transfer of medical technologies.

To study effective frameworks to support medical technology innovation in hospital setting, it is crucial to identify and define the primary objective of innovation, evaluate the existing capabilities, competencies and expertise, assess the level of risk tolerance, decide on the appropriate form of investment, and consider the need of a dedicated centre [12] and/or organizational structure.

Medical technology innovation requires balancing local adaptation, minimizing the risk of diluting its strengths – however when the positive net impact in the cycle of care is unclear, it is unrealistic to sustain motivation and open innovation without incentives for clinicians, industry players, innovators, policymakers, clinicians, and innovators, but especially to patients [84]. Therefore, the main challenge for the future will consist in adopting frameworks that lead to higher levels of hospitals users’ satisfaction, fostering

and maintaining their identity with the hospital institution [105]. Healthcare performance measurement depend on the goals, strategies and structure of the organization, the expectations and interests of the involved stakeholders and regulations [2] – therefore, hospital performance can be measured following the criteria:

Internal measures – data-based indicators (as costs, patient outcomes and hospital community's satisfaction) of the financial, operational, and quality performance of a hospital's internal operations, activities and processes, to monitor and improve efficiency, safety, and outcomes.

External measures – data-based indicators (based on data from external sources, as patient satisfaction surveys, regulatory inspections, third-party assessments, benchmarking with other hospitals or health systems) of the quality and value of products and services that the hospitals delivers to patients and society, to evaluate and improve hospital's reputation, competitiveness and patient satisfaction.

In the realm of healthcare, it is imperative to include hospitals in the technological innovation models, designed to deliver specific outcomes at each stage that can help accelerate from the ideation and development, to adoption and implementation of new solutions [40]. Aimed to generate valuable innovation, such model demands a revision on the internal and external measures, ensuring innovation teams, healthcare professionals, patients, industry partners and policymakers collaborate to provide the necessary resources. Supportive frameworks are needed to enable entrepreneurship to generate new solutions with high returns and transformative impacts on Portuguese healthcare [104].

In Portugal, 81% of clinicians consider that their organization has improved external measures with the adoption and implementation of digital health technologies [75], however recognizing the challenge for innovation to be admitted key to improve healthcare delivery for society and driving economic growth [104]. From funding limitations [2], regulatory barriers [50], small market size, talent attraction and retention, limited domestic production, and lack of interoperable, Portuguese healthcare faces several challenges in developing and commercializing innovative technologies [14], especially for early-stage businesses. According to the European Commission [146], the lack of digitalized Portuguese healthcare data results in a low level of digital health maturity compared to other European countries, and impedes the access, sharing, and analysis of relevant information for research and development, clinical trials, and decision making. Portugal imports about 80% of its medical technologies, equipment and devices [147], and its personnel often move from MedTech to other sectors or regions that offer more attractive opportunities with established firms, such as the United States and other European countries. However, the literature [2][17] suggests that Portuguese healthcare can overcome its challenges by exploring and implementing strategies to create innovation models, where hospitals play a more prominent, participative, decisive and key role.

The study of Polónia and Gradim [17] was the starting point of the current analysis of the medical technology innovation transfer process. After defining each agent – Academica and Technological Infrastructure, Hospital, Government and Regulators and MedTech Industry –, their roles and contribution, different challenges that hinder their performance and impact were identified. Academica and Technological Infrastructures generate and disseminate scientific knowledge, but are affected by low funding

opportunities, lack of incentives, and weak collaboration with other agents (namely to identify real clinical needs). Hospitals are the agents who should adopt and implement innovations and benefit from generated knowledge, but they have low absorptive capacity, lack of resources (such as technological, organizational, financial, strategic and human), legal and bureaucratic barriers. Government and Regulators shape and influence the healthcare ecosystems, but these agents denote a lack of organization, coordination, fragmentation, and inconsistency of policies and regulations. The MedTech industry commercializes and creates value from innovation and knowledge but, especially in Portugal, verifies low competitiveness and lack of support (including financial, regulatory, strategic).

To improve the innovation and knowledge flows in the Portuguese healthcare ecosystem, the authors [17] propose recommendations that address the challenges faced by the four main agents. To foster research and development activities, the academic and technological infrastructures need more funding and incentives, as well as collaboration and networking with other agents. To facilitate innovation adoption and implementation, the hospitals need more absorptive capacity and resources, as well as closer contact with policymakers to comply with regulations and reduce bureaucracy. To create a more favorable and stable environment for innovation, the policies and regulations need to be coordinated, integrated, and consistent. To support the MedTech industry, the access to national and international markets and end-users needs to be enabled. Across all phases, students from different disciplines – such as medicine, engineering and business – should be involved in innovation projects to foster interdisciplinarity of knowledge and skills. Moreover, management subjects should be integrated in life sciences and engineering degrees to disseminate innovation concepts and foster entrepreneurship activities to facilitate the commercialization of scientific results.

Creating and developing a healthcare innovation ecosystem involves several steps, such as identifying the needs of the health system, and the financial, technological, organizational and strategic resources [129]. In these ecosystems, stakeholders need to develop a skill set and multidisciplinary talent from clinical, policymaking, scientific and business backgrounds to remain competitive [105]. Resourceful recruitment and retention strategies, collaborations and partnerships with existing and emerging stakeholders [5], motivated healthcare professionals, more autonomy for healthcare facilities and a national strategy [99] are required to access and retain talent.

5.1 Building Blocks for Hospital MedTech Innovation

To effectively deliver high-quality patient care, it is required to study frameworks that combine vision, commitment, action [131], and understanding of the determinants of innovation in the MedTech transfer process. These determinants include patient-centric value-based hospital models, healthcare ecosystems, innovation culture, acceptance of new technologies, and collaboration and partnerships.

The aim of this study was to identify frameworks to support medical technology innovation and an overview is presented in Table 5. To achieve this, the Portuguese and international elements, contexts, practices, and stakeholders were analysed as agents of the Quadruple Helix Model, which was used to describe the desired Portuguese ecosystem, being these facts were considered when developing the Building Blocks for Hospital MedTech Innovation.

Based on national and international interviews with relevant profiles as representative of the Quadruple Helix Model' agents allowed for validation of challenges and causes of failure referenced in the literature, and the identification of others that will be addressed

in this chapter; accordingly, key lessons learned were highlighted and best practices for fostering hospital innovation in medical technology were discussed, ensuring that it thrives, accelerates, and reaches its full potential.

Derived from literature and empirical data, the following indications were defined as a guide for establishing frameworks to support hospital MedTech innovation and, therefore, frameworks to support hospital MedTech innovation should rely on:

1. Clarification of the purpose of hospital innovation and healthcare ecosystem, specifically in relation to internal and external dimensions, and the commercialization of MedTech solutions.
2. Establishment of defined roles, responsibilities and dedicated structures for hospital management to drive innovation.
3. Cultivating an innovation-oriented need-driven culture which incentivizes agents involved in a value-based patient-centric healthcare.
4. Establishment of a viable funding model via revenue, investments, or alternative financial resources.
5. Foster academia-hospital-industry collaborations, supported by authorities and policymakers, that address unmet needs of end-users, taking expertise and knowledge as a foundation.

To achieve this and grounded on the Results of the qualitative exploratory research, the best practices for hospital MedTech innovation are discussed and the Building Blocks for Hospital MedTech Innovation proposed. Sections 5.1.1 to 5.1.9 present a compilation (and, when necessary, a specification) of effective frameworks to support hospital MedTech innovation.

Table 5 – Overview on the Building Blocks for Hospital MedTech Innovation.

<i>Innovation Process in Hospital Setting</i>	Hospital MedTech innovation requires collaboration and partnerships, technology integration, patient-centred care, health management, and quality improvement. Healthcare ecosystems of innovation must be grounded on patient-centric value-based models and account for infrastructure, technological and human resources, innovation culture, partnerships, capital, and technological contexts. The proposed model based on multidisciplinary pillars requires strategies for health management, health technology and systems assessment, outcome monitoring and measurement, investment risk evaluation and mitigation, and opportunity detection for improvement. Hospitals should engage with patients and healthcare providers to deliver quality and value-based care, address needs, enhance transparency and trust, share data, and foster and strengthen connections with other agents and external partners.
<i>Innovation Process Flowchart</i>	An efficient innovation process in a hospital setting involves identifying and addressing clinical needs with agents involvement, designing and testing in the clinical setting with hospital community and other partners, and assessing feasibility of medical technologies (HTA). Successful innovations are included in clinical workflows and upscaled, while pain points of the process, and organizational, cultural and technological factors are analysed and addressed. The innovation process requires identifying and addressing a clinical need aligned with hospital innovation strategy, screening challenges and ideas, evaluating exploitability of scientific results, developing opportunity statement, fostering innovative entrepreneurial mindset, and promoting innovation culture.
<i>Holistic Patient Care</i>	Hospitals should focus on improving patients' effective quality of life, supporting throughout the care journey, and recognize their responsibility beyond diagnosing and treating, extend to care and monitor the person in a broad, sustainable and effective sense. The innovation process requires collaborating with the hospital community to co-create ecosystem, address regulatory issues, and commercialize medical technologies, coordinating funding level and constraints, identifying funding opportunities, performing de-risking assessment, and defining mission and vision for Portuguese hospitals guided by core principles to promote innovation.

<i>Address Unmet Needs and Valuable Ideas</i>	Hospitals must prioritize and reinforce strategic innovation and innovative technological culture by gathering feedback, screening clinical needs, establishing a value-based framework for patient-centeredness, and addressing challenges and opportunities for innovation. Portugal should establish a cohesive support system and strive to become a centre of excellence in medical research, drawing inspiration from American and European models of hospital and clinical research centres. Building a successful ecosystem requires selecting a competent workforce with clinical, research, biomedical, and technical skills and involving them in the development and implementation of sustainable, need-driven medical innovations following a patient-centred design approach
<i>Collaborations and New Perspectives</i>	Partnership strategies drive innovation in hospitals, which thrives on circulation and interaction of knowledge and agents across settings. Therefore, the collaboration with industry and academic partners and end-users to address healthcare challenges and needs, supported by policymakers, government, regulators, and local administrations is a key factor to add value to innovation. Hospitals can promote collaboration with private partners by implementing streamlined processes for soliciting, testing, and evaluating ideas and projects. The MedTech industry can offer financial support, resources, sustainability advice, regulatory compliance expertise, and feedback. The government can incentivize connections and communication between firms, hospitals, and academia while facilitating regulation and policies to accelerate MedTech's market entry. Competition in the MedTech sector is shifting towards ecosystems that optimize the patient journey and deliver better outcomes at scale. The industry, along with government and regulators, must incorporate regulatory engagement into innovation models, involving healthcare professionals and patients in product design, establishing cross-functional need-driven committees for commercialization, manufacturing, and market access of valuable solutions. Hospitals should welcome proposals (i.e., clinical trials, test beds) and initiatives (i.e., healthcare hackathons). Healthcare hackathons foster innovation by involving diverse participants, providing access to grants, ensuring licensing and technology transfer terms, offering mentorship from experts, and connecting with potential industry and investors. Organizing a hackathon requires meticulous planning and a clear understanding of goals and objectives tailored to the institution's specific needs.
<i>Inclusion of Society in Innovation Models – the fifth helix</i>	Creating a healthcare ecosystem requires continuous evaluation and improvement by the agents, ensuring the integration and outcome improvement of medical technology innovations in clinical practice. Value-based patient-centric model of healthcare delivery provides quality and effective care, reduces costs to patients and gives them more control over their care and treatment

	The involvement of society in health policy and patients in the development and design of care is a strategy for moving forward, but more levers for transformation and improvement are needed. Patient insights and experience inform patient-centred care, which respects and responds to patients' preferences, needs, and values. Patient associations may collaborate with various stakeholders to improve the quality and accessibility of healthcare services.
<i>Innovation Networks, Commercialization Programs and Platforms</i>	Healthcare innovation hubs involve an innovation-focused mission, access to medical technology innovations, engagement of all agents, and physical or digital platforms for collaboration, knowledge and data exchange. Resources for healthcare innovation hubs include clinical settings, industry, government and regulators, need-driven innovation, capital, and infrastructure, to leverage multidisciplinary expertise, entrepreneurial training, and networking. MedTech innovation must be suitable for its end-users and present clear use cases to demonstrate value: informal networking with hospital community is crucial for unmet needs, and a Network of Innovative Hospitals and a national innovation platform could support the development and adoption of solutions by involving all the agents.
<i>Education and Training on Hospital MedTech Innovation</i>	Innovation training programs need continuous adaptation and updating to strengthen innovation management and contribute to the mission of providing specialized care and creating value for patients. Academia and technological infrastructures should adopt an interdisciplinary approach that includes entrepreneurship and health economics, incorporating it into courses such as Engineering. Coursework should provide a comprehensive understanding of health challenges, future technological solutions, economic contexts, and foster learning and life skills. To shift the technological innovation mindset to be more patient-oriented, different academia should offer training in innovation management, leadership development, value in care, and digital transformation. This approach can be applicable in Portugal and other regions, raising awareness among agents about the importance of innovating in healthcare, ensuring sustainability and profitability in healthcare.
<i>Specialized Centers, Professionals and Dedicated Structures</i>	Dedicated structures within hospitals is a strategic approach to reinforce competitive positions, mitigate risks, assess technologies for efficiency gains, provide access to knowledge, and enable the commercialization of innovative MedTech. Decisions (i.e. on adoption) supported by proven, evidence-based cost-effectiveness should be considered when changing the current strategy of adopting innovative medical technologies. Hospitals should divide or delegate efforts, ensuring that at least one centre within a hospital holds competencies in HTA. Portuguese continuous assessment (through management) tools would help stakeholders evolve and adapt in different settings and contexts, continuing to try to achieve convergence of HTA frameworks in other regions. KOLs can assess and advise on investing in innovation, considering the potential and limitations of technologies and leverage the expertise of decision-makers. Industry agents collaborate closely with hospitals, academia, and technological infrastructures, matching challenges, needs and projects with hospital community.

	Clinical engineers may bridge the gap between agents in healthcare ecosystems, contribute to the integration of innovation in hospitals by identifying real clinical needs, contributing to the design, development and test of technologies, de-risking, validating performance and cost-effectiveness, ensuring compliance with standards and regulations, facilitating commercialization and adoption, and contributing to systems integration and interoperability within the hospitals.
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5.1.1 Innovation Process in Hospital Setting

To create and sustain an ecosystem that incorporates hospitals, collaboration and partnerships, technology integration, patient-centred care, health management, and quality improvement [148] should be prioritized. Hospital innovation models should consider five fundamental elements – infrastructure, human resources, innovation culture, strategic partnerships, and capital [131] – and adapt to the regional context. Hospitals should also engage in collaborative practices with patients and other agents to deliver quality value-based and patient-centred care, identify and address needs, enhance transparency, trust, and outcomes, share patient data, integrate technology, and follow regulations and norms that promote proximity [50]. The proposed model supports MedTech innovation in hospital settings by building on the multidisciplinary pillars. This involves developing and adopting health management strategies, assessing health technology and systems, monitoring and measuring outcomes, evaluating and mitigating investment risks, and detecting opportunities for improvement – especially for implementing innovative medical technologies.

5.1.2 Innovation Process Flowchart

It was developed a flowchart to simplify and guide the steps associated to each phase of the innovation process in hospital setting. The Figure 7 illustrates a comprehensive scheme of an efficient innovation process: starting from identifying and addressing the clinical needs, making converge the interest of the quadruple helix agents in the ecosystem – Hospitals, Academia and Technological Infrastructures, Government and Regulators, MedTech industry players – and ensuring the demanded capital, innovation is designed and tested in the clinical setting in close cooperation, namely with clinicians, innovators, business experts, policymakers and patients. For de-risking decision, the Health Technology Assessment (HTA) evaluates the feasibility of the adoption of medical technologies, identifying whether it is suitable for implementation – if any technological advancements are required, or if it is not a viable solution – to later be included in clinical practice and workflows.

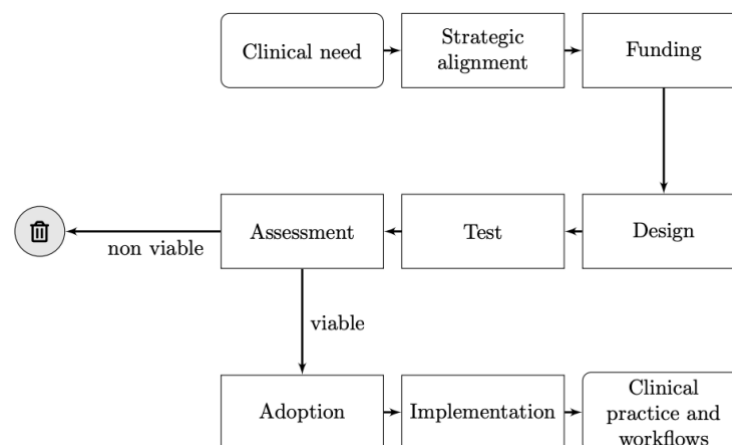


Figure 7. An efficient framework of the innovation process. Adapted from [40].

Focusing on the analysis of specific pain points of the process, as well as organizational, cultural and technological factors, and exploring internal and external measures to address the challenges involved:

Starting with the identification and addressing a clinical need – identified and assessed by hospitals, university-hospitals, health centres and/or partners regarding strategic alignment, scoping, and capital determinants, ensuring the coordination of expectations and value of the innovative ideas –, experts (as MedTech industry experts and experienced researchers) screen challenges and ideas, and later evaluate the exploitability of scientific results. The medical technology innovations must be implementable in the hospital setting, aligned with the hospital innovation strategy and have potential in clinical environment, units and departments, where clinicians and patients – patients themselves, patient associations and their relatives – can be involved as end-users. If approved for scoping, innovators and clinicians develop an opportunity statement with the participation of internal and external partners as other clinicians and researchers, KOLs, consultants, MedTech industry and business experts. A hospital innovation strategy presupposes fostering an innovative entrepreneurial mindset not only among innovators but also among management, administration, clinical services and departments. Hospitals must consistently promote a culture of innovation where communities are encouraged to accept, adopt and implement innovative solutions in clinical workflows, while being supported, incentivized, trained and cooperate in the ideation of new technologies or better workflows. Furthermore, hospitals must collaborate with civil society stakeholders such as patients, healthcare professionals, MedTech industry players, startups and spinoffs, academia, knowledge institutions, non-governmental and governmental organizations, as well as policymakers and attorneys supporting the co-creation of the ecosystem, regulatory issues, and commercialize innovative medical technologies. After verifying the requirements for the project initiation, it is important to coordinate the funding level and constraints, identify funding opportunities, and perform a de-risking assessment.

Portuguese hospitals' mission and vision

To promote innovation, Portuguese hospitals should define a mission and vision based on core principles that guide their actions and decisions. These principles include prioritizing patient care, quality of life and cost-effectiveness, which are the main goals of healthcare delivery. To achieve these goals, hospitals should adopt a patient-centered value-based healthcare model that takes into account the patient's holistic well-being, including their physical, mental, social and emotional aspects. Hospitals should also develop solutions based on clinical needs that are pertinent and relevant in the clinical environment, meaning that they address real problems, improve outcomes and fit the context. Moreover, hospitals should invest in partnerships, collaboration and new perspectives, which are essential to foster innovation and learning. By engaging with different stakeholders, such as researchers, industry, regulators, payers and patients, hospitals can access diverse sources of knowledge, expertise, funding and feedback, and create synergies that enhance their innovation capacity and performance.

5.1.3 Holistic Patient Care

The primary goal of hospitals is to diagnose and treat patients effectively. However, hospitals should also strive to enhance patients' quality of life and support not only during, but also before and after treatment [Rui Henrique, Annex I]. Therefore, hospitals must

recognize that their responsibility for societies' lives, not only for diagnosing and treating a disease or illness condition but ensuring that future healthcare solutions are responsible for the whole person – delivery care in the broad sense.

5.1.4 Address Unmet Needs and Valuable Ideas

Hospitals must actively intervene and prioritize the specific needs of patients and healthcare professionals when (and put an effort to be) involved in the development MedTech innovation projects and solutions, to be implemented in clinical workflows.

By focusing on the collaboration and the dynamic of cross-linking knowledge and expertise – rather than only on what is expected –, hospitals can provide insight into the value, viability and feasibility of new technologies and projects, opening the opportunity for assessing and monitoring the medical technology development and transfer process, allowing for interaction, testing and adaptation, fostering communication between innovators and end-users within the ecosystem.

5.1.5 Collaborations and New Perspectives

The partnership strategy is an essential component for hospitals seeking to drive innovation [40]. The more an innovation circulates across different settings and contexts, the more it, and the stakeholders involved, will change [34]. While Portuguese hospitals have some of the good clinicians and the Portuguese healthcare system is one of the best [149], future healthcare challenges are too complex to be tackled by just one organization [Michel Nemery, Annex I]. Hospitals should merge efforts to overcome silo mentalities by actively involving relevant partners and end-users [Rui Henrique, Annex I].

To support the development of innovative initiatives in Portuguese hospitals, it is also to highlight the importance for policymakers, government, regulators, and local administrations to provide resources and support for hospitals to not only generate revenue, but also establish partnerships with industry, and improve access to data. The MedTech industry can help to provide resources and access to digital tools, support to generate knowledge, helping to close the skills' gap and share valuable and experienced insights based on KOLs and experts' feedback.

Public-private Collaboration and Partnerships

“Private sector organizations can contribute to MedTech innovation by providing financial support, resources, advice on sustainability, and a network to comply with regulations and get legal expertise to small enterprises and businesses” interview with Xavier Monné, Annex I], where “the government can incentivize the connection and communication between universities, hospitals, and academia to create partnerships and encourage the involvement of the private sector” [Xavier Monné, Annex I].

Hospitals can foster collaboration with private partners, from spin-offs and startups to big companies, by implementing a streamlined process for soliciting, testing, and evaluating ideas and projects through digital platforms, gathering, and evaluating data efficiently, ensuring that proposals are assessed in reasonable time.

The competition in the MedTech sector is expected to shift from individual companies to entire ecosystems, to provide an optimized patient journey and better outcomes at scale to achieve sustainable models [5]. Along with Government and Regulators, the industry must incorporate regulatory engagement into innovation models, involving healthcare

professionals and patients in product design, establish cross-functional need-driven committees to transfer scientific results to commercialize, manufacture, and access the market for valuable solutions. Hospitals are expected to receive proposals and propositions concerning technologies and initiatives requiring attention to the collaboration between clinical facilities and MedTech industry. Portugal should create a cohesive support system and become a centre of excellence in the field of medical research, drawing inspiration from European models, specifically examining how clinical research centres involve, dispose and interact [99].

To successfully build an ecosystem, it is essential to select the right workforce – who can conduct standard clinical need’s screening, research, or have biomedical and/or technical skills – and involve them in the development and implementation of sustainable need-driven medical innovations, following a patient-centred design.

Healthcare Hackathons

As reported by interviewees, “hackathons impact is huge” [Francis Tricot, Annex I] and “to ensure the success of a hackathon, it is advisable to have a diverse group of participants including clinicians, technological and business-minded professionals, as well as access to grants for further development or piloting, clear and predictable licensing and technology transfer or spin-out terms, mentorship from established experts, and ideally, a network of investors” [Alan Braly, Annex I].

Organizing an hackathon requires planning and a clear understanding of the goals and objectives tailored to meet the use cases of an institution based on its needs [150].

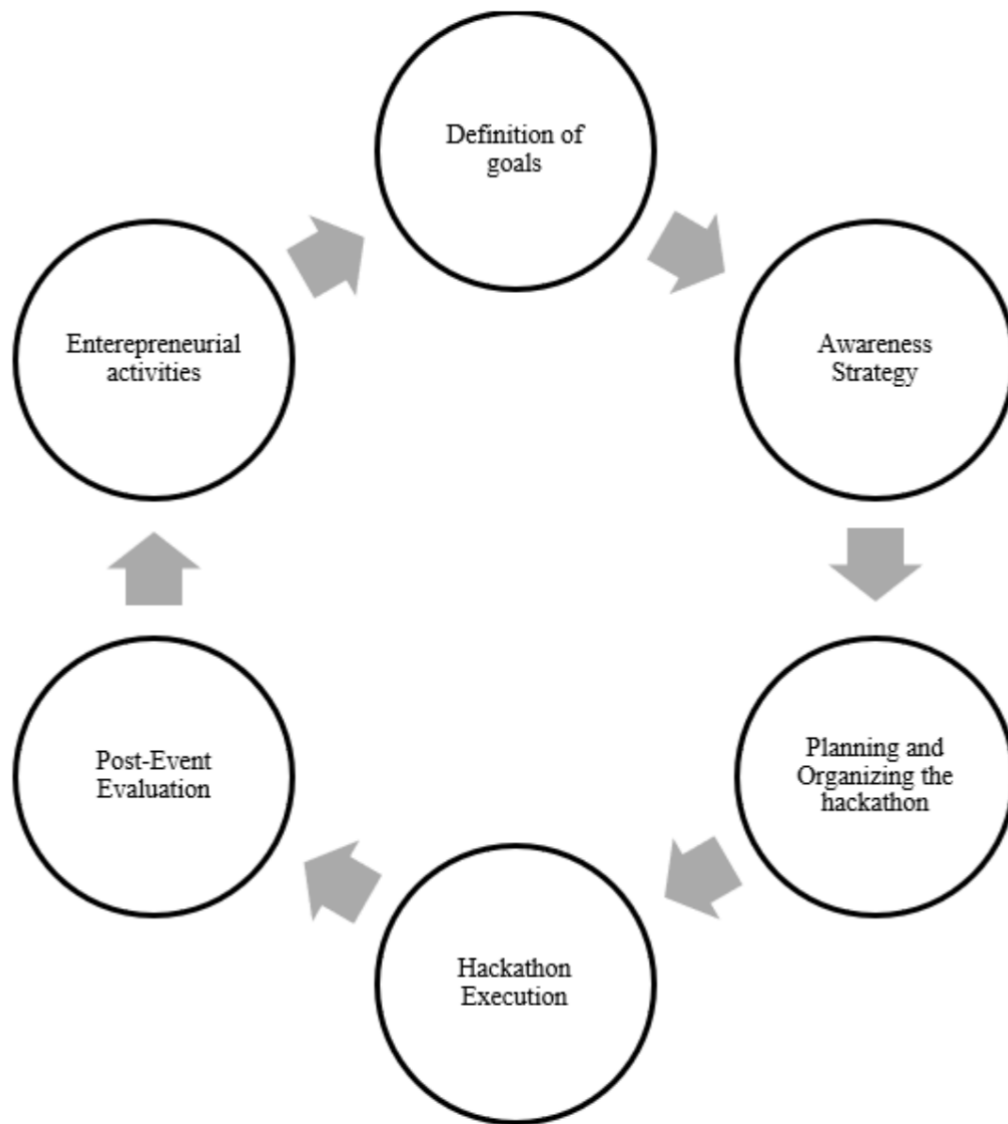


Figure 8. Model for organizing healthcare hackathons [144].

Figure 8 presents a model for organizing healthcare hackathons in hospital settings. Based on it, on the guide suggested in Figure 6, and on the previous analysis in section 4.4, the following steps are proposed as best practices to organize a healthcare hackathon.

Definition of goals

Firstly, it is important to identify the clinical problem or challenge that the hackathon will tackle, such as improving patient outcomes, reducing costs, or enhancing accessibility, for a specific disease or context. The target user group, their needs, preferences, the expected hackathon deliverables, and evaluation criteria should be clear for the participants.

Planning and Organizing the hackathon

The next step is to choose between a thematic or an open-ended hackathon, depending on the problem scope, and select a suitable venue and time frame for the

event, considering the resources and facilities available. The participants should have diverse backgrounds, such as healthcare professionals, patients, engineers, designers, students and entrepreneurs, and should be motivated to join the hackathon (by offering prizes, mentorship, and networking opportunities) and screened.

Hackathon Execution

During the hackathon, the hospital community and the innovators should be matched through speed dating, pitch sessions, or online platforms. The teams should interact frequently and iteratively with the end-users and external stakeholders, such as mentors, sponsors, or experts, who can provide feedback and prototyping cycles to help them refine, re-design and test their solutions. The projects should be evaluated based on predetermined criteria.

Post-Event Evaluation

The final step is to showcase the solutions to a wider audience and invite judges (such as KOLs, business and industry experts, and healthcare providers) to assess them. Constructive feedback and suggestions for improvement in the next hackathon should be given. The teams should be encouraged and supported to continue working on their solutions after the hackathon with the hospitals while being informed and educated on IP and regulatory compliance.

5.1.6 Inclusion of Society in Innovation Models – the fifth helix

Creating a healthcare ecosystem requires a commitment from the agents to ongoing evaluation and improvement, ensuring that medical technology innovations are effectively integrated into clinical practice and lead to improved outcomes [50]. Value-based patient-centric model of healthcare delivery focuses on providing quality and effective care, while reducing costs to patients (at the centre) and giving them more control over their care and treatment [151]. The involvement of society in health policy [34] and patients in the development and design of care is a strategy for moving forward – however, this may be insufficient as several levers for large-scale transformation and improvement are needed.

Patients' insights, knowledge and experience about their own health conditions, treatments, and outcomes, are valuable feedback for providers to develop solutions that address the real impact of medical [152]. Patient associations, groups of patients or patient representatives who advocate for their communities' interests and needs in health care issues, may collaborate with various stakeholders to improve the quality and accessibility of healthcare services. Patient insights can inform the design and delivery of patient-centred care, which respects and responds to patients' preferences, needs, and values.

5.1.7 Innovation Networks, Commercialization Programs and Platforms

Healthcare innovation hubs are spaces or platforms that aim to foster the access and integration of medical technology innovations in clinical practice. They are based on the identification of unmet clinical needs and a mission statement with an “innovation focus” [60][130]. They also require the engagement of clinical stakeholders throughout the innovation process [9][32][60], as well as the collaboration of multidisciplinary teams that merge expertise and cross-knowledge between hospitals, research and academic

institutions, MedTech industry, government and regulators. Moreover, they need access to a stable source of capital, entrepreneurial training and mentors, professional networks, and physical facilities. Building healthcare innovation hubs can be costly and challenging, as they require investment in staffing and infrastructure, involvement of frontline hospital staff, establishment of a governance structure, and measurement of success through metrics such as patents or revenue generated from innovations [153, p. 4]. However, they can also become regional centres of innovation that improve the quality and efficiency of healthcare delivery.

Hospitals Network and Healthcare Commercialization Programs

Healthcare Commercialization Programs and “informal” networks can facilitate the adoption of new technologies by end-users, by promoting collaborations, knowledge sharing, engagement with healthcare professionals, and creating a supportive ecosystem. The MedTech industry should understand end-users’ needs and develop business models that demonstrate the value of their innovative solutions for stakeholders in the healthcare ecosystem [5]. Innovation efforts in healthcare should also prioritize engagement with healthcare professionals to identify and address unmet clinical needs and promote informal networks of healthcare providers and patients [154].

A “Network of Innovative Hospitals” could provide a valuable platform for Portuguese hospitals to exchange knowledge and collaborate on scaling innovative solutions [Jesper Wagner Lopes, Annex I]. Such a network could draw inspiration from the success of the National Network of Innovative Hospitals in Denmark [40], which mobilized an alliance across each hospital, affirming the country’s position as a clinical innovation hub. A similar network in Portugal could enable hospitals to learn from each other’s mistakes and successes in developing and implementing medical technologies, encourage collaboration between facilities, align with the interest to integrate innovation in clinical workflows and foster a culture of innovation among healthcare professionals. This could be a tool for overcoming the communication barriers and approaching innovation in healthcare. “Informal” networks also play a role in connecting healthcare innovators with industry experts who can provide feedback and guidance [154].

For example, the HCP Smarthealth network in Portugal aims to bring together stakeholders from different sectors who participate in the MedTech development process and promote innovation in healthcare [Patrícia Patrício, Annex I]. These networks provide a platform for healthcare professionals, researchers and industry partners to collaborate and share knowledge, enabling the development of new and innovative healthcare solutions that can improve patient outcomes and create value for stakeholders.

National Innovation Platform for Medical Technologies

A national innovation platform for innovation in medical technology could promote and accelerate the identification, development, validation, and implementation of innovative MedTech in Portuguese hospitals. The platform could consist of the collaboration of Hospitals with Academia and Technological Infrastructures, MedTech industry, promoted and supported by Government and Regulators. The platform could enhance interoperability and open data, facilitate data sharing between facilities and agents, reduce costs effectively, and foster value-based patient-centric healthcare [João

Diniz, Annex I]. The platform could also provide grant programs, courses, training to enable a systematic approach to innovation in clinical setting and integrate it into the healthcare and education systems.

5.1.8 Education and Training on Hospital MedTech Innovation

Innovation and development require focused efforts and professionals, not just general technological progress in society. Hospitals must prioritize and reinforce strategic innovation and technological culture, leading to operational sustainable efficiency by gather feedback from hospital community, screen clinical needs, establish a value-based framework for shaping the patient-centeredness future in addressing challenges and scouting opportunities to drive the innovation.

As healthcare needs and conditions change, innovation training programs must be continuously adapted and updated to strengthen innovation management and contribute to the mission of providing specialized care and creating value for patients. Universities and academia in general should incorporate an interdisciplinary approach that encompasses entrepreneurship and basic knowledge in health economics [151], for example in addition to the specialized knowledge acquired in Bioengineering and Biomedical Engineering courses. These educational programs could provide future healthcare professionals with additional skills beyond a traditional curriculum. “Coursework should be adapted to provide a comprehensive understanding of regional and global health challenges and economic contexts, while enhancing learning and life skills such as flexibility, leadership, interpersonal skills, and basic business and entrepreneurial training” [Eduard Soler, Annex I]. To address unmet clinical needs and shift the innovation mindset towards being more patient-oriented, educational institutions should offer transformative training in the fields of innovation management, leadership development, value in care and digital transformation. This could be applicable in Portugal and other regions of interest, where external parties – including authorities and care providers – may also apply for these education programs, creating a cultural change towards better innovation conditions. This approach can help raise awareness among professionals of the importance of innovating and creating solutions that benefit patients, while also ensuring sustainability and profitability in healthcare.

5.1.9 Specialized Centers, Professionals and Dedicated Structures

According to decision-makers from PHSSR, ensure that the adoption of innovative health technologies by the system should be evidence-based and cost-effectiveness [99] – changing the current strategy based on the lowest price [100]. Continuous monitoring and feedback through management tools can help stakeholders involved in the implementation and use of innovations, to evolve and adapt in different settings and contexts, rather than being controlled or coerced towards predetermined outcomes. Despite progress, achieving convergence of HTA frameworks across EU member states remains a challenge, and as such, the Portuguese technology assessment framework should continue to evolve and adapt to address future obstacles [Fernando Lopes, Annex I], aimed at enhancing access to innovative technologies [138].

The creation of dedicated structures within hospitals represents a strategic approach to concentrate and reinforce competitive position, mitigate risks, and evaluate health technologies to ensure cost-effectiveness and efficiency gains, providing access to knowledge and, in turn, enabling hospitals to commercialize products and services, reach

and access new markets, leading to the profitability and sustainability of the healthcare model.

Decisions supported by proven, evidence-based cost-effectiveness should be considered for changing the current strategy based on adopting innovative medical technologies – whether in-house or external, key opinion leaders can assess and provide advice on technological investments, accounting for innovations’ potential, limitations, and expertise of decision-makers. Hospitals must divide or delegate the innovation efforts into or to specialized research and innovation centres – these centres should be physically located within the hospital and guarantee that at least one centre holds competencies in HTA – establishing close collaboration between the Hospital, and Academia and Technological Infrastructures, enabling matching of any given project or wish for development from the clinical setting with the right healthcare professional. In cases where there is a need that justifies multiple centres, particularly specialized in different fields, these centres must have a strong network, share experiences, competencies, and collaborate on different levels to foster the cross-linkage of knowledge.

New Actors: Clinical Engineers

Clinical engineers are specialized professionals who may play a pivotal role in healthcare organizations. In recent years, engineering has applied its principles and contributed to address medical-related challenges [9]. In Figure 9 it is presented an overview on clinical engineers’ contribution, who reunite competencies to bridge the gap between medical technology innovations, and their adoption and implementation in hospital settings. These professional act as innovation managers and supervisors who can leverage the potential of hospitals as active participants in the innovation process [17]. As part of a multidisciplinary team that involves clinicians, researchers, industry partners, and government agencies [148], clinical engineers facilitate communication and coordination among different stakeholders, being involved in activities related to MedTech and innovation management – identifying clinical needs, designing and developing medical technologies, testing, de-risking, validating their performance, cost-effectiveness, safety in compliance with standards, regulations, risk management, and facilitating their commercialization and adoption [148][156], contributing to systems integration and ensuring the compatibility and interoperability of these technologies within the hospital environment.

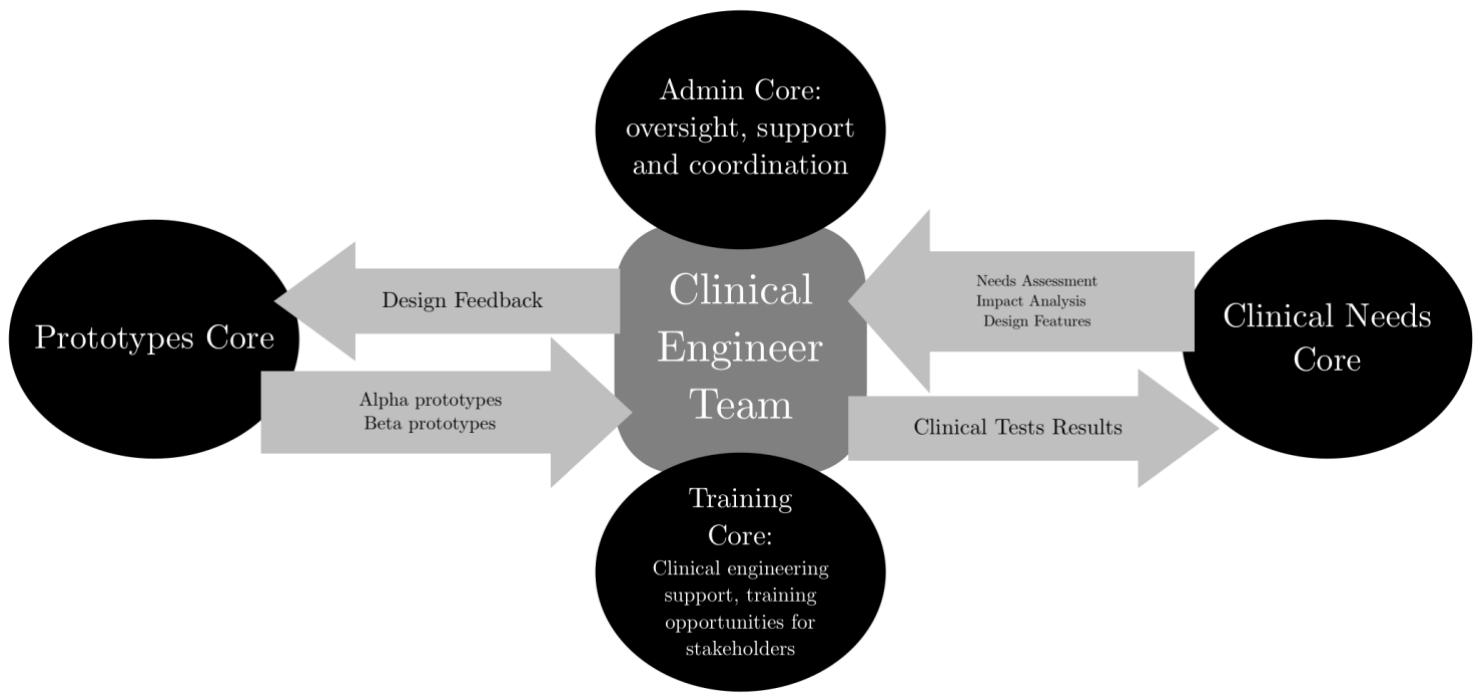


Figure 9. Overview of the contribution of clinical engineers. Adapted from [155].

With a background and experience in medical technology, clinical engineers are able to facilitate the valuable integration of innovation in hospital settings through collaborative efforts with other healthcare providers and administrators, contribute to improved patient outcomes and help establish the hospital as a leader in innovative healthcare delivery [156].

Conclusions and Future Improvements

The aim of this dissertation was to study effective frameworks to support medical technology innovation in hospital setting.

This thesis aimed to answer the main research question “*What effective frameworks can Portugal develop to support medical technology innovation in the hospital setting?*”. The research methods included a preliminary literature review, a stakeholder analysis, unstructured and semi-structured interviews, a detailed literature review and a thematic codification to analyse the data gathered from the interviews. The considered interviewees were thirty-six representatives of the four agents of the Quadruple Helix Model – Hospital, Academia and Technological Infrastructure, Government and Regulators and MedTech Industry – from six benchmarked countries – Denmark, France, Germany, Spain, Switzerland, and the United States – which are international references in (medical) innovation with well-established structures and systems, and Portugal. The specific objectives were to investigate the challenges and causes of failure, the key factors for successful MedTech innovation, and the contributions of different agents to support medical technology transfer in hospital setting. The data analysis and findings revealed that innovative medical technologies are essential for the creation of the Portuguese ecosystem and that Portuguese hospitals need to enhance their internal and external measures. The Key Lessons Learned and Recommendations were presented as a compilation of best practices from the interviews and literature, from which the Building Blocks for Hospital MedTech Innovation emerged as a suggestion of effective frameworks to support medical technology innovation in (Portuguese) hospital settings.

This study identified challenges and causes of failure, key factors for success, and suggests effective frameworks to support MedTech innovation in hospital setting. Regulatory, financial, technological, strategic, and organizational challenges were identified, as well as insufficient evidence of real clinical need, safety and cost-effectiveness, healthcare professionals’ resistance to innovative medical technologies and their compatibility with existing systems and clinical workflows. The key factors for success reported include need-driven projects, collaboration and partnerships, and a patient-centred value-based model. The study also emphasized the importance of involving all agents in the innovation process, suggesting that successful medical technology innovation in hospital settings requires a combination of vision, commitment, and action – from where, aligning all the agents, a healthcare ecosystem arises.

Effective frameworks presuppose the clarification of the purpose of hospital innovation and healthcare ecosystems, the establishment of defined roles and responsibilities for hospital management, fostering an innovation-oriented culture, promoting collaborations between agents, and empowering hospitals involvement on innovation process from inception to maturity phase of innovation processes,

collaborating on designing, testing and sharing data on the realm of ethical consideration. From these findings and grounded on data analysis from the interviews and literature, this study suggests nine recommend Building Blocks for Hospital MedTech Innovation (“Innovation Process in Hospital Setting”, “Innovation Process Flowchart”, “Holistic Patient Care”, “Address Unmet Needs and Valuable Ideas”, “Collaborations and New Perspectives”, “Inclusion of Society in Innovation Models – the fifth helix”, “Innovation Networks, Commercialization Programs and Platforms”, “Education and Training on Hospital MedTech Innovation”, “Specialized Centers, Professionals and Dedicated Structures”) which consisted on effective frameworks to support medical technology innovation in hospital settings. The latter were grounded on multidisciplinary pillars that involve collaboration and partnerships, technology integration, value-based patient-centred care, health management, and quality improvement. The steps and challenges of the innovation process, from identifying clinical needs to commercializing medical technologies, were outlined and the importance of providing holistic patient care that improves patients’ quality of life and supports the care journey was emphasized. It was suggested that hospitals should foster an innovation culture that prioritizes and reinforces organization, strategic innovation, and innovative technological culture. Finally, it highlights the role of collaborations and new perspectives in driving innovation in hospitals, and the need for Portugal to establish a cohesive support system and become a centre of excellence in medical research.

The most outstanding findings of this study were the positive potential of healthcare hackathons to promote cross-linkage of knowledge and clinical need screening and how could they be organized, and Health Technology Assessment as a de-risk strategy to assess safety and cost-effectiveness of medical technology innovation.

In this dissertation, findings and recommendations confer limitations, namely its qualitative exploratory character, the short population studied and research period. Future studies can explore the development of a more robust at a multi-level framework to support medical technology innovation in hospital setting, the decentralized approach of hospital management, autonomy for Portuguese hospitals to take decisions and organizational strategies – namely in Clinical Innovation Units, Innovation Hubs and Specialized Centers –, innovation committees, revision of policies, norms, regulation, and other initiatives to foster the co-development and creation of MedTech innovations and healthcare’ ecosystems, with emphasis on the alignment of mission, vision and objectives of different agents.

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Annex I

Table I. 1– Unstructured interviews: interviewees’ profiles, key lessons learned and recommendations shared in the interviews.

Region	Quadruple Helix Agent	Contact person Position, Institution	Key Lessons Learned and Recommendations from the interviews
Europe (Denmark)	MedTech industry	Jesper M. Wagner Head of Medical Device Consulting and Office Manager, NIRAS	NIRAS is a consultancy company that provides services to hospitals to ensure compliance, choose and implement technologies, and build effective hospitals where people can get better faster and more effectively. MedTech innovation is a vital resource for the Nordic healthcare ecosystem, which faces a lack of infrastructural and human resources (such as hospitals and healthcare professionals). Denmark is a leader in MedTech innovation, mostly due to its culture of innovation and technology, health platform that collects, analyzes and shares patient data, and a close collaboration between the government, hospitals, and the industry. Some of the challenges for MedTech innovation are related to compatibility, interoperability, and tracking and relying on the results of the technologies. Efforts on HTA are being made to access cost-effectiveness on technologies.

			Some of the advantages of Denmark for MedTech innovation are the small size of the country, the proximity between agents promoted by platforms and (informal) networks, the transparency and trust in the relationships, and the high level of of clinicians accepts of innovation.
Europe (France)	Academia and Technological Infrastructure	Julien Matricon Technology Transfer Officer, Assistance Publique (Hôpital Saint-Louis AP-HP)	Funding is a major challenge for MedTech innovation in France, and more efforts are needed to convince the administrative and funding agencies of the importance of investing in this field. Also, there is a lack of a structured program for MedTech innovation in France, and the existing acceleration programs are not accessible or aligned with the needs of the hospitals and MedTech companies. The TTO is located inside the hospital, which facilitates the identification and screening of needs, but there is still a gap in communication and collaboration between clinicians and researchers. The TTO focuses mainly on improving treatment protocols and tools, rather than developing disruptive technologies, which may limit the potential for innovation and impact. The TTO should have a multidisciplinary team that includes experts in science, law, medicine, management, and health policy, to provide comprehensive and quality services to the clients and stakeholders. The public system incentivizes researchers to innovate and protect their technologies by sharing royalties with them, unlike the private sector, which may create a competitive advantage for the public system. The researchers have a high awareness of the value and importance of innovation and protection of technologies for collective health and national reputation, but they need more education and guidance on how to produce results and commercialize their technologies. The TTO is selective in protecting technologies that bring revenue streams, rather than pursuing quantity or statistics, which may reflect a strategic vision and a focus on quality.
Europe (Portugal)	MedTech industry	Luís Costa Project Manager, Glintt	Glintt is a company that provides informatic solutions to Portuguese hospitals but only has access to clinical data through its software. For this reason, Glintt has only one MedTech project in collaboration with a hospital and a university, which benefits the hospital in terms of funding, scientific publication, and reputation. Glintt faces challenges in terms of bureaucracy, personal data protection, and competition in the MedTech market, especially from the US.

			The company operates in Portugal and does not have a formal IP strategy or a legal team involved in MedTech project, relying on informal agreements and trust with its partners. Public hospitals have less autonomy and more barriers to adopt MedTech innovations than private hospitals, which are driven by reimbursement, revenues, and profit. Clinicians may resist new technologies for various reasons, such as fear of failure, lack of skills, or preference for traditional methods.
Europe (Spain, Catalonia)	Hospital	Eduard Alonso Head of innovation unit and tech transfer, Parc Taulí Hospital Universitari	Adoption of technology is a major challenge, as healthcare professionals often lack time, incentives, and training to engage with new medical technology. Lack of funding, especially in the public sector, poses challenges for hospitals and their innovation units in competing for resources and attracting government attention and support. Cross-linking information and merging the expertise of innovators with the needs of clinicians is essential but often lacking, requiring collaboration and information sharing between different actors. It is crucial to prioritize efforts to address the challenges of technology adoption, engaging clinicians and providing training on new medical technologies. Educational and challenging programs, such as accelerators, hackathons, and workshops, can inspire and accelerate innovation based on identified gaps in the hospital setting. Stanford and MIT are references of entrepreneurial education. Establish educational programs within hospitals, in partnership with clinicians and business leaders, to inspire and educate the next generation of innovators are the future. Innovation units in hospitals vary in complexity, responsibility, and collaboration, requiring specific frameworks and approaches for translating scientific results into valuable medical technology. It is crucial to encourage collaboration and information sharing between innovators and clinicians, bridging the gap between scientific/engineering expertise and clinical needs.
Europe (Spain, Catalonia)	Hospital	Ismael Àvila Head of the fundraising Department, Parc Taulí Hospital Universitari	Biocat is a governmental initiative of Catalonia that supports the healthcare ecosystem and links academia with the industry, focusing on biotechnology, MedTech devices, and digital health. Technology transfer in the healthcare ecosystem can be based on public-private collaboration, technologies developed at TTO's hospital, or development of technologies bought to the hospital. Technology transfer can be either need driven or tech driven, depending on whether the innovators invent to fit the identified need within the hospital or invent and then find the market for their technology. Public hospitals depend on public money and private funding to support their technology transfer efforts, and face competition and challenges in finding customers and partners for their technologies.

			Reimbursement is based on the number of patients per hospital, and data monetization is a complex and sensitive issue due to GDPR and data protection regulations.
Europe (Switzerland)	Academia and Technological Infrastructure	Jonas Pollar Licensing Manager, PACTT Technology Transfer Office	Challenges to overcome in healthcare include address the need for hospital community to actively engage with researchers and industry players, standardize processes, align institutional visions, and raise IP awareness to stay competitive in the fast-paced healthcare ecosystem. It is crucial for hospitals departments and innovation units to perform market research and analysis to assess a MedTech innovation's opportunity and impact before investing significant resources in its development. The cross-linkage of knowledge and experiences is extremely importance for multidisciplinary teams in the innovation process, comprising both business experts, healthcare professionals and research/science/engineering experts, to effectively bridge the gap between academia, hospitals and industry. Authorities, hospitals and the industry must encourage researchers to explore the available funding opportunities and other resources through grants and events for innovative projects. Efficient communication channels and education on IP between researchers and (hospitals) TTOs to streamline the MedTech transfer process and ensure that valuable innovations are protected and commercialized appropriately. A balanced distribution of reimbursement between the TTO, laboratory/department, university, and researcher is recommended to incentivize collaboration and provide fair recognition for all stakeholders involved in the innovation process. Disseminate innovation concepts and opportunities provided by MedTech educational programs, accelerators, incubators and initiatives, and encourage innovators to actively participate in these programs to gain experience on innovation concepts and enhance their academic metrics, recognizing the changing landscape of success in academia, bringing valuable technologies to the market and helping to automate hospital tasks.
United States	Academia and Technological Infrastructure	Zara Nemati Technology Licensing Associate,	In Stanford, licensing associates manage the entire cycle of technology transfer from IP to market entry, but they are understaffed and face challenges in hiring qualified staff. Ideally, should engage in the process from inception. Stanford has a unique ecosystem that fosters innovation and entrepreneurship, with a royalty scheme that incentivizes innovators, a marketing team that cooperates with TTO, a platform that connects innovators and customers, and professors with contacts in the industry.

		Stanford University	Stanford only patents technologies that bring revenues, rather than pursuing quantity or reputation, and licenses based on the value and potential of the licensee, not to eliminate competition. Stanford Biodesign is a program that educates and challenges alumni, graduates and students to innovate based on identified needs in the healthcare sector, and has been adapted and implemented in different contexts and regions. Patentability analysis and strategic applications are important for healthcare technology, as the European system is more diligent than the US system, but Stanford has many incentives to license health-related technologies.
United States	MedTech industry	Clintt Mathews Entrepreneur, Ex-MedTech company	Hospitals are important stakeholders, as they are close to the needs and can provide feedback and validation for the technology, but they need to invest more and be patient with the return. Hospitals should form partnerships with universities to prototype and evaluate risks before implementation. By doing so, they can help to facilitate the transfer of innovative medical technologies and improve patient outcomes. Clinicians often resist new technologies, as they feel confident in their skills and authority, and do not see the need or value of innovation. Researchers lack education and guidance on how to execute and commercialize their ideas and focus on grants and publications rather than adding value to their innovations. Technology transfer should focus on de-risking the technology, by testing and prototyping it in the market, before protecting and implementing it. The Biodesign program by Stanford at Missouri was discontinued due to the lack of a culture of entrepreneurship and the slow and costly translation of innovative technology in the healthcare sector. Educational programs are advisable but, to be successful, must account on regional context. Healthcare hackathons were well succeeded.

Table I. 2 – Semi-structured interviews: interviewees’ profiles, key lessons learned and recommendations shared in the interviews.

Europe (Denmark)	MedTech industry (Venture Capital)	Christian Waarst Business Accelerator and Investment Manager, Accelerace	The MedTech industry faces challenges such as lack of viable business models, funding, development and production partners, and scaling. Acceleration programs can provide various resources to support MedTech innovation, but candidates need to find programs that fit their needs, interests, and stages of development. Regulatory support is a common and essential resource: the proximity of government, regulators and policymakers is key. MedTech industry players must collaborate on regulatory landscape to accelerate market entry. The EU is behind the US in terms of MedTech industry development, due to differences in funding, collaboration, and market size. Denmark is improving its situation by fostering innovation and data availability, share and exchange in hospital settings. Risk assessment is part of regulatory approval, but it is not the mission of hospitals. Hospitals should delegate de-risking tasks (such as HTA) to dedicated centers, structures and professionals and optimize their decision-making.
Europe (Denmark)	Hospital	Michel Nemery Founder of the innovation unit at RAIT (Radiological AI testcenter), Herlev Hospital	Hospitals should allocate resources to create a better workplace and more value for patients. Co-creation between hospitals, academia and industry is essential for developing medical technologies that meet the needs of patients and healthcare staff, rather than just the ideas of engineers and data scientists. The healthcare hierarchy is outdated and lacks incentives for healthcare professionals to engage in partnerships with the industry. There is also a general aversion to industry on clinicians, but private partnerships are necessary to solve healthcare problems. Clinical innovation units, informal networks and innovation platforms are a way to involve clinicians, scientists, and businesses in collaboration and to design the future of healthcare using state-of-the-art technology. Innovation programs and initiatives should be based on more than just matchmaking, and measure success by the outcome of the collaboration, such as the number of lives saved or the improvement in quality of life. Hackathons are a framework to support MedTech innovation in hospital settings, as they break down silos and encourage collaboration among different groups to drive innovation in the healthcare sector.
Europe (France)	Government and Regulators	<i>Anonymous</i>	Patent attorneys play a role in protecting companies and organizing the relationship with hospitals, which can be challenging due to bureaucracy, chain of rights, and IP inexperience on the administration side. Intellectual property is an economical tool to prevent monopoly and is critical for hospitals, which are often hostages of the lack of competition due to the high specialization of the domains they are involved in.

		French and European Patent Attorney	Innovators should keep in mind that they will never file a lawsuit against a hospital, and target the moral persons around the relationship that they can go after if things go wrong. They should also be aware of the difficulties of enforcing a real NDA strategy with hospitals. Working with MedTech innovation in a hospital setting is similar to working in an academic setting, but different from working in a corporate setting, due to the administrative issues and public life agendas of hospitals. The MedTech is evolving rapidly, but at a rate that is driven by local economies and politics. Hospitals play a role in driving innovation, but they face challenges such as the EPO's refusingness to grant some patents. However, there is also a lot of money available to fund MedTech innovation, creating opportunities for growth and impact.
Europe (France)	Hospital	Marianne Lahana Health Lawyer, Doctor of Public Law, Co-founder of OPEN YOUR LAW & MED.INNOV Podcast, France	Hospitals face challenges such as finding the right funding sources, complying with regulations, and managing health data. They should move towards more partnerships and calls for projects to work closely with companies and R&D. Hospitals must have a supporting role in MedTech innovation, as they are the primary interested parties and should allow for innovations to be tested and designed based on their feedback. Also, it is desirable they provide access to data and financial resources to facilitate access to innovations for patients and enhance healthcare delivery. Acceleration programs are relevant as long as there is long-term partnership commitment and evaluation of the innovations in a mature phase. Legal and regulatory frameworks impact the development and adoption of MedTech innovation in the hospital industry, sometimes making it very difficult to move forward. The new MDR at European level is an example of a challenge for innovation. Along with public authorities and policymakers, the collaboration between hospitals and MedTech companies is essential for driving innovation in the sector, and hospitals must surround themselves with the whole ecosystem. Policymakers and regulators should cooperate by simplifying the processes and bureaucracy to accelerate MedTech market entry.
Europe (France)	MedTech industry	Franck Tricot Senior VP Strategic	Independent hospitals struggle to innovate due to limited budgets and the pressure to maintain patient care standards. To overcome this, they should prioritize attracting and retaining key healthcare professionals and staff to expand their medical services and patient population.

		Partnerships, Synapse Medicine ex-Market Development Director, Zimmer Biomet Robotics (formerly MedTech SA)	Large academic hospitals have more efficient innovation processes, involving cross-functional teams and collaboration between scientists, operational staff, biomedical engineers, IT experts, and finance professionals. Creating incubators that provide startups with access to data and personnel can further enhance innovation. Hospitals should actively monitor new technologies and establish partnerships with public bodies responsible for scanning, assessing, and trialing innovative solutions. Allowing healthcare professionals to invest time and expertise in local innovation projects or startups can foster innovation and provide financial benefits. Startups should thoroughly understand user needs, market viability, and viable business models before deploying technical solutions. Involving user patient associations, focus groups, biomedical and clinical engineers, and IT specialists from the early stages is crucial to prevent project blockages. Healthcare hackathons are solutions that are emerging and seem to have an hugely positive impact on ecosystems. Data connectivity and sharing is essential for MedTech innovation. Hospitals should ensure interoperability and connect to multiple data centers and data lakes from various sites and regions. This helps reduce cognitive bias in development and promotes healthy competition among sites, regions, and countries. MedTech companies should foster partnerships with hospitals' management, Chief Medical & Information Officers (CMIOs), clinical and biomedical engineers, nurses, and non-medical staff. Engaging these stakeholders, who possess valuable knowledge and understanding of processes, can increase the likelihood of adoption. Co-developing solutions with hospitals and using them as reference centers for training and certification is recommended. Allocating resources for applied research and running multi-centric clinical studies in hospitals demonstrates the effectiveness of MedTech solutions and drives adoption. Engaging with key opinion leader healthcare professionals and participating in industry conferences positively impact innovation. Adhering to regulatory requirements and considering alternative approaches, such as decentralized clinical trials, can help navigate regulatory challenges. Tracking key performance indicators related to patient outcomes, process efficiency, resource optimization, and reduction of medical errors provides measurable insights into the impact of MedTech innovation.
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Europe (Germany)	Hospital	Sven Friedl Technology Transfer Digital Health and MedTech professional, Charité BIH Innovation	Facilitating translation methods from research to the market is crucial for bringing MedTech solutions to patients. Organizations like the TTO of Charité BIH play a vital role in finding MedTech partners and supporting spin-offs and startups born in the University-Hospital. Funding programs should be focused on both biotech and pharma, as well as digital solutions, to cover a broad spectrum of MedTech innovation. Investing in scouting activities enables researchers to generate ideas and actively seek partnerships. Collaboration and communication between clinicians, researchers, policymakers, regulators, and other stakeholders are essential. Coordination within university alliances or similar networks can facilitate knowledge sharing and support the development of innovative solutions. Public hospitals should not be seen as developers of MedTech for commercialization. Instead, they should focus on implementing technologies that enhance patient care. Valuable data collected in hospitals should be used for investigation projects rather than being monetized. Bridging the gap between researchers and product developers is a significant challenge. Validation of scientific results for scaling should be prioritized, and researchers need to be encouraged to engage with the market to ensure successful commercialization. Overcoming regulatory barriers and aligning political interests with the goals of technology transfer offices (TTOs) is crucial. Increased support and resources are necessary to navigate the regulatory landscape and facilitate the successful translation of MedTech innovations.
Europe (Germany)	MedTech industry	Stephan Schliack Chief Operating Officer, midge medical GmbH	MedTech innovation aims to address the unmet clinical needs of patients and healthcare professionals by involving them in the co-creation process along with key opinion leaders (KOLs) and usability experts. Within the industry and hospitals, innovation faces funding challenges due to the focus on price rather than value and impact of the solutions. Companies seek to overcome this by collaborating with group purchasing organizations (GPOs), hospitals, and KOLs, and demonstrating the sustainability of its solutions. Healthcare technologies are subject to rigorous but diverse regulatory frameworks that entail high costs and delays. The company engages with the other stakeholders in the ecosystem, adopts a user-centered approach and conducts user experience (UX) studies to optimize its solutions and meet the safety and quality standards. For companies, MedTech innovation requires effective measurement of its success and impact using key performance indicators (KPIs) such as gross profit (GP), earnings before interest and taxes (EBIT), market penetration, post-market surveillance data, customer satisfaction analysis, and complaint level analysis.

			Hospitals are key partners in data management and exchange to overcome the barriers of effectiveness and trust to commercialize MedTech solutions. The company partners with US players and innovators to achieve this because of their value-based models and entrepreneurial mindsets.
Europe (Portugal)	Academia and Technological Infrastructure	José Miguel Diniz Public Health Resident Medical Doctor, Administração Regional de Saúde de Lisboa e Vale do Tejo ARSLVT	The Portuguese healthcare system faces several challenges in the implementation of medical technology, including a small market size, limited government funding, complex data requirements, low interoperability, and resistance from clinicians. The Portuguese healthcare system faces limitations in data sharing within hospitals and the potential for monetization without compromising individual privacy. There is a need for critical appraisal of technologies to ensure that the data collected and shared is used ethically and responsibly. To effectively promote medical technology in Portuguese hospitals, cooperation between patients, healthcare professionals, innovators, governments, regulators, and INFARMED (the Portuguese National Authority of Medicines and Health Products) is necessary. Additionally, the involvement of biomedical and clinical engineers is crucial to support the implementation and adoption of new technologies. To enhance the implementation of medical technology in Portuguese hospitals, there is a need for increased salaries and training for clinicians, evaluation of value-based healthcare ecosystems, the use of robust techniques in engineering and medicine to facilitate communication flow, and the implementation of bioengineered approaches to support adoption. To ensure the effective implementation and adoption of medical technology in Portuguese hospitals, there is a need for a critical appraisal of the technologies being used. This can be based on UK's HTA (Health Technology Assessments), which evaluate the clinical and cost-effectiveness of medical technologies, and help ensure that the technologies being used are both effective and efficient.
Europe (Portugal)	Government and Regulators	Vasco Dias Data protection officer, INESC TEC; Patent and TM attorney and a European Trademark and Design	To overcome adoption challenges and clinician resistance in hospitals, conducting an ethnographic study to understand clinicians' perspectives and facilitate the adoption of MedTech innovations is needed. About privacy and security concerns in MedTech projects, being aware of legal uncertainties and doubts, providing personalized advice, and establishing digital partners. To ensure privacy and intellectual property from the conception of technology development, the early involvement of data protection officers, patent, trademark attorneys in MedTech projects, is recommended (or an actor able to navigate the regulatory landscape) up to the proposal stage. The value of data aggregation, exploring the possibility of compensating citizens for their data, and ensuring ethical use of data is key. The EU regulatory framework, launching the "Health Space" for sharing health data in Europe, and discussing interoperability to overcome structural challenges.

		Attorney (before EUIPO)	For hospitals support in innovating in the MedTech, the creation a TTO or similar service is advised - that combines expertise in technology valorisation, including clinicians, engineers, business and management, and legal expertise. Improving Portuguese hospitals' expertise in intellectual property and personal data to retain knowledge and talent is imperative.
Europe (Portugal)	Hospital	Rui Henrique Hospital Administration, IPO	The resistance to the entry of medical technologies in hospital setting is mostly due to the inertia of the system and the lack of interoperability. Overcoming this challenge requires resources and recognition of the costs associated with change management. Clinicians need to be exposed to technologies outside their workplace to bring them into their workplace. Training is needed for clinicians to become proficient in the technology, and the determination of who will become proficient depends on the number of cases for which they will use the technology. The cost-benefit evaluation committee is responsible for evaluating the need for technology adoption, willingness and receptivity of the clinical service to adopt, and the feasibility within a financial plan to make the acquisition viable. Patient acceptance is becoming increasingly important in the decision-making process for technology adoption, with patients being receptive to technology that can treat them better. Patient input is collected through surveys, and the opinions of a sample group of patients are taken into consideration. Hospitals contribute to the transfer of medical technology primarily through their involvement in clinical trials. The hospital environment has a repository of data available for internal audit and research purposes, but the monetization of this data does not occur. Portuguese Hospitals do not typically support acceleration programs or initiatives to support the development of technologies, as the hospital setting is not structured to support entrepreneurship (neither resources - financial or human - nor vision).
Europe (Portugal)	Hospital	Micaela Seemann Monteiro Chief Medical Officer for Digital transformation,	A dedicated role for MedTech innovation can provide strategic direction and coordination to improve healthcare delivery and outcomes, and other organizations should establish similar positions to drive digital innovation. CUF's success in leveraging advanced equipment is attributed to the presence of multidisciplinary teams and up-to-date technology: their hospitals and healthcare facilities promote collaboration across different specialties to enhance performance, cost-effectiveness and patient outcomes. CUF's approach to acquiring new medical technologies involves considering various aspects as technical, clinical, management, and commercial considerations: a comprehensive evaluation process for new medical

		José de Mello Saúde	technologies – this assessment ensures the selection of relevant and effective technologies, to make informed technology investments. Partnerships and collaborations with Academia and Technological Infrastructures, specifically for clinical trials and technology evaluation, provide CUF with valuable insights and expertise for research, innovation, and the adoption of cutting-edge technologies. Interoperability of IT systems for seamless data exchange and integration must be a priority to enhance communication, improve patient care and technological advancements across healthcare settings. The active involvement of administrators governs and regulators in technology evaluation and investments ensures that the selected technologies align with the healthcare systems and hospitals’ goals and are integrated effectively.
Europe (Portugal)	MedTech industry	Patrícia Patrício Knowledge and Intelligence manager, Health Cluster Portugal	Hospitals are key actors in innovation by co-creating, testing, using, and providing data for tech solutions. MedTech programs offer resources to validate solutions in real settings and increase trust in technologies among clinicians. Frameworks to support MedTech in hospitals vary according to the partners and goals, such as enhancing academic-hospital partnerships, accelerating programs, creating networks, and establishing dedicated structures in hospitals. Portugal faces challenges in creating a healthcare ecosystem, such as coordinating initiatives among partners, accessing capital and market, and fostering entrepreneurial culture. Clinical engineers with medical and engineering skills are needed to facilitate communication and identify technological needs, especially in hospital management positions.
Europe (Portugal)	MedTech industry	Francisco Ramires Account Manager, Promptly Health	MedTech industry faces challenges such as regulatory compliance and security, bureaucracy, decision-making hierarchy, and budget constraints. European hospitals have a more commercial profile than Portuguese hospitals, which have scarce innovation teams and sell patient data to the industry through brokers. Internal acceleration programs within large companies are more sustainable, while accelerator programs face obstacles such as mentor quality, lack of contextualization, and insufficient industry involvement. Collaboration and innovation are essential for advancing the MedTech industry.

Europe (Portugal)	MedTech industry	Fernando Lopes Commercial Executive, CMR Surgical	MedTech innovation in Portuguese hospitals faces funding and resource management challenges, especially human resources and outdated DRG table. Health gains should be the main criterion for assessing innovation, along with patient safety and regulatory compliance. Collaboration among hospitals, industry, and government/regulators is essential to bring innovative products and technologies to market. Hospitals need to change training models to develop competencies and adopt risk-sharing partnerships to support MedTech innovation in their organizations. Academia can assist hospitals in introducing MedTech innovation in procurement, implementation, training, and evaluation of health gains, using downstream and upstream models.
Europe (Portugal)	MedTech industry (and Venture Capital)	David Carvalh�o Board of Directors of Venture Builder, UNIONvb Co-founder, IHCARE - INNOVATION HOSPITAL CARE, SA EIT Expert, European Commission – Horizon Europe program	The main challenges for MedTech innovation in hospitals are regulatory issues and the readiness to run pilots, which can hinder the market access of innovative technologies. The main factors for developing and managing tech portfolios are technological feasibility, R&D cost, and clinical and economic benefits of the solutions. The main criteria for assessing the potential of a MedTech start-up are the existence of a real need, the skills of the project team, and the technological and economic aspects of the solution. The role of evolving technology in healthcare is crucial to cope with demographic pressure and improve efficiency and quality of services, which creates opportunities and challenges for investors. The main trends in MedTech innovation are AI, big data, IoT, robotics, and biotechnology, which can transform healthcare delivery and outcomes.

Europe (Portugal)	MedTech industry (and Venture Capital)	António Murta Managing Partner and co- founder, Panthena	Hospitals are key actors in supporting medical innovation, especially in acute care and pharmacology. MedTech transfer faces challenges such as investment and regulatory barriers, and adoption resistance from clinical and management decision-makers. Pathena supports MedTech innovation in hospitals through collaboration agreements, continuous process improvement, and close collaboration with specialists. Successful hospital structures for innovation involve access to anonymized medical imaging data, specialists for labelling/classification, and digital assistance tools supported by advanced AI. Regulators ensure patient safety and proper protocols for clinical evaluation of solutions. Pathena evaluates startups for investment based on the “unmet medical need” and the quality of the promoting team in science, medicine, technology, and management. Hospitals can add value by contributing to the development and adoption of new MedTech solutions, which can lead to new solutions, increased scalability and productivity, business generation, and updated clinical teams. Accelerator programs, hackathons, and other initiatives can have a positive impact on innovation, especially when there is a consistent process and high demand for new startups.
Europe (Spain)	MedTech industry	Juan Carlos Antony Iberia Regional Executive Manager PCS, GE HealthCare	MedTech innovation in the hospital setting faces challenges such as optimization of resources and infrastructures, digitization, environmental sustainability, and clinical needs not satisfied, with AI as a cohort. MedTech industry faces additional challenges such as raw material and components availability, cost increases, and logistics costs and freight availability. Working in international markets such as Iberian and Latin American ones can have differences and challenges such as digitization level, innovation preference, investment capacity, etc. Developing and managing product portfolios depends on factors such as market dynamics, competitors’ landscape, commoditization level, value proposal and differentiation. Working with hospital stakeholders to ensure effective integration of new MedTech innovations requires good and adherent training. Measuring the success of a MedTech innovation in a hospital setting can involve metrics such as outcomes improvement, level of coverage/implementation, or agreement with the hospital to foster competitiveness and enhance reputation. Participating in initiatives such as MedTech acceleration programs, hackathons, etc. can have a positive impact in long-term and lead market behavior. Training plays a key role in supporting the adoption of new MedTech innovations, and hospital staff should be properly trained and professional.

			Hospitals, government/regulators, and academia are very relevant in the process of MedTech inception to the market, as they are involved in clinical validation, regulation, and education. Developing and implementing strategic plans for products and business units involves an annual business plan that is reviewed periodically, and main metrics are market share, sales margin and volume, and product lifecycle.
Europe (Spain, Catalonia)	Hospital, Academia and Technological Infrastructure, and MedTech industry (Venture Capital)	Xavier Monné President of the Board of Governors, Sant Pau Hospital Member of the Board of Trustees, Fundación Banco Sabadell Strategy advisor, Astanor Ventures Senior Advisor for Strategic Initiatives, Universitat	MedTech innovation faces challenges in four pillars: strategical, financial, legal, and more. These include integration and interoperability of technologies, motivation and skills of clinicians, pressure on National Health Services, trade-offs between funding and impact, regulatory compliance and speed, clinical validation, supply-chain level, cost-effectiveness, sustainability, and data management and value. Hospitals are key actors in supporting MedTech innovation by participating in clinical trials, enhancing the adoption and use of new technologies, providing data for AI and big data applications, and accessing new diagnostic and therapeutic solutions. Bridging the gap between R&D and industry requires addressing the strategy for MedTech innovation from ideation to commercialization, accelerating the growth and entry in the market, and encouraging the sustainability practice. Small enterprises and businesses are key for MedTech innovation, but they need investors to promote their growth, advise on sustainability, provide resources and network, and help with regulatory issues. It is important to link academia-hospital-academical infrastructures-MedTech industry and the government must incentivize this connection by funding individual companies or businesses that tackle societies' unmet needs and providing expertise to agilize regulatory issues. Hubs based on partnerships between university-hospitals and academia are key for all the stakeholders of the ecosystem to meet: innovators can address unmet needs, investors can identify need trends and expertise of innovators, industry can support smaller businesses while tackling the same clinical need.

		Oberta de Catalunya	
Europe (Spain, Catalonia)	MedTech industry (Venture Capital)	Sebastian Anastassiou Head of Investments, Nina Capital	Venture capital firms collaborate with hospitals, the central partners for MedTech innovation, to identify and evaluate clinical needs and develop solutions that meet stakeholder expectations. MedTech investments should balance financial returns and positive outcomes: venture capital firms assess the demand for innovative technologies and align with stakeholder interests, based on the social impact and financial results of their investments. Pilot studies and technology assessments in hospital settings are key to increase the adoption risks of MedTech: venture capital firms support and facilitate the implementation of, for example, clinical trials, and involve KOLs in assessing the value of technology and providing feedback for improvement. Venture capital firms regularly review reports and analyze companies to track industry progress, keep up with developments and trends for effective healthcare innovation investment, and monitor the rise of businesses addressing specific topics as indicators of emerging trends and potential opportunities.
Europe (Switzerland)	MedTech Industry	Louis Potter Co-founder, Outsight International Ex-Innovation Advisor, MSF Sweden Innovation Unit	MedTech innovation in hospital settings faces challenges such as modernizing infrastructure and standards, ensuring connectivity, interoperability and power, and standardizing information systems across facilities and organizations. Hospitals can foster a culture of innovation and encourage the adoption of new technologies by implementing standards that ensure future interoperability, adapting proven innovations, and working closely with national staff to ensure contextual appropriateness. Companies but specially hospitals should analyze the market potential, create genuine improvement and profitable products, and use the knowledge of local people. Regulatory or legal barriers that can hinder MedTech innovation in hospitals include ethical standards, regulatory frameworks, etc. These can be a mix of HIC, WHO and localized standards. Having a clear plan and strategy is essential. Accelerator programs, hackathons and other such initiatives in medical technology are nice ideas, but very rarely work. They are only useful if the problem has been properly explored through a systems lens and there is funding to take forward promising ideas. Developing quality medical technology takes years and huge amounts of funding: hackathons are usually just exercises for corporates to feel like they're doing good.

			Hospitals can measure the success and impact of new MedTech solutions on patient outcomes and hospital operations by folding them into standardised M&E processes (cost/benefit etc). These should be independent and not influenced by partnerships with the private sector. Recommendations for hospitals looking to develop an effective framework to support MedTech innovation include focusing on proven designs and technologies, ensuring expertise in procurement teams, and negotiating hard with the private sector.
Europe (Switzerland)	Government and Regulators	<i>Anonymous</i> Legal counsel IP TTO, Lausanne	Academic hospitals promote innovation and technology development with integrity and ethical regulations. Educating and guiding researchers within the hospital setting is essential to prevent dissemination of research results without proper IP protection. Clearly delineating contributions, especially in partnerships with the private sector, is a challenge when developing and commercializing medical technologies. Research agreements can help to manage contributions. The interviewee's office does not advise clients on IP-related regulatory requirements, as they do not engage in commercialization themselves. When negotiating licensing agreements for medical technology IP, it is advisable to reserve use rights for research and education purposes, avoid sharing or transferring ownership, and focus on licensing and management. Overcoming challenges in IP protection within the hospital setting involves understanding the project, establishing legally framed relationships with partners, and using NDAs before sharing information. Balancing IP protection with the widespread adoption and use of technology for improved patient care can be achieved by retaining partial ownership, limiting licenses to specific fields of use, reserving IP for research purposes and academic teaching, and encouraging partners to actively utilize the IP. The main focus is improving people's lives, but the approach may vary depending on the nature of the technology.
United States	MedTech industry	Giovanni di Napoli President of the gastrointestinal business,	Key challenges in bringing MedTech innovation to hospital setting are identifying unmet clinical needs, linking product complexity to real use case, ensuring safety and validation, and being patient and getting approval. US and EU markets have some similarities but also differences due to healthcare systems organization. EU market is complex because of different cultures and systems across countries. EU market is also harder to enter now because of MDR, which requires more documentation than CE, making US market easier to

		Medtronic	penetrate. It would be desirable if each country could develop an healthcare ecosystem with a shared mission and vision. Doctors must and do integrate teams across MedTech development to provide the need that the innovation must address. They are also partners for testing, validation and prototyping as end-users. At Medtronic, cooperative team is key for success, with project engineers ensuring the coordination of operations. Government, regulators and policymakers must help the industry to bring innovation and advance healthcare systems. To mitigate risks, health technology assessments are performed and processes are validated. The cycle of development is long, so it needs to be adapted in smaller steps from ideation to quality, performance, design, etc. of the innovation. If there is a need to abandon a technology, it should not be feared, as it frees time and money to invest on valuable technologies. Initiatives to foster collaboration among academia-industry-hospitals include internal Hackathons at Medtronic, where the most appealing project is funded by the company. Medtronic tried to implement a MedTech acceleration program but it was too time consuming. There are plenty of frameworks, but the quality of the team, the expertise, and the ideas are more important. Ideally, an aligned mindset of the team, with people with the same mission, communicating and with the right skills is the key for success.
United States	Academia and Technological Infrastructure	Aleksandar Marinkovic Engineer and scientist in high-performing R&D teams, Medtronic and Harvard University	Collaborate with hospitals on research and clinical trials for medical technology innovation is a common practice in Massachusetts, where healthcare-related initiative are shifting from MedTech Acceleration Programs to large companies' R&D programs and hackathons. Participate in shaping strategic vision and proposing new products that strengthen market position are success ingredients for the growth of Medtronic. Hospitals' research are valuable inputs for medical technology development – reason why data sharing is so important. The limitations of hospitals in conducting feasibility and development processes for medical technology innovation were recognized. Lead and coordinate engineering teams developing surgical and diagnostic instrumentation for various applications.

United States	Hospital	Alan Braly Senior Director and Global Portfolio Strategy, Foundation Medicine	Integrating new technology requires adapting to workflows, working with existing systems, or investing in integration capabilities, as well as ensuring a clear payment path. To support MedTech innovation in hospitals, collaboration and partnerships with internal champions, clinicians, patients, and industry partners are necessary. Successful MedTech innovations address critical needs, have clinical champions, and provide value in terms of outcomes, safety, cost, experience, or data. Hospitals are key sources and partners of MedTech innovation, as they identify unmet needs and test new solutions. FMI partners with oncology departments to use and generate evidence for its new diagnostic assays. Building trust and relationship with stakeholders who face the problem that the innovation solves is key for engagement. The interviewee has experience in commercializing new technology from Harvard hospitals, and identifies some success factors such as multidisciplinary teams, grants, clear licensing terms, and mentorship. Success can be measured by converting unpaid pilots to paid customers, and by demonstrating value in terms of clinical, economic, or experiential outcomes. Start-ups should find and develop internal champions at hospitals who can advocate for their innovations during evaluations and trials.
United States	Hospital	John Collins Director of Innovation Platforms, CIMIT Co Founder, Reed Collins LLC	CIMIT is an organization that fosters collaboration among clinicians, engineers, and business professionals to solve important healthcare problems. Hospitals are essential for identifying needs and providing feedback and input for MedTech development and adoption. Clinicians are key stakeholders for trailing and disseminating new technologies and setting the standard of care. Clinical engineers facilitate the MedTech transferring, bridging the gap between medicine and science. The main challenge and cause of failure in MedTech transfer is the lack of understanding of the clinical and economic aspects of innovation. The case methodology is a helpful tool for innovators to learn the process of innovation in healthcare, with the support of facilitators. Hackathons are an interesting approach to foster cross-linkage of knowledge. Funding sources should align with the mission of the innovators, who should be passionate about finding important problems and solutions. Startups must show market traction to attract larger partners, and hospitals can offer opportunities for testing and spreading new technologies.