

FIT4MEDROB

D3.6.1

DIMENSIONS OF THE INNOVATION ECO SYSTEMS #1

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Piano nazionale per gli investimenti complementari al PNRR Ministero dell'Università e della Ricerca

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1 EXECUTIVE SUMMARY

This report presents the research progress related to the definition, classification and discussion of the relevant dimensions of the innovation eco-systems of robotic rehabilitation technologies. This analysis is included in the Activity 3 of the Fit4MedRob Initiative. The analysis aims to comprehensively investigate the dimensions of innovation ecosystems surrounding robotic rehabilitation technologies. The investigation lays on three levels of analysis: macro, meso, and micro levels. At the macro level, the objective is to identify environmental barriers and facilitators influencing the integration of robotic rehabilitation into healthcare systems. This involves examining regulations, infrastructures, and institutions to understand their role in shaping the adoption of innovation practices between the business and knowledge ecosystems. The goal is to understand how various actors collaborate, share knowledge, and innovate together to possibly advance robotic rehabilitation and its integration into healthcare systems. At the micro level, the objective is to understand the barriers and facilitators of technology acceptance at a behavioural level. This includes examining user perceptions and interactions with robots, identifying factors influencing acceptance or rejection, and designing interventions to overcome barriers and encourage adoption. The report outlines the current and future empirical steps that we identify to achieve these objectives.

The following diagram presents a structured overview of the main activities conducted throughout the project timeline so far. The collection and analysis of the literature on innovation management has allowed to define a conceptual model to address the different dimensions of the Innovation Ecosystem (IE), differentiating among macro, meso, micro levels of analysis. The activities performed have focused on stakeholder collaboration, regulatory and financial evaluation, strategic business modelling, and user perception models. Given the multi-faceted nature of this initiative, significant cross-disciplinary interactions have taken place to establish a comprehensive understanding of the factors influencing the successful integration of robotic rehabilitation solutions.

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In particular, engagement with **legal and clinical teams** has facilitated the definition of the search strategy to highlight the main issues to financial policies, envisaging how current regulatory barriers, structures and institutional frameworks effectively limits or support the long-term viability of these technologies. Active involvement with **decision-makers, industry representatives, and healthcare professionals** has provided critical input to design a strategy for the qualification of the robotic rehabilitation sector.

The progress is fully in line with the expected timeline (Gantt chart below).

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2 INTRODUCTION

In recent years, the study of robotic rehabilitation has witnessed significant advancements, offering promising solutions for improving patient outcomes and enhancing the delivery of rehabilitation therapies. However, despite these technological breakthroughs, several challenges persist in effectively integrating robotic rehabilitation into clinical practice and ensuring widespread acceptance. These challenges range from affordability and accessibility of advanced robotic technologies to concerns about safety, patient acceptance, and compatibility with existing healthcare systems. The cost of many advanced robotic rehabilitation technologies remains prohibitive, limiting access for patients, particularly those in remote communities or regions with limited resources. Moreover, the successful integration of robotic rehabilitation into clinical practice requires careful consideration of compatibility with existing healthcare systems, efficient training of healthcare professionals, and adherence to rigorous safety protocols and regulatory standards. Additionally, patient acceptance of robotic technologies should be considered as fear of technology, discomfort with robotic devices, or a preference for human contact with therapists may hinder adoption.

Current studies on robotic rehabilitation technologies adopt various approaches to explain the factors that facilitate or hinder the adoption of technologies. The majority of works recognise the primary role of user perception in determining the successful adoption of a novel technology. For this reason, creating a set of conditions that positively influence users' attitudes and consequent behaviour is of primary importance. When examining the user's role, two distinct user groups emerge. The first group is represented by patients who are the end-users of the technology, while the second group is represented by therapists who play a critical role in facilitating and supporting patients' adoption of the technology. Both patients' and therapists' attitudes are crucial in determining the adoption of technology. Behavioural barriers and resistance to change from caregivers represent substantial obstacles to successful adoption [1]. Therefore, the importance of therapists' attitudes, alongside the benefits of the device, is crucial to ensure the successful adoption of robotic rehabilitation [2]. Implementing a plan that actively fosters a positive attitude among operators and clarifies the benefits of robotic training will generate positive experiences for both therapists and patients [2].

Research has demonstrated that the use of robotic technology is overall effective and well-tolerated by patients [3]. Robotic technology enhances therapy efficiency and accessibility facilitates data collection, enables simultaneous treatment of multiple patients, and allows for remote therapy sessions, enabling patients to remain in their comfort zones [4]. However, certain segments of the patient population, such as the elderly, may encounter challenges. Therefore, there is a need for effective communication of therapy benefits, targeting professionals (i.e., therapists and medical doctors) and policymakers [3]. Perceived usefulness and perceived ease of use can improve the user's attitude and experience, but they need to be associated with training and embedded technological support [5]. The lack of these resources hinders the implementation of the technology and opens a gap between the learning necessity of the clinicians and the actual training provided [5]. The lack of available resources, including training and technological support, can be attributed to a narrow view of the innovation ecosystem. In some cases, organizations or stakeholders may focus solely on developing or introducing the technology itself without adequately considering the broader ecosystem in which it will be implemented. This narrow view can result in overlooking the necessary resources and support systems needed for successful adoption and implementation [6].

A significant gap exists in the literature, where there is a lack of a multi-layered view or complexity in characterizing the ecosystem surrounding innovations such as robotic rehabilitation technologies [7]. The overarching research objective of this study is to perform a thorough investigation of the innovation ecosystem that may enable (or hinder) the adoption of robotic technologies in rehabilitation. The innovation ecosystem serves as the context against which our research unfolds. This ecosystem can be ideally broken up into three distinct levels: Macro, Meso, and Micro. At the Macro level, we examine the broader societal, institutional, economic, and regulatory factors that influence the adoption of robotic rehabilitation centres, Universities and other relevant bodies, shedding light on the specific structural and cultural factors. Finally, the Micro level zooms in on the individual interactions and decision-making processes of healthcare professionals, patients, and other stakeholders involved in the adoption

process. At this level, we draw upon the Technology Acceptance Model (TAM) [8] and the behavioural principles of digital nudging [9-11], to provide a comprehensive understanding of the factors influencing technology acceptance in the context of robotic rehabilitation.

This study seeks to contribute to the field of robotic rehabilitation with a comprehensive investigation of the innovation ecosystem. Our research has three primary objectives. First, it aims to map the innovation ecosystem surrounding robotic rehabilitation technologies, identifying key stakeholders and their interactions. We aim to provide insights into the barriers and facilitators influencing the integration of robotic rehabilitation into healthcare systems. Second, the objective is to study the interactions between knowledge and business ecosystems and the role of networks and open innovation. This entails examining how various actors within these ecosystems collaborate, share knowledge, and innovate together. Lastly, the study aims to investigate behavioural barriers and facilitators affecting the adoption of robotic rehabilitation technologies at both the patient and therapist levels. Through this exploration, the research aims to identify factors influencing technology acceptance and to design interventions to overcome barriers and encourage adoption.

The report is structured as follows. In the next section, we introduce the concept of the Innovation Ecosystem (IE), exploring its definition and core elements. The macro level of the IE is examined in section 4, where we explore the role of regulations, infrastructures, and institutions. Section 5 delves into the meso level of the IE, focusing on the role of networks and interdependencies between the business ecosystem and the knowledge ecosystem. The micro level of the IE is the focus of section 7, where we analyse the role of user perception. This section covers topics such as the Technology Acceptance Model, the evolution of user perceptions, and the role of digital nudging. Lastly, in the conclusions, we summarize the key findings of the report and discuss their implications for the field of robotic rehabilitation.

3 THE INNOVATION ECOSYSTEM

3.1 Definition and Core Elements of Innovation Ecosystems

An innovation ecosystem refers to a network or interconnected system of diverse stakeholders, including individuals, organizations, institutions, and resources, that collaborate and interact to foster innovation and economic growth within a particular region, industry, or domain [12]. The concept draws an analogy from biology, where it refers to a living organism and its interactions with the environment. In the healthcare environment, an ecosystem is a large community of institutions, actors, activities and artefacts that cooperate to develop goods and services that are valued by customers.

The role played by innovation ecosystems in the development of new technologies is significant. As highlighted in a report by the European Commission, there are several ways in which innovation ecosystems foster the development and application of new technologies [13]. These range from stimulating creativity and idea generation to facilitating collaboration and partnerships. Additionally, they drive economic growth and competitiveness and address societal challenges. Of utmost importance, especially concerning our research objectives, is the promotion of knowledge sharing and learning. Within innovation ecosystems, knowledge sharing and learning are encouraged through various channels, enabling individuals and organisations to stay informed about the latest trends, technologies, and best practices [13].

It is difficult to "imagine that any modern multi-process organisations will succeed without an innovation ecosystem that comprises suppliers, business partners, and customers [and other stakeholders] working together" [14]. Any innovation or technological initiative will rarely stand-alone [15]. Co-creation, participation, and collaboration among different players hold immense value within robotic rehabilitation, as it enables stakeholders to collaboratively develop innovative solutions that address complex needs [16-18]. By engaging in co-creation initiatives, such as involving therapists, patients, technology developers, and healthcare providers, in the design and development of robotic rehabilitation technologies, healthcare organizations can ensure that the resulting solutions are tailored to the specific requirements and preferences of end-users. The success of a technological ecosystem thus depends on the extent to which its subcomponents are complementary and synergistic [19].

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The relevance of the innovation ecosystem is prominent in the development and application of new technologies such that the success of an innovating organization "often depends on the effort of other innovators in its environment" [16p. 306]. The importance of interdependences, coordination and exchange networks is a recurring theme in the innovation literature [14, 20]. This interdependence is particularly important in the early phases of technological development as the technological challenges tend to decrease over time as technologies mature [12]. The nature of these challenges is embedded, in new technologies, in the discovery, design, and development [21], as well as in integrating new components into traditional organisation structures [22].

At the early stage of technology development, innovation ecosystems are characterized by a complex interplay of cooperation and competition [23, 24]. Cooperation within an innovation ecosystem fosters collaboration and knowledge sharing among participants [25]. These collaborations promote knowledge spillovers, overcome coordination failures, and enhance resource pooling [26]. A collaborative approach promotes synergies, accelerates the pace of innovation and encourages the exchange of ideas in settings of open innovation [27]. Ultimately, cooperation enables the partners involved to address complex challenges more effectively and develop innovative solutions that have a broader impact on society [28].

On the other hand, competition within an innovation ecosystem serves as a catalyst for innovation by creating a more dynamic environment [29]. Competition incentivizes market players to strive for excellence, driving continuous improvement and innovation [30]. It encourages organizations to differentiate themselves, develop unique value propositions, and push the boundaries of their capabilities.

Despite the role played by competition, cooperation remains the main mechanism of value in an innovation ecosystem [24]. A major feature of these ecosystems is the complementarity among innovation subjects, wherein diverse stakeholders collaborate synergistically to drive innovation and economic growth. This complementarity enhances the efficiency of innovation ecosystems by facilitating knowledge sharing, resource pooling, and the exchange of ideas [12]. Consequently, successful organizations should recognize the importance of matching their innovation strategies with the ecosystem in which they operate, ensuring that their approach capitalizes on the collaborative potential inherent in the ecosystem's dynamics. The significance of the innovation ecosystems underscores the importance of mapping them to anticipate future developments and formulate optimal strategies [31, 32].

3.2 THE DIMENSIONS OF THE INNOVATION ECOSYSTEM

Traditionally, an innovation ecosystem has been defined as a network of interconnected organizations, individuals, resources, and technologies that collaborate to support the development, commercialization, and adoption of innovations [12]. This definition places a strong emphasis on collaboration and complementarities among ecosystem participants, highlighting the importance of cooperation and synergy in driving innovation. However, more recently, the concept of an innovation ecosystem has evolved to encompass a broader array of factors and dynamics. According to Granstrand and Holgersson [7] an innovation ecosystem is now understood as "the evolving set of actors, activities, and artefacts, and the institutions and relations, including complementary and substitute relations, that are important for the innovative performance of an actor or a population of actors" [7, p. 1]. The peculiarity of the new definition of innovation ecosystems lies in its comprehensive consideration of various components and relationships within the ecosystem. Unlike previous definitions that mainly focused on collaboration between actors, this new definition focuses on the core concept that an ecosystem is a system made of both a set of components and a set of relations. As shown in **Error! Reference source not found.**, the expanded concept of innovation ecosystem includes different elements such as:

- Actors: the term "actors" refers to the various entities or participants involved in the ecosystem. These actors can include individuals, organizations, institutions, government agencies, research institutions, universities, startups, established companies, investors, and other stakeholders who play a role in driving innovation within the ecosystem. Actors interact with each other, collaborate, compete, and engage in activities that contribute to the overall innovation and value creation within the ecosystem.
- 2) Activities: refer to the various actions, processes, and engagements undertaken by the actors within the ecosystem to drive innovation and create value. These activities can include research and development, knowledge sharing, collaboration, networking, technology transfer, commercialization of innovations, investment in new ventures, and other initiatives aimed at fostering innovation and growth. Activities within an

innovation ecosystem are diverse and dynamic, reflecting the interactions and engagements among different actors.

- 3) Artifacts: refer to the tangible and intangible outputs, products, technologies, resources, and innovations that are created, exchanged, and utilized by the actors within the ecosystem. Examples of artefacts within an innovation ecosystem can include new products, services, prototypes, patents, software applications, research findings, intellectual property, data sets, best practices, standards, and other tangible and intangible assets that contribute to the innovation process. These artefacts serve as building blocks for further innovation, collaboration, and commercialization efforts within the ecosystem.
- 4) Institutions¹: refer to the established rules, norms, regulations, and frameworks that govern the behaviour and interactions of the various actors within the ecosystem context. These institutions provide the structure and guidelines within which innovation activities take place. Institutions can include formal entities such as government regulations, industry standards, intellectual property rights, legal frameworks, and policies, as well as informal norms, practices, and relationships that shape the dynamics of the ecosystem.
- 5) **Relations** (including **complementary** and substitute **relations**): refer to the connections, interactions, and dependencies among the various elements within the ecosystem, including actors, artifacts, activities, and institutions.
 - a. **Complementary relations** involve interactions where two or more elements within the ecosystem work together synergistically to enhance each other's capabilities or outcomes. For example, actors may engage in complementary activities to leverage each other's strengths and resources, or artefacts may have complementary features that enhance their value when used together.
 - b. Substitute relations, on the other hand, involve interactions where one element can replace or serve as an alternative to another element within the ecosystem. This can occur when different artefacts or actors offer similar functionalities or solutions, allowing for competition or substitution based on different preferences or requirements.

The innovation ecosystem serves as the research context for our project and will guide our empirical work. We will adopt the structure outlined by Granstrand and Holgersson [7] as shown in Fig. 1 to inform our investigation into the components and relationships of the ecosystem of robotic rehabilitation. More information will be provided about the method in the dedicated section of this report.



Fig. 1 Innovation Ecosystem [7].

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¹ In the context of innovation ecosystems, institutions can play a twofold role as both actors and context.

4 MACRO LEVEL OF IE: REGULATIONS, INFRASTRUCTURES, AND INSTITUTIONS

The existing literature on innovation diffusion mostly focuses on "a single-layer analysis of the ecosystem" [33, p. 2057]. This approach overlooks the complexity of the system and neglects potential influential factors that may affect the phenomenon under investigation. To overcome this limitation, we take a broad approach to define the ecosystem innovation and explore the environment breaking it down into three levels of analysis.

At the macro level of analysis, our objective is to identify the barriers and facilitators influencing the integration of robotic rehabilitation into healthcare systems. This involves examining regulations, infrastructures, and institutions to understand their role in shaping the adoption of innovative technologies like robotic rehabilitation.

4.1 THE ROLE OF REGULATIONS

The macro context with supranational institutions, regulations and infrastructures represents the first level of analysis. At the macro level, we examine the broader societal, institutional, economic, and regulatory factors that influence the adoption of robotic rehabilitation technologies on a large scale. This includes analysing global trends, government policies, and healthcare regulations that impact the implementation of robotic technologies in rehabilitation settings.

The global demand for rehabilitation services is on the rise due to factors such as population ageing, a growing prevalence of noncommunicable diseases, advancements in medical care, and the increased availability of assistive products [34]. The World Health Organization (WHO) calls for urgent and concerted global action to address the rehabilitation needs of a significant number of individuals, particularly those from low- and middle-income countries [35]. There is a pressing need for regulations to create favourable conditions in this field. The WHO [35] propose 10 areas of action to influence policy-makers and regulations to move in this direction:

- 1) Creation of strong leadership and political support.
- 2) Strengthening rehabilitation **planning** and **implementation** at national and sub-national levels.
- 3) Improving **integration** of rehabilitation into the health sector and **strengthening intersectoral links** to effectively and efficiently meet population needs.
- 4) Incorporating rehabilitation into Universal Health Coverage.
- 5) Building comprehensive and inclusive rehabilitation service delivery models.
- 6) Developing a strong **multidisciplinary** rehabilitation workforce.
- 7) Expanding financing.
- 8) Collecting **information** relevant to rehabilitation to enhance health information systems.
- 9) Building research capacity and expanding the availability of robust evidence for rehabilitation.
- 10) Establishing and strengthening **networks** and partnerships in rehabilitation.

In recent years, healthcare systems have responded significantly to the WHO's call to action. There has been a growing emphasis on formal laws and regulations aimed at achieving significant health outcomes [36]. The regulation aspect is crucial because a legal framework contributes to the quality, safety and efficiency of care, promotes the shift to preventive and personalized care, and supports the availability of long-term care for people in need [37]. It also guarantees the standardisation of care processes and quality assurance [36]. However, across countries, the response has varied in terms of the scope and reach of rehabilitation services.

The development of robotic rehabilitation requires a legal framework inspired by the WHO's call to action but should also be integrated with specific key enabling points, which we will discuss in the following sections.

4.1.1 National and Regional Authorities and Universal Health Coverage

National legislation in many countries institutionalizes a universal approach to rehabilitation coverage, however, this approach is not formally and coherently expressed in policies [36]. The role of concerted policies is of primary importance in developing effective, quality, and inclusive robotic rehabilitation. These policies should be inspired by the WHO's call for action and regulate the field as it emerges and grows. In the case of Italy, universal health coverage is recognised by the national health system, but it is the regional level of government that is responsible for the

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delivery of health services via local health authorities [38]. The regional responsibilities for delivering health services can lead to variations in implementing policies and practices across different areas within the same country. This decentralized approach may result in disparities and inclusivity problems in access to and quality of healthcare services, including robotic rehabilitation [39]. Additionally, variations in regional priorities, healthcare infrastructure, and expertise may influence the pace and extent of adoption of these technologies [40]. However, a decentralized approach may on the contrary favour innovation by allowing it in regions where there is greater disposition or more favourable conditions. Innovation can emerge from various regions or clusters where there might be unique needs, expertise, or localised knowledge spillover [26].

Another big obstacle to guaranteeing universal coverage for robotic technologies is the cost-related aspect. The cost of rehabilitation robots is still very high when compared to drug-based and human-based therapies [41]. As mentioned, these costs could also lead to differences in the allocation of resources and funding for healthcare initiatives, potentially affecting the adoption and integration of robotic rehabilitation technologies in different regions.

4.1.2 Harmonization

The field is still in its infancy, some products are already in operation, while others have been regularly introduced. Although the market is rapidly expanding, it will likely take considerable time before important innovations find their way into regular healthcare practice. To ensure the safe and effective integration of these innovations into regular therapy plans, robust and harmonised regulations are essential. Despite the attempt to harmonize the requirements to favour innovation initiatives in the field through programs such as the International Medical Device Regulators Forum (IMDRF), the extent to which harmonization is truly implemented is still very low [42]. The lack of harmonization has significant implications. For example, stricter regulation by the Food and Drugs Administration (FDA) has caused many companies to focus on the European market because of an easier entry and implementation strategy [43]. This example demonstrates how a lack of harmonization can lead to regional disparity and uneven diffusion of technology [44].

To ensure the program's overall effectiveness and go beyond the efficacy of individual innovation projects, it is advisable to incorporate two "horizontal" components: one addressing legal considerations and the other focusing on ethical concerns [37].

4.1.3 Regulatory and Legal Barriers

Complex and stringent regulations, intellectual property laws, and bureaucratic hurdles can stifle innovation by creating barriers to entry, increasing costs, and limiting the ability of innovators to bring new ideas to market. Clear and coherent regulation allows developers to design their technology in conformance with requirements from the early stages of product development. With appropriate and simplified regulations, devices can be designed and commercialised to fulfil both patients and health organisations' needs. It has been recognized that the processes, timelines, and requirements involved in regulating a medical device often represent a significant obstacle to its clinical implementation [42]. Clinical devices must undergo valid clinical trials that demonstrate their validity before being introduced into therapy plans. Clinical devices must undergo stringent pre-market approval pathways with randomised controlled trials that carry both a high risk and high cost. Strict regulations in this process can translate into additional costs and delays in access to the market [45].

Developing a robust clinical strategy is essential, particularly in understanding the pathways and schemes of each target jurisdiction. This is crucial because when a device is of moderate risk or is based on earlier technology, it may be exempt from clinical trial requirements. Understanding these regulatory nuances and tailoring the clinical strategy accordingly can streamline the approval process and accelerate the introduction of the technology into the market [42].

Another aspect related to technology characteristics is the degree to which it can be easily integrated into the healthcare system. Many technologies have faced challenges in implementation due to the potential costs associated with integration [42]. When a device is unable to fulfil the needs of a particular healthcare system, additional costs may arise, such as the need for extra equipment, changes in protocols, or staff training. All these factors can disincentivise or hinder technology adoption [46]. The characteristics of these devices should therefore be designed to address the clinical problem with particular attention to minimise integration issues [44, 47].

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Finally, a further barrier to robotic rehabilitation diffusion is related to Health Technology Assessment (HTA) which is the assessment of various impacts of technologies in the process of adoption under several aspects including clinical, sociological, and economic aspects [48]. Among all the requirements, the economic requirement is the most stringent. Failure to provide sufficient evidence of economic sustainability may represent a barrier to the diffusion of any medical device [42]. This aspect is further expanded in the deliverable D3.4.

4.1.4 Tax Reductions and Incentives for R&D and Innovation

Tax incentives can indeed assist in the adoption of robotic rehabilitation technologies. By offering tax incentives, governments can encourage healthcare institutions, rehabilitation centres, and individuals to invest in robotic rehabilitation equipment. These incentives may include tax credits, deductions, or exemptions for the purchase, installation, or use of robotic devices for rehabilitation purposes [13].

Crowdfunding, seed funding, and challenge prizes should be also included in the future of robotic rehabilitation as promotion initiatives [13]. Crowdfunding provides individuals with the chance to support projects they find compelling and contribute to the realization of someone else's vision. In return, supporters often receive benefits from the resulting product, emphasizing the element of reciprocity within crowdfunding. Crowdfunding for robotic innovation in rehabilitation can indeed be beneficial. It allows for the pooling of resources from a large number of individuals who are interested in supporting innovative projects.

4.1.5 Environmental Regulations

Environmental challenges derive from the need to address various global issues, such as climate change, pollution, and biodiversity loss, outlined in Agenda 2030. This global initiative, also known as the Sustainable Development Goals (SDGs), was adopted by the United Nations in 2015 and consists of 17 goals aimed at promoting sustainable development and addressing pressing environmental and social issues. Many countries and organizations have developed sustainability regulations and policies aligned with the goals and targets outlined in Agenda 2030 to mitigate environmental degradation and promote environmental sustainability.

The emphasis placed on addressing environmental concerns and sustainability challenges may inadvertently hinder the adoption and diffusion of robotic technologies. Sustainability constraints present barriers with at least two significant aspects to consider in their value chain. Firstly, robot manufacturing can be constrained by the need to save energy and reduce CO2 emissions. Secondly, concerns arise regarding resource scarcity and the recyclability of materials. Achieving sustainability may involve introducing circularity principles, such as crushing older parts or products and sorting the materials, or through disassembly and automatic sorting of specific parts as needed [49].

4.1.6 Ethical and Social Implications

Ethical considerations, including concerns about privacy, security, and equity, can pose barriers to the development and adoption of certain innovations, especially in emerging fields such as artificial intelligence, biotechnology, and nanotechnology.

Ethical principles are built on the concepts of justice, non-maleficence, beneficence, and autonomy. As mentioned by Johnson, et al. [39], the robot technologies employed must prioritize user safety by being designed to avoid causing harm, ensuring appropriateness and affordability, providing assistance only when necessary, and demonstrating effectiveness, reliability, and cost-effectiveness. They should also prioritize user safety, respect user freedom and privacy, and secure personal health data. Additionally, they should uphold principles of justice and responsibility by training on a diverse dataset and maintaining human-human relations [39]. When robots are integrated with artificial intelligence and high levels of autonomous behaviour additional emotional and behavioural issues should be considered as ethical implications [50]. The ethical issue will change as autonomy increases [39].

If a robotic rehabilitation technology fails to align with these ethical principles, it may face resistance or reluctance from patients, clinicians, and regulatory bodies. Their adoption may be hindered if technology fails to adhere to the ethical standards above described.

In addition to these issues, robotics may dramatize already existing disparities and increase the so-called *technological divide* between richer and poorer areas [51]. This phenomenon describes a growing gap between those who have access to resources, information and opportunities related to technology, and those who do not. The introduction of robotic rehabilitation may pose some challenges in this direction due to the potential costs,

infrastructure requirements, training, need for ongoing maintenance and focus on specific needs. The importance of inclusivity has already been recognised by supranational organisations such as the OECD [52], which promotes digital inclusivity through an agenda featuring seven flagship initiatives. It is crucial to maintain focus on this issue to avoid the adverse effects of uneven diffusion of digital and robotic technologies.

4.1.7 Reimbursement and Access to Finance

Reimbursement is associated with the fiscal compensation granted by governments or insurance companies associated with the provision of robotics rehabilitation. It refers to the process by which healthcare providers, such as hospitals, clinics, and physicians, receive payment for the services they provide to patients. This payment often comes from third-party payers, such as insurance companies or government healthcare programs. The amount of reimbursement depends on factors such as the type of service provided, the setting in which it was delivered, and the patient's insurance coverage.

The policy decision to grant reimbursement for a specific medical technology is considered a facilitator of technology diffusion and it is essential to determine the success or the failure of a new devise introduction [42]. The reimbursement policy represents one of the most challenging aspects of introducing robots in rehabilitation. As discussed, its success may depend on the technological and clinical requirements as well as the degree to which the technology can be integrated into the targeted healthcare system.

Disruptive technologies, such as robots, may face significant challenges due to the long and complex process of acceptance [see 53 for a similar case on disruptive technology]. Therefore, developing an early reimbursement strategy becomes essential to fully exploit the potential commercial opportunities associated with innovative technologies [42]. Limited reimbursement coverage represents a huge barrier even when the technology is recommended by clinical guidelines.

Other mechanisms such as the payment system (prospective system vs. fee-for-service) as well as the heterogeneity of reimbursement systems between different jurisdictions are aspects that influence the adoption of robotic rehabilitation [42].

4.2 THE ROLE OF INFRASTRUCTURES

4.2.1 Market Structure, Competition and Globalization

Concentrated markets dominated by a few large incumbents can deter innovation by reducing competition and creating barriers to entry for new entrants. Lack of market incentives for innovation may also discourage investment in R&D and new technologies. Large companies tend to reduce the level of competition by restricting access to the market. However, even for large companies, it is difficult to obtain all the necessary knowledge to develop innovation. At the same time, smaller companies are not able to create innovation ecosystems with them in a core position, therefore they tend to participate in existing innovation ecosystems [24].

This means that the success of an ecosystem does not depend on the dimensions of the participants but on the degree of complementarity and cooperation between partners [24]. Cooperation is currently recognised as the main mechanism for value creation in an innovation ecosystem [54]. Therefore, we argue that when environments are characterised by large players that operate in a regime of *technological oligopoly* policymakers should promote collaboration and foster complementary relations between participants [7].

4.2.2 Technologies and Enabling Infrastructures

The use of robotics for healthcare purposes is expected to become a major trend in the next years [37]. Affordability, defined by the Cambridge Dictionary as "the extent to which something is affordable, as measured by its cost relative to the amount that the purchaser can pay," is one of the main requirements for a technology to be widely adopted in healthcare settings. Considering the high costs associated with healthcare technologies, including robotics, ensuring affordability is crucial to making these innovations accessible to a larger population and healthcare institutions. Affordability depends on the wealth of the purchaser and their willingness to provide these services to the largest possible share of the population.

Johnson, et al. [39] provide several recommendations on how to provide affordable technology:

• Commercialization of simple devices with training for patients and operators.

- Incorporate cognitive training together with motor training.
- Leverage country-specific cultural characteristics to increase motivation for training.
- Use transportable and/or portable devices to be shared as a community service.
- Incorporate disease-specific assessment metrics to monitor recovery progression.
- Ensure robots are safe to use with minimum supervision.
- Target cost-effective intervention.
- Maximise local resources (e.g., use of local resources to support local economies).
- Leverage other affordable technologies (e.g., widely available mobile and cellular technologies).
- Design robots to maximize the enjoyment of the human-machine interaction experience.

Besides the characteristics of the technology, the inadequate physical and digital infrastructure, including transportation networks, communication technologies, and internet connectivity, can limit access to markets of innovative technologies. Therefore, it is important to look at the broad enabling technologies, that cooperation with other robotic application fields should facilitate. One of the main benefits of robotic rehabilitation is the potential increased accessibility due to the use of advanced technologies that overcome geographical barriers.

Telerehabilitation, a form of robotic rehabilitation, offers several advantages, including increased accessibility to rehabilitation services, particularly for those in rural or underserved areas [4]. Telerehabilitation relies on enabling technologies and infrastructures, particularly the Internet, to facilitate remote communication and interaction between patients and healthcare providers. Enabling technologies, also known as general-purpose technologies, have strong complementarities with existing or new technologies [55]. The development of specific features of robotic rehabilitation is contingent on the advancement of enabling infrastructures, such as high-speed internet connectivity, secure data transmission protocols, and interoperable communication platforms [4]. These infrastructures provide the foundation for telehealth and telerehabilitation services, allowing the integration of robotic rehabilitation technologies into remote care delivery models.

4.3 THE ROLE OF INFORMAL INSTITUTIONS

Informal institutions are unwritten rules, norms, and practices that govern social interactions and behaviour within a society or organization [56]. Unlike formal institutions, which are codified into laws, regulations, and official procedures, informal institutions are often based on tradition, culture, customs, and shared beliefs. These informal rules and norms shape individuals' actions and decisions and can have a significant impact on various aspects of society, including politics, economics, and social relations.

4.3.1 "Soft" Elements

The introduction of robotic rehabilitation models should encompass in addition to the research aspect also a combination of research, development, and application to ensure a full understanding of the mechanism. Soft elements of innovation, such as societal attitudes towards risk-taking, failure, and entrepreneurship can either encourage or discourage innovation. Cultural factors such as resistance to change, fear of failure, and aversion to uncertainty may create barriers to innovation adoption and diffusion. Given the novelty of the field, achieving acceptance and implementation will be complex. For instance, one effective strategy to influence behaviour is to identify opinion leaders, who can serve as champions for the technology. These individuals play a facilitating role, as influential figures often inspire imitative behaviour among potential users [57].

The cognitive dimension of the ecosystem has a significant importance in adopting a new technology. For example, cognitive artefacts can contribute to creating an internal sensemaking process that involves information seeking and meaning ascription [58]. The creation and diffusion of new cognitive maps can lead to the development of new business models that integrate the use of new technologies [58]. This participative process fosters collaboration and consensus building, facilitating experimentation and transformation, thereby speeding up the innovation process [58]. A research approach that presupposes active participation is Participatory Action Research (PAR). The process of PAR assumes that all relevant stakeholders are actively involved in the research process to address a specific problem or issue. It is rooted in the principles of democratic participation and aims to combine action and reflection to bring about innovative change. This approach represents a shift from traditional positivist methods by

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acknowledging that observers can influence the phenomena they study and bring a set of values that impact the research. Engaging stakeholders through PAR can be crucial in the context of robotic rehabilitation because it enhances the relevance and acceptability of innovations, empowers participants, and fosters a sense of ownership and commitment to the successful adoption of new technologies [59].

When examining *soft* elements also individual factors, aspects such as age, time since completing training, the type of training or qualifications, academic affiliations, innovativeness, perception of innovation, workflow, and fear of negative outcomes, including litigation, all influence the clinical implementation of technology [42]. These aspects carry fundamental policy implications and will be better described in section 5 where micro-level aspects will be discussed.

4.3.2 Communication

To raise awareness and promote the involvement of stakeholders, awareness activities should accompany any innovation program. Considerable attention should be paid to good communication and cooperation with programmes in related fields.

The process of demonstrating clinical evidence associated with performance, safety and effectiveness is essential to enable key decision-makers to recommend the device for adoption. Issues such as slow publication time and inefficient communication channels or divulgation strategies can significantly limit the introduction of a new technology due to insufficient awareness or lack of knowledge [60].

Communication in innovation is not solely about disseminating knowledge and raising awareness; it also plays a crucial role in facilitation, fostering a common language, introducing new ideas, and deconstructing stereotypes. From a strategic management perspective, innovation communication can be seen as an integrative management capability [61]. This dynamic capability allows organisations to adapt and thrive by effectively managing the flow of information and ideas. Knowledge creation within a company involves both the generation of new knowledge and the transfer and use of this knowledge across functional groups, geographical locations, and time periods. Most of this knowledge is tacit [62], embedded in the experiences and skills of individuals, while codified or explicit knowledge enables easier transfer. The use of knowledge is guided by "common knowledge," which includes common language, shared values, and overlapping knowledge bases, ensuring that information is effectively utilised across the organisation. Effective communication strategies can thus help break down negative stereotypes and reinforce positive behaviours, contributing to a more innovative and collaborative organisational culture [63].

5 Meso level of IE: The Role of Networks and Interdependencies

At the meso level of analysis, our objective is to explore the networks and interdependencies, as well as open innovation practices, between the business and knowledge ecosystems. This entails examining how various actors within these ecosystems collaborate, share knowledge, and innovate together to advance robotic rehabilitation technologies and their integration into healthcare systems.

At this level, the innovation ecosystem is characterized by two distinct but largely cooperating ecosystems: the business ecosystem and the knowledge ecosystem [33, 64]. In the business ecosystem, key actors include manufacturers of robotic rehabilitation devices and equipment. Additionally, healthcare providers, such as hospitals, clinics, and rehabilitation centres, are key business actors as they utilize robotic rehabilitation technologies. Other important business actors are insurance companies, which may influence the adoption of robotic rehabilitation by providing coverage and reimbursement for these services.

On the other hand, in the knowledge ecosystem, research institutions and universities are fundamental actors. These institutions conduct research and development activities to advance knowledge in the field of robotic rehabilitation. They explore new technologies, develop innovative solutions, and evaluate the effectiveness of robotic rehabilitation interventions through scientific studies and clinical trials. Furthermore, healthcare professionals, including physiotherapists, occupational therapists, and rehabilitation specialists, are vital knowledge actors. They contribute expertise in patient care and therapy, providing valuable insights into the design and implementation of robotic rehabilitation programs. Additionally, professional associations play a role in disseminating knowledge,

setting standards, and fostering collaboration among researchers and practitioners in the field. Table 1 summarise the innovation ecosystem at the meso level.

Table 1 Business and Knowledge Ecosystem					
Business Ecosystems (actors)	Knowledge Ecosystem (actors)				
Technology companies	Research Institutes				
Medical device manufacturers	Educational Institutions and Universities				
Startups	Healthcare Professionals				
Investors	Professional Associations				
Hospital and Clinics	Patients and Caregivers				
Rehabilitation Centres	Training and Education Programs				
Insurance Companies	Network and community (open innovation)				
Source: our elaboration from Johnson, et al. [39]					

5.1 BUSINESS ECOSYSTEM

5.1.1 Technology Companies and Medical Device Manufacturers

These actors are the innovators involved in the development, testing, and implementation of robotic rehabilitation technologies. They bridge the gap between research and practical application, taking insights from academic research and turning them into usable products and services.

5.1.2 Startups

Startups are entrepreneurial actors that often emerge from academic research, where scientists and engineers identify opportunities to translate their knowledge into real-world applications. One of the key contributions of startups is their ability to innovate rapidly and experiment with new approaches. Unlike larger corporations, startups are typically more agile and adaptable, allowing them to explore unconventional ideas and take risks in pursuit of groundbreaking innovations. Moreover, startups often serve as catalysts for collaboration and partnerships within the innovation ecosystem. They frequently collaborate with academic institutions, research organizations, and healthcare providers to validate their technologies, conduct clinical trials, and gather real-world feedback. By developing innovative products and services, startups can contribute to creating new market opportunities and disrupt traditional approaches to therapy and rehabilitation.

5.1.3 Investors

Investors provide the financial resources necessary to fuel the development, growth, and commercialization of innovative technologies. They include venture capital firms, angel investors, corporate venture arms, and government funding agencies. Investors could provide early-stage funding to startups and entrepreneurial ventures in the robotic innovation space. This initial capital is essential for conducting research, developing prototypes, and establishing proof of concept. Startups necessitate this initial funding to hire talented staff, acquire necessary equipment, and cover operational expenses as they work towards bringing their products to market. Investors also contribute to providing strategic guidance, industry expertise, mentorship, and network opportunities.

5.1.4 Hospitals, Clinics and Rehabilitation Centres

Hospitals and clinics provide real-world environments where new robotic rehabilitation technologies can be tested, evaluated, and refined. These institutions offer access to diverse patient populations, allowing developers to assess their innovations in clinical settings. They can provide feedback on the design, functionality, and ergonomics of robotic rehabilitation devices based on their firsthand experience working with patients. Clinicians also play a crucial role in identifying the specific needs and challenges faced by patients, guiding the development of tailored robotic solutions that address these clinical requirements.

Hospitals and clinics are gateways for the integration of robotic rehabilitation technologies into routine clinical practice. As early adopters, these institutions explore the feasibility of new technologies and their inclusion into existing workflows and treatment protocols. They develop guidelines and protocols for the use of robotic devices

and train healthcare staff in their operations. They represent the end-users of robotic technology, and their adoption influences significantly market demand and commercial success of new devices.

5.1.5 Insurance Companies

Insurance companies provide coverage for healthcare services. The adoption of robotic rehabilitation can be influenced by the reimbursement rates for these services. Higher reimbursement rates can incentivize healthcare providers to invest in robotic rehabilitation technologies and offer them to patients.

5.2 KNOWLEDGE ECOSYSTEM

5.2.1 Research Institutes

These institutions, which include universities, research centres, and academic laboratories, are responsible for conducting fundamental and applied research across various fields, including science, engineering, medicine, and technology. Through their research activities, they generate new knowledge, develop innovative technologies, and advance the understanding of complex problems.

5.2.2 Educational Institutions and Universities

Educational institutions primarily focus on providing formal education and training to students, researchers, and professionals. They include universities, colleges, and technical, medical or business schools. They provide a full range of academic programs equipping students with the knowledge and skills needed to contribute to innovation. The role and functions of educational institutions and Universities may overlap with those of the research institutes as educational institutions also engage in research activities besides teaching and learning.

5.2.3 Healthcare Professionals

Healthcare professionals, including doctors, nurses, therapists, and technicians, often serve as frontline users of robotic rehabilitation systems. Their direct interaction with patients allows them to identify gaps in current treatment methods and recognize opportunities where robotic technologies can be integrated to improve patient outcomes. They can provide valuable insights during the design and development phase by offering practical perspectives on the functionality, usability, and safety of robotic systems.

Beyond the direct contribution, healthcare professionals can also influence the adoption and diffusion of robotic rehabilitation technologies within their organizations and professional networks. Their endorsement and advocacy can significantly impact the acceptance and integration of robotic systems into clinical practice.

5.2.4 Professional Associations

These entities, such as medical associations or rehabilitation therapy organizations, provide guidelines, standards, and professional support for the implementation of robotic rehabilitation. They operate at the meso level by influencing practices and norms within the field. They may champion the adoption of new technologies within their departments, encourage investment in robotic infrastructure, and contribute to the development of clinical guidelines and best practices for robotic-assisted therapy.

5.2.5 Patients and Caregivers

The involvement of patients and caregivers is essential in various stages of the innovation process. They are endusers of the device and can provide firsthand experiences and perspectives on the impact of these technologies on their daily lives and healthcare experiences. By articulating their preferences and requirements they provide important feedback to identify unmet needs and challenges.

Patients and caregivers also participate in the process of evaluation and validation of robotic rehabilitation technologies providing crucial data on the effectiveness, safety, and user experience of robotic interventions. Their experiences and endorsements can significantly influence the acceptance of robotic rehabilitation solutions among other patients, caregivers, and healthcare professionals.

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5.2.6 Training and Education Programs

Training and education programs address skill gaps and ensure that healthcare professionals remain up to date with the latest advancements in robotic rehabilitation. Continuous professional development opportunities enable clinicians to enhance their skills, stay informed about emerging technologies, and adapt their practice to evolving standards of care. By providing access to workshops, seminars, and online resources, these programs empower healthcare professionals to incorporate evidence-based practices and innovative approaches into their clinical practice.

These programs foster interdisciplinary collaboration and knowledge exchange among healthcare professionals, researchers, and industry partners. By bringing together experts from various disciplines, these programs facilitate the exchange of ideas, best practices, and research findings related to robotic rehabilitation.

5.2.7 Interdisciplinary Collaboration

This involves collaboration between different healthcare disciplines (e.g., physiotherapy, occupational therapy, engineering) to design and deliver effective robotic rehabilitation interventions. It includes topics such as interdisciplinary communication, teamwork, and the integration of diverse expertise to optimize patient outcomes. Innovators often collaborate with both macro-level entities (such as government agencies or healthcare systems) and micro-level stakeholders (such as clinicians and patients). These collaborations involve securing funding, navigating regulatory requirements, and tailoring technologies to meet user needs.

5.2.8 Network and Community (Open Innovation)

Innovation ecosystems of robotic rehabilitation heavily rely on networks to establish a sound multidisciplinary community. In the 1990s, many researchers emphasized the collaborative aspect of innovation processes whose endeavour goes beyond the boundary of the single firm and involves the formation of alliances, cooperation, and collective arrangements [65, 66]. Chesbrough [67] formally introduced the concept of 'open innovation' to break down organizational 'silos' and overcome boundaries for collaborative innovation. Information technology companies have since adopted this approach to integrate both internal and external sources of ideas and channels to market, aiming to advance their technological platforms [55].

6 METHOD: OUR APPROACH TO ECOSYSTEM MAPPING

To map and analyse the innovation ecosystem of robotic rehabilitation some principles will be borrowed from SNA. By examining the interactions and dependencies among actors, activities, artefacts, and institutions within this ecosystem, we aim to understand the dynamics that drive innovation and the factors that facilitate or hinder the adoption of robotic rehabilitation technologies. This analysis will help identify key influencers and structural regularities that impact the adoption process, providing insights into how to foster a supportive environment for innovation in robotic rehabilitation. More information will be provided later in this report in the methodology section.

6.1 SOCIAL NETWORK ANALYSIS (SNA)

To understand and analyse the innovation ecosystem Social Network Analysis (SNA) is one of the most common methods. SNA is a methodological approach that focuses on patterns of relationships between actors, ranging from individuals to departments and organisations. SNA is primarily concerned with the study of social structures and the interactions within them. It aims to describe networks of relations as fully as possible and to trace the patterns, sequences, and flows of resources, such as information, within a given connected setting of actors [68].

This technique has grown significantly over the past decade due to the restructuring of organisations into entities with fewer hierarchical levels and more permeable internal and external boundaries [69]. SNA provides a rich, rigorous, and systematic means for scholars to assess networks and their structure, as organised or enabled by various information systems [70]. From the perspective of innovation ecosystems, SNA uncovers the web of interactions and dependencies among various actors, facilitating a deeper understanding of collaboration dynamics. Such information allows stakeholders to identify key connections and leverage them to enhance innovation

processes, resource allocation, and the diffusion of new technologies, ultimately driving the ecosystem's development and performance.

SNA can be divided into key concepts: open and closed networks, actor centrality, and core and periphery structure [71, 72]. Open networks, characterized by structural holes, link otherwise disconnected groups, enabling access to diverse and novel resources. Closed networks feature direct or third-party connections among all actors, fostering trust and cohesive interactions but also leading to information redundancy. Centrality measures, such as degree and betweenness, indicate nodes' power and influence within the network. Core-periphery structures differentiate core actors, who benefit from dense knowledge flows, from peripheral actors, who access new information through external connections. Understanding these concepts is crucial for analysing and leveraging social networks to enhance innovation and collaboration.

The methodology of SNA, unlike traditional social science methods, rely on 'attribute data' about actors' properties. SNA focuses on 'relational data', dealing with the properties of network relationships among actors [71, 72]. This approach views actors as interdependent, with relationships acting as channels for tangible and intangible resources and social structures conceptualised as patterns of relations among social actors [73].

6.2 Key Interventions Enabled by SNA

Social Network Analysis (SNA) enables five key interventions that can enhance the innovation ecosystem in robotic rehabilitation [69]. First, information about the network can promote effective collaboration within strategically important groups. It offers the possibility to identify and address the isolation of key specialities, thereby improving knowledge sharing and integration among researchers, clinicians, and healthcare organizations. Second, SNA supports critical junctures in networks that cross boundaries, such as between research institutions and clinical settings, helping to identify and resolve collaboration breakdowns. Third, mapping relationships across functional boundaries, such as between different departments or institutions, reveals collaboration patterns and identifies opportunities to combine expertise for advancing robotic rehabilitation technologies. Fourth, assessing collaboration across hierarchical boundaries helps organisations understand how hierarchy influences information flow and knowledge exchange, enabling better strategic adaptation. Lastly, SNA ensures integration within groups following strategic change initiatives, such as new technology implementations or organisational restructuring, by assessing the health of informal structures, addressing potential misalignments, and fostering new, productive relationships essential for innovation.

6.3 LIMITATION OF SNA IN THE CONTEXT OF OUR STUDY

While SNA is a powerful tool to map out ecosystem innovation, it may not be completely optimal in the context of robotic rehabilitation due to characteristics specific to this field. The innovation ecosystem in robotic rehabilitation involves a complex interplay between diverse stakeholders, including researchers, clinicians, patients, developers, and policymakers. SNA can map relationships and interactions, but it may struggle to capture the full complexity and multidimensionality of these networks, especially when it comes to integrating clinical outcomes, technological advancements, and regulatory changes.

Innovation ecosystems are highly dynamic, with relationships and interactions constantly evolving. SNA typically provides a snapshot in time, which may quickly become outdated. Regular updates and continuous monitoring are required to maintain an accurate representation, which can be resource-intensive and challenging to manage.

SNA focuses on quantitative metrics such as centrality, density, and betweenness, which may overlook important qualitative aspects of relationships, such as trust, motivation, and cultural differences. In the context of robotic rehabilitation, these qualitative factors are crucial for successful collaboration and adoption of new technologies.

Collecting accurate and comprehensive data for SNA can be difficult, especially in a field that spans multiple disciplines and institutions. Privacy concerns, data sharing restrictions, and the reluctance of some stakeholders to participate can result in incomplete or biased network data.

The robotic rehabilitation field often relies on existing healthcare and research systems. Integrating SNA insights with these systems to inform decision-making and strategic planning can be complex, requiring alignment of methodologies and data formats.

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6.4 ADDRESSING SNA LIMITATIONS

To mitigate these limitations, we need a methodology that extends beyond mere description to suggest necessary changes to adopt, use, and disseminate these technologies. Such an approach should not only identify existing network structures but also actively promote and support conditions that foster innovation.

Principles and methodologies borrowed from territorial marketing strategies can partially address the problem as they provide a framework for promoting and enhancing the ecosystem of robotic rehabilitation technologies. By leveraging the promotional aspects of territorial marketing, we can enhance the visibility and attractiveness of robotic rehabilitation technologies, thereby facilitating their introduction as rehabilitation options. This approach ensures that the adoption and diffusion of robotic rehabilitation are supported not only by identifying network structures but also by proactively creating a favourable environment for innovation and investment.

Territorial marketing actions typically involve several phases aimed at promoting a specific geographic area to attract investment, tourists, residents, or businesses. This approach applied to the context of Fit4MedRob aims to:

- Assess the strengths and limitations of robotic rehab technologies.
- Suggest and induce initiatives and changes necessary to promote the related market and industry, attracting new investment and generating interest and adoption from hospital facilities, citizens, and new businesses.

Table 2 compares the phases and activities of a territorial marketing strategy with the specific activities performed for analysing the current ecosystem of robotic rehab and promoting supporting solutions.

Activities/Macro- phases	Territorial marketing	Fit4MedRob initiatives for designing and sponsoring an attractive ecosystem for the existing and new stakeholders
	Conducting a thorough analysis of the territory's strengths, weaknesses, opportunities, and threats (SWOT analysis).	Conducting a thorough analysis of the robotic rehab market's strengths, weaknesses, opportunities, and threats (SWOT analysis);
Analysis and research	Identifying target audiences, including tourists, investors, businesses, residents, and other key stakeholders.	Identifying target audiences, including investors, businesses, residents, and other key stakeholders.
	Gathering market research data on consumer preferences, competitor strategies, and industry trends.	Gathering market research data on hospital facilities preferences, competitor strategies, and industry trends.
	Defining clear objectives and goals for the territorial marketing campaign.	Defining clear objectives and goals for the marketing campaign.
Strategy Development	Formulating a comprehensive marketing strategy that aligns with the territory's brand identity and values.	Formulating a comprehensive marketing strategy for shifting the current market standards toward a mix of supporting and complementary robotic technology, that is aligned with users' non-negotiable identities and values.
	Segmenting target audiences and determining the most effective channels and messaging for each segment.	
	Establishing key performance indicators (KPIs) to measure the success of the campaign	
Planning and Implementation	Developing a detailed action plan outlining specific tasks, timelines, and responsibilities.	
	Allocating resources, including budget, personnel, and technology, to support the execution of the marketing strategy.	
	Creating marketing materials, content, and campaigns tailored to each stage of the customer journey.	Creating marketing materials, content, and campaigns tailored to each application of robotic solutions

Table 2 Territorial marketing vs. our approach.

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	Implementing promotional activities across various channels, such as advertising, public relations, events, and digital marketing.	Implementing promotional activities across various channels, such medical and technical advertising, public relations, events, etc.
	Monitoring the performance of the marketing activities in real-time using analytics tools and metrics.	
Monitoring and Optimization	Analysing data to identify areas of improvement, optimize campaign effectiveness, and make data- driven decisions.	
	Adjusting tactics, messaging, and targeting based on feedback, market trends, and audience response.	
	Continuously testing new ideas and strategies to stay competitive and relevant in the market.	
	Assessing the overall impact and effectiveness of the territorial marketing campaign against the established KPIs.	Assessing the overall impact and effectiveness of the marketing campaigns toward robotic rehab solutions and the related ecosystem against the established KPIs.
Evaluation and Feedback	Soliciting feedback from stakeholders, including visitors, residents, businesses, and partners, to gain insights into their experiences and perceptions.	Soliciting feedback from stakeholders, including local or foreign investors, businesses, and partners, to gain insights into their experiences and perceptions.
	Identifying successes, challenges, and lessons learned to inform future marketing initiatives and strategic planning.	
	Reporting results to key stakeholders and leadership to demonstrate the return on investment (ROI) and the contribution of the marketing efforts to the territory's growth and development.	Reporting results to key stakeholders and leadership to demonstrate the return on investment (ROI) and the contribution of the marketing efforts to the sector of robotic rehab's growth and development.

Note that the mentioned phases, scopes, and outcomes are closely related to the definition of sustainable business models and plans (see Deliverable 3.4). In more detail, the reported activities define the macro-conditions and scenarios through which sustainable business models can be designed and implemented.

6.5 THE DESIGN AND ORGANIZATION OF WORKING TABLES

Since a territorial marketing strategy often includes participatory activities aimed at co-designing solutions that will impact communities, we have chosen to promote and establish working groups. These groups engage a diverse range of stakeholders. Heterogeneity serves as a source of innovation and opportunity, facilitating the coordination of various skills, competencies, experiences, and sometimes conflicting interests and goals.

Heterogeneity also allows to bridge the macro and meso level of investigation bring together representatives from various institutions, including hospitals, research centres, technology developers, policy makers, and patient groups. By fostering direct communication and collaboration, working tables help to identify and address specific local barriers and opportunities for implementing robotic rehabilitation technologies. They enable stakeholders to share insights, coordinate efforts, and develop tailored action plans that reflect the unique needs and conditions of their respective organisations and communities.

Each working table comprises:

- Participants who collaborate to reduce barriers and foster coordination and dialogue among various dimensions, scenarios, and interests. This collaboration has the potential to achieve the Fit4Med targets and beyond, emphasizing collective efforts rather than individual contributions alone.
- Participants who continue to carry out activities related to the scope of the working table over time. They adopt tools or facilitate the adoption of dedicated tools within the communities they represent.

Therefore, a working table itself presents a valuable opportunity to overcome communication barriers among the diverse subjects of the innovation ecosystems. A common language serves as a fundamental tool for reducing barriers, coordinating complementary efforts, and mitigating conflicting objectives toward common goals:

• Sustaining the industry and market for sustainable robotic rehab solutions.

- Improving or restoring the health conditions and well-being of citizens who require physical and cognitive support and rehabilitation.
- Building the critical mass to act as the intermediary with public institutions, proposing and promoting necessary
 initiatives and changes for an ecosystem supporting sustainable production and use of rehabilitation robotics.
- Attracting new investments, solutions and initiatives.

6.6 PURPOSE OF WORKING TABLES

The creation working tables aims at involving local residents, stakeholders, and communities in the decision-making processes related to the marketing and promotion of a specific technological ecosystem. It emphasizes the importance of including the voices and perspectives of those who live, work, and interact within the territory when developing marketing strategies and initiatives aimed at promoting the region. The initiatives of Fit4MedRob are adapted for developing strategies for improving the ecosystem of robotic rehab (see

Table 3).

Table 3 Working tables.

Actions and characteristics of participative democracy for designing and implementing territorial marketing strategies	Actions of working tables for designing and implementing the robotic rehab ecosystem
Community Engagement: Encouraging active	Encouraging active involvement and input from local industries,
involvement and input from local residents,	businesses, and organizations in the development of marketing

macro-barriers.

involvement and input from local residents, businesses, and organizations in the development of marketing plans and strategies. This could involve holding public forums, workshops, or surveys to gather feedback and ideas.

Collaborative Planning: Engaging in collaborative planning processes where multiple stakeholders work together to identify goals, priorities, and strategies for promoting the territory.

Citizen Participation: Providing opportunities for citizens to actively participate in decision-making processes related to territorial marketing, such as through advisory committees, citizen panels, or participatory budgeting initiatives.

Transparency and Accountability: Ensuring transparency in the decision-making process and accountability to the community by openly sharing information about marketing initiatives, opportunities, budget allocations, and outcomes. Engaging in collaborative planning processes where multiple stakeholders work together to identify goals, priorities, and strategies for promoting the ecosystem's conditions for boosting the production, use and diffusion of sustainable robotic rehab solutions. This could involve forming partnerships between government agencies, businesses, community groups i.e., all the representative of those stakeholders that can drive the diffusion of robotic rehabilitation reducing the identified

plans and strategies. This could involve holding public forums,

workshops, or surveys to gather feedback and ideas.

Extending the co-design of robotic rehab solutions between technology produced patients and service providers to the active participation of public institutions and representatives of the industry. By incorporating participative democracy principles into ecosystem strategy efforts, stakeholders can create more inclusive and effective strategies that reflect the diverse interests and needs of the community of patients, technology developers and integrators, service providers, etc. This can lead to greater buy-in and support for initiatives at the innovation ecosystem level, as well as a stronger sense of ownership and pride in the promotion of robotic rehab.

6.7 THE FIRST WORKING TABLE: ACADEMY, RESEARCH UNIT OF SERVICE PROVIDERS, AND THE INDUSTRY

A preliminary working session was convened in February, bringing together academia, industry representatives, legal and ethical experts, health economists, innovation leaders from rehabilitation service providers, and industry partners. The primary objective of this initial gathering was to assist industrial partners in addressing the following questions:

- What factors, not within the industry's control, can improve the acceptance, adoption, and diffusion of robotic rehab solutions?
- What conditions within the innovation ecosystem are necessary, and at what level?
- What interactions and collaborative activities among institutions, groups, etc., can facilitate and expedite the enhancement of physical, digital, legal, and political infrastructures/systems needed for the robotic rehab industry to thrive?
- Which other stakeholders (external to Fit4MedRob) need to be involved?
- What activities must be planned and conducted to ensure the project's objectives are sustained within their deadlines and beyond?

Name	Institution	Type of stakeholder
Giuseppe Turchetti	Sant'Anna School of Advanced Studies, Pisa	Academy
	(Full professor, Fit4MedRob, Mission 1, activity 3 leader)	
Giovanni Comandé	Sant'Anna School of Advanced Studies, Pisa	Academy
	(Full professor, Fit4MedRob, Mission 1, activity 4 leader)	
Leopoldo Trieste	Sant'Anna School of Advanced Studies, Pisa (Technologist, Institute of Management)	Academy
Francesca Gennari	Sant'Anna School of Advanced Studies, Pisa	Academy
	(Research affiliate, Institute Dirpolis)	
Furio Gramatica	Fondazione don Gnocchi Onlus	Service provider (research unit)
	(Director, Development and Innovation)	
Valerio Gower	Fondazione don Gnocchi Onlus	Service provider (research unit)
	(Development and Innovation)	
Cecilia Gatti	Tecnobody*	Industry
Stefano Marcandelli	Tecnobody (CEO)	Industry
Giovanni Piccininno	Item-Oxygen*	Industry
	(Project manager)	
Nicola Laurieri	Item-Oxygen*	Industry

• What conditions, efforts, and factors are necessary to prevent Fit4Med from becoming one of many projects unable to offer sustainable solutions and strategies in the medium and long term?

* Companies already involved in Fit4MedRob

The working groups agreed to identify external to the consortium new subjects and stakeholders for new working tables.

Subsequent working tables will involve representatives from both private and public institutions tasked with addressing the issues identified in the questionnaire. Each type of barrier to the diffusion of robotic rehab solutions not only implies environmental and external conditions but also involves a group of stakeholders responsible for these barriers. These stakeholders may collaborate with others to mitigate these barriers. Each working table aims to take care of and manage the coordination of involved stakeholders, offering strategies and practical actions to overcome specific barriers.

In this strategy, the adopted approach for assessing and improving the ecosystem for robotic rehabilitation solutions involves designing dedicated questionnaires to be administered to companies developing and delivering robotic rehabilitation and supporting technologies, as well as related services. These questionnaires aim to assess the current strengths and weaknesses of the industry, opportunities and threats posed by complementary technologies, gaps or opportunities in existing infrastructures, and the legal, ethical, and policy constraints and opportunities affecting the production and diffusion of robotic rehabilitation solutions.

7 MICRO LEVEL OF IE: THE ROLE OF USER PERCEPTION

As mentioned, the adoption of technology is influenced by the innovation ecosystem in which potential users operate. The innovation ecosystem, comprising various stakeholders and institutions, provides the context within which technology adoption occurs. However, individuals also bring their own perceptions and beliefs about the benefits and usability of the technology. These individual factors, including personal experiences, preferences, beliefs, and social influences, interact with the external environment to influence adoption decisions. Therefore, while the innovation ecosystem sets the stage for technology adoption, individual perceptions and beliefs complement these factors in shaping actual adoption behaviours.

At the micro level of analysis, our objective is to understand the barriers and facilitators of technology acceptance at the individual (behavioural) level. We also aim to design nudging strategies to favour the adoption of technologies. This involves examining how individual users perceive and interact with robotic rehabilitation technologies, identifying factors that influence their acceptance or rejection, and designing interventions to overcome barriers and encourage adoption.

7.1 THE TECHNOLOGY ACCEPTANCE MODEL

The Technology Acceptance Model (TAM) is one of the most popular frameworks used to understand and predict how users adopt and use new technologies. Developed by Fred Davis [8], TAM is based on the Theory of Reasoned Action [78] and the Theory of Planned Behaviour [79]. This model is particularly fit for predicting technology acceptance at an individual level of analysis. TAM offers a simple yet powerful framework for understanding and predicting user acceptance of new technologies, focusing on key factors such as the perceptions of users and/or operators. While the TAM primarily focuses on individual user perceptions and intentions towards technology acceptance, it also acknowledges the potential influence of environmental variables and the influence of the innovation ecosystem on the adoption process. These environmental variables may indirectly impact users' perceptions of usefulness and ease of use, influencing their adoption decisions. Additionally, extensions and adaptations of TAM, such as TAM2 [80] and TAM3 [81], have further expanded the model to incorporate additional factors, including external variables, to provide a more comprehensive understanding of technology acceptance processes.

TAM posits that an individual's intention to adopt a technology is influenced by two primary factors: perceived usefulness and perceived ease of use.

- a) *Perceived usefulness* is defined as "the degree to which a person believes that using a particular system would enhance his or her job performance" [8, p. 320]. In other words, it is an individual's subjective assessment or belief regarding the extent to which a particular technology or innovation would enhance their performance or productivity in achieving specific goals or tasks.
- b) Perceived ease of use is defined as "the degree to which a person believes that using a particular system would be free of effort" [8, p. 320]. In other words, it refers to an individual's subjective perception of how effortless or convenient it is to use a particular technology. It is related to factors such as the user interface design, the intuitiveness of the interaction process, the availability of adequate support and guidance, and the overall user experience. Essentially, perceived ease of use depends on the level of perceived complexity associated with using the technology.

The importance of these two features in determining the degree of technology acceptance is supported by two main streams of psychology literature. The theoretical significance of perceived usefulness is confirmed by several theoretical frameworks such as the theory of reasoned action and its derivatives [78, 79]. These frameworks are based on expectancy models that generate a motivational "force" within individuals, influencing their behaviour in specific directions. The strength of these beliefs determines the level of motivation to engage in a particular behaviour [8].

On the other hand, the theoretical significance of the perceived ease of use derives from the theory of self-efficacy [82]. According to the principles of self-efficacy theory, the perception of how easy or difficult it is to perform a behaviour is directly related to the actual performance of that behaviour. It is not sufficient that a behaviour is perceived as beneficial, individuals also need to perceive it as possible or feasible for them to perform. If a behaviour is perceived as too difficult or impractical to perform, individuals may be less likely to adopt it, even if they recognize its potential benefits. The behaviour is therefore explained in terms of a cognitive cost-benefit trade-off [8]. This

calculation involves weighing the perceived benefits of the action against the perceived costs, both in terms of effort or difficulty and potential negative outcomes. Figure 2 outlines the model in its early formulation.



Fig. 2 Technology acceptance model.

Source: Davis [8] and Davis, et al. [83]

7.2 THE EVOLUTION OF THE TECHNOLOGY ACCEPTANCE MODEL

The TAM has made significant progress in explaining and predicting user acceptance. However, the model was characterised by some limitations. The first limitation concerns the lack of external variables. The model primarily focuses on the internal beliefs and perceptions of users without considering external factors that could influence technology acceptance and usage. Second, the model has limited ability to explain actual user behaviour as it does not account for the factors that could translate intentions into actual behaviour. Third, the model was too simplistic as it assumes that users make decisions only on their perceptions thus overlooking other cognitive and social factors. Finally, the lack of context specificity limited TAM's ability to capture the unique characteristics and dynamics of specific acceptance contexts.

These limitations stimulated the development of a model extension by [80] aiming at overcoming the deficiencies of the original formulation. This enhanced model, referred to as TAM 2, introduced several key improvements, including the incorporation of subjective norms. Subjective norms represent users' perception of the social pressure exerted by significant others regarding the acceptance or rejection of a particular behaviour [78]. The rationale for including subjective norms lies in the recognition that individuals may decide to adopt a technology under the influence of social pressure, even if they perceive that the technology is not beneficial to them. Social pressure can influence intention or behaviour directly, but can also be internalized by the user, meaning that the beliefs of significant others are incorporated into one's belief structure, indirectly influencing behaviour through a change of perceived usefulness [80]. This extension addresses the deficiency of external influence in the original formulation by incorporating the role of external variables into a decision model primarily centred on user perceptions. Additionally, it adds a layer of complexity to the simplistic formulation of the original model.

The second improvement was to include a contingency in the model that refers to the mandatory vs. voluntary settings. The theory predicts that the role of subjective norms is evident and significant in mandatory settings but not in voluntary settings [80]. This difference can be attributed to the nature of social pressure and individual autonomy. In mandatory settings, such as organizational mandates or regulatory requirements, individuals may feel compelled to comply with the expectations of important referents due to the consequences of non-compliance. Therefore, subjective norms play a more significant role as individuals are motivated to conform to social expectations to avoid negative repercussions. On the other hand, in voluntary settings where individuals have more autonomy and freedom of choice, the influence of subjective norms may be less pronounced. In these contexts, individuals are not constrained by external mandates and make decisions based on their own perceptions, rather than conforming to others.

Another addition is related to the role of image. Individuals often respond to social normative influences to establish or maintain a favourable image within a reference group [84]. If an innovation or a new technology is perceived to enhance the user's status or elevate their standing within the reference group, the acceptance of that particular technology is more likely [80].

The predictive capability of the model has been improved by adding the role of social norms and recognising its strong effect on users' behaviour. As individuals gain more experience, they tend to rely less on external norms or social pressures to guide their actions. This occurs because experience increases confidence in one's own judgment and decision-making abilities [85]. Additionally, as preferences and priorities become more established through personal experiences, individuals may feel less compelled to conform to societal expectations [86]. With time, selective attention to information that aligns with existing beliefs may diminish the influence of normative pressures that do not resonate with personal experiences [87]. Moreover, the autonomy gained through experience fosters independent decision-making, reducing reliance on external influences. Finally, exposure to diverse situations can cultivate resistance to social influence, leading individuals to make choices based on internalized standards and preferences.

A further extension of the TAM model has been proposed by [81] to take into account the potential role of intervention in technology adoption. Recognizing the limitations of TAM and TAM 2 in providing actionable guidance on how to design strategies promoting the adoption of specific technologies, scholars incorporate new key elements into the theoretical model [81]. More precisely TAM 3 focuses on the key antecedents of the perceived ease of use. These antecedents provide insights into the factors that influence an individual's perception of how easy or difficult it is to use a particular technology. These determinants encompass various aspects such as the clarity of instructions, the complexity of the interface, the availability of support resources, and the individual's prior experience with similar technologies. Understanding these determinants allows researchers and practitioners to identify areas for improvement in technology design, training programs, and support systems to enhance the user experience and promote technology adoption.

TAM 3 identifies at least five antecedents of perceived ease of use that can be relevant to the field of technology adoption in robotic rehabilitation:

- Perception of External Control. It identifies the degree to which a potential user believes that resources are available and will be deployed to support the use of the new technology [88]. A higher degree of perception of external control is expected to be associated with a higher level of perceived ease of use.
- 2) Technology Anxiety. It is related to the degree of "an individual's apprehension, or even fear when she/he is faced with the possibility of using [new technologies]" [89]. A higher level of anxiety is expected to be associated with a lower level of perceived ease of use.
- 3) Technology Playfulness. This antecedent is associated with "the degree of cognitive spontaneity in microcomputer interactions" [90, p. 204]. It represents the intrinsic motivation associated with using any new system that leads to satisfaction, pleasure, and positive effect [91]. High levels of playfulness are expected to have a positive effect on perceived ease of use.
- 4) Perceived Enjoyment. It measures the extent to which "the activity of using a specific [technology] is perceived to be enjoyable in its own right, aside from any performance consequences resulting from system use" [89, p. 351]. It represents a hedonistic aspect of using the technology capturing the user's subjective experience of pleasure and enjoyment derived from interacting with it.
- 5) **Objective Usability**. It is a "construct that allows for comparison of systems based on the actual level (rather than perceptions) of effort required to completing specific tasks" [89, p. 350-351]. The rationale for including this variable is based on the assumption that even if a user possesses low self-efficacy and high anxiety, with increased direct experience s/he will increase its familiarity with the technology and is expected to perceive it to be easier to use. New knowledge becomes available through experience with an increased use of simplified decision rules, reduced information search, and better focus on information about repeated choice [92]. Figure 3 presents a graphical representation of the model.



Fig. 3 View of the models TAM, TAM 2, and TAM 3. Source: Venkatesh and Bala [81]. TAM 3 provides an important contribution to explaining the intention-behaviour gap by examining the antecedents of the perceived ease of using technology. By incorporating dimensions such as playfulness, anxiety and enjoyment, TAM 3 offers insights into why individuals may intend to use technology but may not adopt it. This gap between intention and behaviour is a crucial aspect that characterises many behaviours including technology adoption. TAM 3 helps bridge this by including experiential and affective elements in the model.

7.3 MERGING USER PERCEPTIONS AND INNOVATION ECOSYSTEM

By leveraging TAM, we can gain valuable insights into users' perceptions and intentions towards the acceptance of our innovative rehabilitation technologies, informing our design and development efforts. In addition to this, TAM can be adapted to examine the attitudes and behaviours of various user groups, including clinicians and operators. As mentioned, these groups play an important role in the adoption and implementation of new technologies, especially in healthcare settings such as robotic rehabilitation. By applying TAM principles, we can assess clinicians' perceptions of the usefulness and ease of use of a technology, as well as their attitude and intention to adopt it. We can gain insights into their acceptance and readiness for incorporating the technology into their workflows. This understanding can guide the development of targeted interventions or support systems aimed at addressing any barriers or concerns identified among clinicians and operators, thus facilitating the successful integration and utilization of the technology within their practice contexts.

While TAM is primarily focused on individual-level factors, the inclusion of subjective norms, which reflect perceptions about the environment and institutional pressures, can indeed incorporate insights from the innovation ecosystem. By considering how external factors influence individuals' perceptions and attitudes towards technology adoption, TAM becomes adaptable to different levels of analysis, including the ecosystem level. This ensures that TAM remains communicable with approaches at higher levels of analysis, providing a more comprehensive understanding of technology adoption within complex innovation ecosystems.

7.4 THE ROLE OF DIGITAL NUDGING

The concept of nudging gained significant attention after the publication of the book "Nudge: Improving Decisions About Health, Wealth, and Happiness" by Thaler and Sunstein [10]. The publication of this book popularized the concept of nudging and sparked widespread interest in applying behavioural insights to policymaking, marketing, and other areas. Nudge means "any aspect of the choice architecture that alters people's behaviour in a predictable way without forbidding any options or significantly changing their economic incentives" [10, p. 6]. While the research on nudging lists a variety of methods, six principal techniques guide the design of nudges [10]: (1) improving the salience of the incentives but without altering them or introducing new incentives, (2) improving the understanding of the mapping between individual choices and future outcomes of the choices, (3) promoting positive and beneficial behaviour by default, (4) providing feedback to individuals when they perform or under-perform to improve their performance, (5) accounting for and expecting users to err (to minimize the consequences of the erred choices), and (6) structuring complex choices as a set of simpler ones.

The concept of nudge works, because individuals (particularly individuals with limited cognitive power) struggle with information processing [93] and tend to make decisions faster, mostly based on heuristics and cognitive biases [94]. This phenomenon is visible even more in digital choice environments where individuals have to manage the information flow and understand the information itself simultaneously, thus suffering from higher information overload [95].

Nudges have been initially studied in offline choice environments, but scholars introduced the term 'digital nudging' to investigate those nudges enabled by digital technology [11]. The idea of digital nudging derives from that broader concept and refers to "any intended and goal-oriented intervention element (e.g. design, information, or interaction elements) in digital or blended environments attempting to influence people's judgment, choice, or behaviour in a predictable way that (1) is made possible because of cognitive boundaries, biases, routines, and habits in individual and social decision-making, (2) works by making use of those cognitive boundaries, biases, routines, and habits as integral parts of such attempts, (3) preserves the full freedom of choice without forbidding or adding any rationally relevant choice options, (4) does not limit the choice set or make alternatives appreciably costlier in terms of time, trouble, social sanctions, and so forth, (5) nudges must be able to easily recognize when and where they are subject to being nudged (type-transparency), as well as what the nudger's goals of this intervention are, in addition to how and why the nudge is working (token-transparency), and (6) increases the private welfare of the nudged individual (pro-self) or the social welfare in general (pro-social)" [96, p. 11]. Digital nudging enables designers and treatment developers to reduce individuals' cognitive effort and give them more decisional power (Bartosiak et al. 2021). Furthermore, digital choice environments allow tracking users' behaviour, temporal triggering and giving real-time feedback on the effectiveness of interventions [97].

Studies in healthcare and medicine investigate the application of the digital nudging approach in the context of improving patient care or increasing health literacy [98-100]. Some initial discussion on the use of digital nudges on a mass scale to prevent the spread of negative health-related behaviours sparked during the Covid-19 pandemic [101]. On the more applied side, rehabilitation scholars claim that the human factor is still the most relied on, despite robust development of effective behavioural and medical therapies [102]. Thus, digital nudging can be applied to successfully and sustainably change both patient and solution-provider behaviour toward better healthcare decision-making [102]. Early evidence shows that such interventions can be successful in the rehabilitation of coronary heart disease to motivate physical activity among patients [100]. More recently, scholars suggested that an Al-driven nudge tool is an acceptable and appropriate solution to minimize user burden and automate the data entry requirements in medication adherence among patients [98]. Thus, in the context of the Fit4MedRob project, digital nudging techniques can address key challenges and barriers to acceptance, improve user engagement and adherence, tailor the user experience, and ultimately maximize the impact of robotic rehabilitation technologies on patient outcomes and healthcare delivery. To our knowledge, it is one of the first projects to investigate robotic agents to nudge multiple actors to improve rehabilitation efforts.

7.5 CURRENT AND FUTURE STEPS TO DESIGN SPECIFIC INTERVENTIONS

7.5.1 Design Science Research Methodology (DSRM)

The Design Science Research Methodology (DSRM) is an iterative research approach used in the discipline of Information Systems and similar disciplines to design, develop, and evaluate innovative artefacts or solutions to address specific problems or challenges [103].

Following the methodological best practices [103], we are going to implement six phases of the study:

Phase 1: Problem identification and motivation. We are starting with the definition of the specific research problem (technology acceptance within the innovation ecosystem of robotic rehabilitation) and justify the value of a solution. This phase is aimed at two outcomes: (a) motivating the research team and the audience to pursue the solution and (b) understanding the reasoning associated with the understanding of the problem.

Phase 2: Define the objectives for a solution. Building on phase 1, we set the specific objectives of a solution. We are going to infer both quantitative (e.g. to what extent our solution is better than existing ones) and qualitative objectives (e.g. how our solution is going to support solutions to other problems within the ecosystem).

Phase 3: Design and development. In this core activity of the method, we are going to create the artefact in the form of constructs, models, and instantiations of the innovative ecosystem of robotic rehabilitation. This activity includes determining the desired functionality and its architecture.

Phase 4: Demonstration. After the first iteration of the design efforts (and after each following one), we are going to demonstrate the use of the artefact to solve one or more instances of the specified problem. This phase will involve the use of the solution in experimentations, simulations, case studies, or other suitable activities.

Phase 5: Evaluation. In this phase, we measure how well the artefact supports a solution to the problem by comparing the objectives of a solution to the observed results. We give more details on this phase in section 5.5.2. At the end of this activity, we will be able to decide if to iterate back to phase 3 to improve the solution or to continue to the next phase.

Phase 6: Communication. We are going to communicate the results of our efforts in line with the dissemination of the Fit4MedRob project.

This method has been chosen for its suitability in addressing the challenges that can derive from designing and developing models of technology acceptance in the context of rehabilitation technology. Our research falls into the DSRM genre of DSR studies [104], as it focuses on an applicable artefact development. The design of the solution is guided by meta-requirements (MR) derived from a theoretical framework. While we build on the flexible process, we commit to the design rigour for our solution. To ensure the rigorous creation of MRs and the following design of the solution [105, 106], we apply deductive reasoning grounded in kernel theories and the expertise of the authors. We build on two kernel theories – TAM and nudge theory, to secure generalisability and reasoned argument for our solution.

DSRM's problem-driven nature ensures that our research is anchored in practical issues faced by patients, therapists, and healthcare providers. Additionally, the iterative approach of DSRM allows us to continuously refine and improve our solutions based on feedback and results evaluation. By focusing on creating tangible solutions, DSRM ensures that our research efforts culminate in practical and actionable outcomes that can directly impact patient care and therapy outcomes. Moreover, the theory-driven aspect of DSRM ensures that our design decisions are informed by relevant theories and best practices from various disciplines, contributing to the robustness of our solutions. Finally, the interdisciplinary nature of DSRM allows us to potentially source expertise from diverse backgrounds, enriching our research process with different insights.

7.5.2 Evaluate the Effectiveness of HMI in a Dedicated Lab

Human-machine interaction (HMI) is a multidisciplinary subject that encompasses the study of interactions between humans and computers, as well as the design of systems that enhance human performance and experience [107]. This interaction can be facilitated through natural user interfaces such as gestures [108]. Vision-based motion estimation is another key aspect of HMI, with applications in sign language translation, virtual environments, and medical systems [109]. The reliability of man-machine systems is also influenced by human interactions, which can be designed and planned using specific techniques [110].

The application of human-machine interaction in rehabilitation is rapidly evolving, with a focus on improving task performance and individual motor learning [111]. Improvements are achieved through the development of HMIs that enable direct brain-computer communication [112], and the use of passive assistive robots [113] and rehabilitation robots [114] that can adapt to user routines and needs [115]. These systems are designed to capture motor-related data and control external devices [116] and are increasingly incorporating artificial intelligence to enhance user experience and adaptation [117].

We plan two phases of evaluation in this first iteration of the DSRM cycle: (1) functional evaluation to discover potential defects of the solution prototype, and (2) observational evaluation conducted as a field study, in which a pilot implementation of the artefact will allow to monitor its use [105]. In order to achieve this goal, we will implement several types of DSRM output evaluation [118]:

- 1. Prototype will demonstrate the utility or suitability of the implemented solution.
- 2. Technical Experiments will help us understand the performance of the solution implementation. This type is designed to evaluate the technical performance, rather than its performance concerning the real world.
- 3. Subject-based Experiments will constitute a major part of our evaluation to test whether our assertions are true. This type will involve human subjects in both lab and field experiments.
- 4. Illustrative Scenario is aimed as a final evaluation of the application of the solution to a synthetic or real-world situation aimed at illustrating the suitability or utility of our outcome.

From the practical point of view, to evaluate our solution, we are planning to test our hypotheses in a Human-Machine Interaction (HMI) Lab which is a dedicated research facility or workspace where interactions between humans and machines can be observed and analysed. The lab, which will be created through a joint effort between the University of Pisa and the University of Pavia, should be equipped with specific technologies and resources such as sensors, display technologies, prototyping equipment, software development kits, data analysis software, simulation tools, usability testing equipment, collaboration tools, and ethnographic tools, to facilitate research and experimentation on human-machine interaction.

In an HMI Lab, researchers conduct experiments, design prototypes, and evaluate user experiences to understand how different factors, such as interface design, feedback mechanisms, and user preferences, influence the interaction between humans and machines.

The benefit of testing these hypotheses in a lab setting, particularly a Human-Machine Interaction (HMI) Lab, lies in its unique advantages over other methods. HMI Labs offer controlled environments that allow researchers to manipulate variables precisely and observe interactions between humans and machines under controlled conditions. This controlled experimentation enables researchers to isolate factors influencing human-machine interaction, leading to more reliable results. For example, in an HMI Lab, digital nudging techniques can be applied to influence users' behaviour and decision-making during interactions with various types of machines, interfaces, and technologies.

8 CONCLUSIONS

In conclusion, this report serves as the deliverable document of activity D3.6.1 of the Fit4MedRob (Fit for Medical Robotics) project, funded by the Italian Ministry of University and Research. Its primary aim is to comprehensively investigate the dimensions of innovation ecosystems, breaking down the analysis into three distinct levels.

The first part of the analysis focuses on the macro level. The objective is to identify the barriers and facilitators influencing the integration of robotic rehabilitation into healthcare systems. This involves examining regulations, infrastructures, and institutions to understand their role in shaping the adoption of innovative technologies like robotic rehabilitation.

Moving to the meso level, the objective is to explore the networks and interdependencies, as well as open innovation practices, between the business and knowledge ecosystems. This entails examining how various actors within these ecosystems collaborate, share knowledge, and innovate together to advance robotic rehabilitation technologies and their integration into healthcare systems.

At the micro level of analysis, the objective is to understand the barriers and facilitators of technology acceptance at the individual (behavioural) level. We also aim to design nudging strategies to favour the adoption of technologies. This involves examining how individual users perceive and interact with robotic rehabilitation technologies,

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identifying factors that influence their acceptance or rejection, and designing interventions to overcome barriers and encourage adoption.

For each level of analysis, we have outlined both current and future empirical steps to achieve our objectives. Looking ahead, we aim to perform the following activities that will be outlined in the next report:

- Continue with the territorial market approach and data collection through working tables.
- Conduct focus groups and interviews with relevant stakeholders to gather insights for a subsequent survey.
- Administer a survey to investigate the level of involvement of relevant actors in collaborative activities.
- Identify problems and define objectives for a solution (steps 1 and 2 of DSRM) through user inquiries and a comprehensive literature review.

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